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Clinical and radiological evaluation of a second-generation uncemented modular short stem shoulder prosthesis

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Inhaltsverzeichnis

Abkürzungsverzeichnis.....	4
Publikationsliste.....	5
Veröffentlichungen der kumulativen Dissertation.....	5
Weitere Publikationen des Doktoranden.....	5
Vorträge.....	5
Einleitung.....	7
Background.....	7
Introduction to shoulder prostheses.....	7
Stress shielding and humeral implants.....	7
Short stem prostheses.....	8
Clinical outcomes.....	9
Aim.....	9
Materials and Methods.....	9
Study design.....	9
Clinical evaluation.....	10
Radiological assessment.....	10
Statistics.....	10
Ethics.....	10
Results.....	11
Demographics.....	11
Clinical.....	11
Radiological.....	12
Discussion of key findings.....	13
Limitations.....	15
Overall conclusion.....	16
Zusammenfassung.....	17
Clinical and radiological evaluation of a second-generation uncemented modular short stem shoulder prosthesis with a proximal porous coating.....	17
Klinisch und radiologische Evaluation einer unzementierten modularen Kurzschaft- Schulterprothese der zweiten Generation mit proximaler Beschichtung.....	18
Veröffentlichungen.....	20
Veröffentlichung 1.....	20
Veröffentlichung 2.....	32
Danksagung.....	59
Literaturverzeichnis.....	60

Eigenanteil des Doktoranden an den vorgelegten Publikationen 63

Abkürzungsverzeichnis

RC	Rotator cuff
TSA	Total shoulder arthroplasty (anatomical)
RSA	Reverse shoulder arthroplasty
PyC	Hemi-protheses with a pyrocarbon head
FU	Follow-up
CS	Constant score
ROM	Range of motion
VAS	Visual analogue scale
OA	Primary osteoarthritis
CTA	Cuff tear arthropathy
FR	Filling-ratio

Publikationsliste

Veröffentlichungen der kumulativen Dissertation

- 1) Kleim BD, Garving C, Brunner UH. RSA, TSA and PyC-Hemiprotheses: Comparing indications and clinical outcomes using a second-generation modular short stem shoulder prosthesis. AOTS. DOI: 10.1007/s00402-020-03529-w. Accepted 14.07.2020.
- 2) Kleim BD, Garving C, Brunner UH. Cementless curved short stem shoulder prostheses with a proximal porous coating: ingrowth properties at 2-5 years of radiological follow-up with clinical correlation. JSES. <https://doi.org/10.1016/j.jse.2020.02.025>. Article in press.

Weitere Publikationen des Doktoranden

- 1) Kleim BD, Malviya A, Rushton S, Bardgett M, Deehan DJ. Understanding the patient-reported factors determining time taken to return to work after hip and knee arthroplasty. *Knee Surg Sports Traumatol Arthrosc.* 2015 Dec;23(12):3646-52. PMID: 25193567.
- 2) Malviya A, Wilson G, Kleim B, Kurtz SM, Deehan D. Factors influencing return to work after hip and knee replacement. *Occup Med (Lond).* 2014 Sep;64(6):402-9. doi: 10.1093/occmed/kqu082.
- 3) Baker P, Muthumayandi K, Gerrand C, Kleim B, Bettinson K, Deehan D. Influence of body mass index (BMI) on functional improvements at 3 years following total knee replacement: a retrospective cohort study. *PLoS One.* 2013;8(3):e59079. doi: 10.1371/journal.pone.0059079. Epub 2013 Mar 19.
- 4) Bardgett M, Lally J, Malviya A, Kleim B, Deehan D. Patient reported factors influencing return to work after joint replacement. *Occup Med (Lond).* 2015. doi: 10.1093/occmed/kqv187. First published online: December 13, 2015.
- 5) Kleim BD, Siebenlist S, Scheiderer B, Imhoff AB. Irreparable Rotatorenmanschettenruptur – inverse Prothese und Alternativverfahren. *Unfallchirurg.* 2020 Nov 27. doi: 10.1007/s00113-020-00922-3. Online ahead of print.

Vorträge

- 1) Podium Vortrag: Kleim BD, Malviya A, Rushton S, Bardgett M, Deehan DJ. Understanding the patient-reported factors determining time taken to return to work after hip and knee arthroplasty. European Orthopaedic Research Society (EORS) 22nd annual meeting Nantes 2014.
- 2) Poster Vortrag: Kleim B, Garving C, Brunner U. Ergebnisse einer Kurzschaftschulterprothese 2-4 Jahre postoperativ. 25. DVSE Jahreskongress, Regensburg 2018.
- 3) Podium Vortrag (Fr. Dr. Garving): Garving C, Kleim B, Brunner U. Pyrocarbon versus TSA: 2 Jahres Ergebnisse einer matched pair Analyse. 25. DVSE Jahreskongress, Regensburg 2018.
- 4) Poster Vortrag: Garving C, Kleim B, Brunner U. Pyrocarbon versus TSA: 2 Jahres Ergebnisse einer matched pair Analyse. 28 SECEC-ESSSE Congress Geneva 2018.
- 5) Poster Vortrag: Kleim B, Garving C, Brunner U. Cementless short stem shoulder prostheses with a proximal porous coating: Ingrowth properties at 2-5 years radiological follow-up with clinical correlation. 14° international congress of shoulder and elbow surgery, Buenos Aires 2019.

6) Podium Vortrag: Kleim B, Garving C, Brunner U. Unzementierte Kurzschaft
Schulterprothesen mit einer proximalen porösen Titan-Plasmaspray-Beschichtung: Radiologische
Einwachseigenschaften 2-5 Jahre postoperativ mit klinischer Korrelation. 26. DVSE Jahreskongress,
St. Gallen 2019

Einleitung

Background

Introduction to shoulder prostheses

Shoulder arthroplasty is an increasingly common solution in the management of osteoarthritis, rheumatoid arthritis, cuff-tear arthropathy, osteonecrosis, as well as intra-articular fractures of the proximal humerus^{12, 20}. The design of shoulder prostheses has seen a number of modifications recently, particularly to the anchoring of the humeral component. The first rudimentary shoulder replacements were undertaken in the late 1800s and early 1900s, outdating even hip prostheses, for patients with infection due to tuberculosis¹⁶. Neer then began to develop shoulder prostheses in the 1950s, driven by poor outcomes after complex fractures²⁹. His prosthesis had a long humeral stem which anchored, with or without the use of cement, in the humeral diaphysis. Fenestrations in the four fins which connected the shaft to the head were thought to promote bone ingrowth, as well as providing a refixation site for the fragments of the tuberosities.

Since then many different designs have been trialled. Three configurations of shoulder prosthesis have prevailed, each with different indications for use. All of these involve a replacement of the articular surface of the proximal humerus. Hemiprotheses are solely humeral replacements, articulating with the native glenoid. These traditionally have a cobalt-chrome surface, a complication of which is glenoid wear and pain^{17, 36}. Pyrocarbon is a material which has shown biomechanical properties similar to cartilage and is therefore hoped to ameliorate the problem of glenoid wear in patients with hemiprotheses³². These are often implanted in younger patients with intact rotator cuffs (RC) and little disease of the glenoid, to avoid complications and revision of a glenoid replacement further down the line. Additionally, in anatomical total shoulder arthroplasty (TSA) the glenoid surface is reamed and replaced, usually with a polyethylene component. This is indicated for patients with intact RC and advanced glenohumeral arthritis and aims to replace the native anatomy of the shoulder as accurately as possible. Lastly, reverse shoulder arthroplasty is employed when the RC is not intact, or functionally insufficient as reflected by a high degree of static subluxation of the humeral head. These prostheses invert the concave and convex components of the joint so that the head is now on the glenoid side and the socket on the proximal humerus. They are semi-constrained, so they have inherent stability without the need for the RC to centre the joint during movement. Inverting the components leads to a medialisation of the centre of rotation, which decreases the shear forces and allows fibres of the deltoid muscle to take over some rotational function to compensate for the RC².

Stress shielding and humeral implants

Wolf's law states that bone metabolism responds to mechanical stimuli. Thereby high loads bring about increased osteoblastic activity and higher bone density. Conversely, when bone is exposed to little stress osteoclastic activity is upregulated resulting in lower density. Stress shielding is a biomechanical phenomenon which behaves according to these rules. It describes a reduction of bone density resulting from decreased mechanical stimulation of bone surrounding an implant. This was first described around hip prostheses, but has since been found around the humeral component after shoulder arthroplasty^{11, 28}. Substantial losses of bone stock around the proximal humerus have been reported, which may lead to implant loosening, predispose to fractures, make revision surgery more complicated and could impact on the clinical outcome long term.

The humeral anchoring has been an active topic of research and development. In addition to causing stress shielding, a classical long humeral shaft was found to inhibit the optimum axis for implantation, make revision surgery difficult, reduce bone stock and act as a diaphyseal stress riser leading to fractures^{14,28}. Shortening the humeral component of a shoulder prosthesis brings about more natural stress distribution¹⁰. Therefore a trend to reduce the size of the humeral component developed: Stemless, short stem and surface-replacement prostheses emerged¹⁴. Resurfacing procedures have been performed for 30 years and have shown improvements in function and pain whilst limiting bone loss^{22,27}. They do not allow adequate exposure to replace the glenoid surface, so are solely used as hemiprotheses. However, whilst reducing complication rates, outcomes after revision of these have not been shown to be superior to revision of conventional stemmed prostheses³⁰. Stemless shoulder prostheses have shown promising results which functionally are comparable to the classic stemmed prosthesis and have low rates of radiological loosening^{5, 18, 24, 37}. These also spare bone stock during revision operations compared with standard shafts. However, their use is limited to anatomical prostheses; they cannot be converted to a reverse design in most cases as this applies greater forces onto the components and anchoring. Therefore, another anchoring system needed to be developed, leading to the emergence of short stem humeral components.

Filling ratio is a term which describes the relative diameter of the implanted stem in relation to the patient's bone structure (implant diameter divided by humeral diameter). Not only the stem length, but also the of the filling ratio have been found to influence the extent of stress shielding and resulting bone loss^{26, 28, 31, 35}. The larger the diameter of a stem, the stiffer it becomes and stiffer implants carry more forces along the shaft to its distal tip, shielding the metaphysis.

Short stem prostheses

Short stemmed shoulder prostheses are a novel design type which can be used for all indications for which standard stems are employed, including RSA with good early outcomes^{1,23}. The stem shape can be curved, reducing trauma to the RC, or straight, which theoretically causes less stress shielding¹⁰. The first-generation of these showed good functional outcomes and few complications^{3,34}. They are bone stock sparing, allow an anatomical proximal humeral reconstruction and have been shown to reduce stress shielding at the metaphysis¹⁰. The emergence of modular short stemmed prostheses promises simple revision options, ideally without stem removal. Conversion of these from anatomic to reverse, in cases with rotator cuff insufficiency, has shown good early outcomes^{13, 23}. When implanted without cement as a press-fit prosthesis, this decreases operative time and is hoped to make explanting the shaft, if required, in revision surgery simpler. However, authors including Casagrande et. al. raised concerns over high rates of radiographic loosening using a first-generation model of uncemented short stem prosthesis⁷.

To combat this, a proximal porous coating for better metaphyseal fixation was introduced. Other authors have begun to describe the clinical and radiological properties of these second-generation short stem prostheses^{26, 31, 35, 38}. Schnetzke and Raiss both reproduced findings of increased bone remodeling with higher filling ratios due to stress shielding^{31, 35}. However, they did not differentiate between the types of remodeling processes which occurred, or consider other factors which may interact with these processes. The findings of Tan et. al., though statistically insignificant, suggested lower levels of proximal bone resorption in the presence of the porous coating³⁸.

Clinical outcomes

The clinical properties of different types of standard stem shoulder prostheses (TSA, RSA and Hemi-) have been investigated to some extent. It has been reported that TSA has a better outcome and more pain relief than hemiarthroplasty⁶. TSA has been shown to benefit from greater internal rotation compared to RSA in patients who had contralateral implantation of both⁹. As both TSA and hemiarthroplasty have been found to have disappointing results when implanted for osteoarthritis with posterior subluxation of the humeral head, a trend has emerged to revert to RSA in extreme cases^{15, 21, 25}. Schnetzke reported good early clinical results of second-generation short stem prostheses when implanted as an anatomical TSA³⁵. However, despite now becoming widely used, the clinical properties of this new stem type when used in all its different variations (as an anatomical, reversed or hemiprotheses), have not been examined.

Aim

The aim of this project was to investigate the clinical outcomes of this second-generation modular short stem shoulder prosthesis, in all of its different forms. We also set out to further describe the outcomes achieved with each prosthesis type for different indications. Furthermore, to describe the radiological ingrowth properties of this new stem with a proximal porous coating and investigate factors which could impact on this. This knowledge should help to inform clinicians' pre- and intraoperative decisions when considering operative solutions with these implants for their patients.

Materials and Methods

Study design

The study was designed by Benjamin Kleim (BK) with the advice of Prof. U. Brunner (UB) and Dr. C. Garving (CG). A retrospective single-centre consecutive cohort study was carried out. All 103 patients which underwent joint replacement operations with a second-generation modular short stem shoulder prosthesis (Aequalis Ascend Flex™, Wright medical, Bloomington, USA) at Agatharied hospital, between May 2013 and June 2015, were invited for regular follow-up (FU). Implanted were TSA, RSA and hemiprotheses with a novel pyrocarbon head (PyC). The clinical and radiological examinations took place in our outpatient clinic. Inclusion criteria for the clinical evaluation were a minimum of 2 years FU. 9 Patients who had complications which rendered them incomparable to the rest of the cohort were excluded (please see detailed list in **Publication 1**, under "patient population and study design"). Additionally, one patient with a titanium hemiprosthesis, instead of PyC due to a nickel allergy, was excluded to maintain a uniform subgroup. This yielded a population of 76 patients. The remaining 17 patients (18%) were lost to FU for reasons such as old age and frailty, death (unrelated to the operation or prosthesis), missing data or refusal of follow-up examinations.

The patient population for the radiological assessment included all patients from the clinical evaluation for which we had x-rays in AP and axillary views, in adequate projection for a reliable analysis, at least 2 years postoperatively. 2 of the 76 patients did not meet these criteria, leaving a study population of 74.

Clinical evaluation

Patients were examined at regular intervals in the FU clinic by residents of the department of trauma and orthopaedic surgery at Agatharied Hospital, supervised by UB. BK was the main resident in charge of seeing patients in the FU clinic and carried these examinations out whenever the duty rota allowed, accounting for a large proportion of the patients. The range of active and passive range of motion (ROM), pain 0-10 according to the visual analogue scale (VAS), strength and Constant score⁸ (CS) were routinely measured pre- and postoperatively. Internal rotation was quantified, by a method designed by BK, according to the level actively reached by the patient (see **table 1 of publication 1**). The data used for the study was retrospectively taken from the patient notes. The data collection was largely performed by BK, with a small minority of cases being contributed by CG.

Radiological assessment

X-rays of the operated shoulder were taken routinely during the postoperative FU visits. These were analysed according to a protocol, using methods described by Denard¹¹, which was compiled by BK. Corresponding to this, the filling ratio was calculated as the diameter of the stem divided by the diameter of the humerus at the same level. 4 measurements were taken, one proximally and one distally, each in the AP and axillary projection (see **figure 2 of publication 2**). The mean average of these measurements was then taken as the filling ratio. The location of bony adaptations was described in terms of the 10 zones (see **figure 1 of publication 2**). New to this project was a categorical quantification of the extent of bone resorption, developed by BK. Zones with reduced bone density, in comparison to perioperative x-rays, were scored with 1 point. A zone with complete collapse of the bone onto the stem was given 2 points. The points were summed up for each patient to give a resorption score. Furthermore, the x-rays were analysed for periprosthetic lucent lines, stem/shaft alignment and formation of sclerosis around the stem. The analysis was independently performed by BK and CG using a diagnostic monitor. Where discrepancies occurred, cases were discussed and a value agreed upon.

Statistics

For each publication, BK performed the statistical analysis using the statistics software SPSS V25.0 (IBM). For the clinical paper the t-test and paired t-test were employed to investigate statistical differences in pre- vs postoperative function as well as between subgroups. For the radiological study, multiple linear regression was used to ascertain the relative impact various factors such as age, sex, prosthesis type and clinical function had on bone remodelling processes. The interaction of different forms of bone remodelling was also investigated. A significance level of $p < 0.05$ was applied throughout the statistical analyses.

Ethics

Ethical approval was sought from and granted by the ethics commission of the medical faculty of the Ludwig-Maximilians-University Munich (reference number: 667-15) in advance of study commencement. This was initially requested by a colleague Xaver Wimmer and was extended by means of an amendment through the efforts of BK.

No funding was sought or received for the completion or publication of this work.

Results

Demographics

The cohort of 76 patients included in the clinical evaluation consisted of 45 female and 31 male patients with an average age of 68.5 (range 22-84). The mean average of FU was 31.4 months (range 23-55). The most common diagnoses leading to arthroplasty were primary osteoarthritis (OA) and cuff tear arthropathy (CTA), accounting for 44 and 24 of the cases respectively. For a detailed breakdown of the demographics please see **Table 2 of publication 1**. Of these, a 58 year old female and 59 year old male patient, each with a preoperative diagnosis of primary osteoarthritis receiving TSA, were not included in the radiological examination. One was excluded due to lack of an axillary x-ray at latest FU and one due to inadequate projection of the AP x-ray.

Clinical

Cohort and prosthesis types

The cohort as a whole and all subgroups benefited from a significant improvement in all measured outcomes after joint replacement. The CS improved from a preoperative average of 38.2 to 78.3 postoperatively. Pain reduced from a mean of 6.6 to 1.0 on the VAS. Abduction increased from 88° to 129°, forward flexion from 93° to 137°. The internal rotation score rose from 1.4 to 2.6, which corresponds to the gluteal regions and lumbar spine respectively. External rotation also improved from 21° to 40°.

When comparing the improvements achieved with the different configurations of this modular prosthesis some significant differences were uncovered. On the whole it can be said that TSA outperformed PyC and RSA. PyC and RSA gave rise to equal increases in the CS, whereas TSA patients improved significantly more. TSA alleviated preoperative pain more than PyC. TSA bettered PyC and RSA in delta values of abduction, flexion and external rotation. Both TSA and PyC had greater improvements in internal rotation than RSA.

Diagnosis

To help predict how well the different prostheses improve clinical outcomes when used for individual diagnoses, a comparison between subgroups was made. This showed that when used to treat osteoarthritic shoulders TSA, which had a lower preoperative function, had a significantly greater improvement in the CS than PyC hemiprotheses ($p= 0.026$). The absolute functional outcome however was equal ($p= 0.95$). In the comparison between RSA and TSA in osteoarthritis patients, we showed that TSA had a significantly greater increase in the CS ($p= 0.011$) and a higher postoperative CS ($p= 0.002$). There was no significant difference between RSA and PyC when applied for OA, although a trend of a better outcome with PyC seemed to emerge. The comparison of the prostheses types for other diagnoses did not yield significant differences.

To answer the question of whether the outcomes for TSA, RSA and PyC differ depending on the preoperative diagnosis, a statistical comparison was made. In the PyC subgroup, patients operated for OA and arthritis resulting from instability seemed to improve more and reach a higher postoperative CS than those with avascular necrosis and fracture sequelae. There was no difference in the outcomes after RSA, whether they were operated for OA, CTA or an irreparable rotator cuff tear. For TSA no comparison was possible, as all patients had a diagnosis of OA.

Glenoid morphology

The glenoid morphology in OA, as classified by Walch and later modified by Bercik⁴, has a bearing on the grade of arthritis as well as the ability of the RC to centre the glenohumeral joint. It was therefore interesting to see how this new modular prosthesis performed in the different settings. For TSA the final outcome was equal between type A and B glenoids. However, though not statistically significant, patients with type A glenoids seemed to have more improvement compared to their preoperative function than type B. Interestingly, this trend was reversed when implanting PyC. Patients with B glenoids had significantly more improvement in the CS than those with type A ($p=0.034$), again reaching the same function overall. When applied for arthritis with a B type glenoid PyC and TSA performed similarly. In type A glenoids, however, TSA gave rise to a significantly larger gain in the CS than PyC ($p>0.0001$). The functional outcome reached, however, was comparable between those with PyC and TSA.

Complications

Among the study group of 76 patients, there were 2 cases of postoperative Haematoma which required evacuation and 2 patients with postoperative Anaemia requiring a blood transfusion. Neurological deficits were evident in 4 patients postoperatively, resolving spontaneously in the following months. There were 2 cases of stress fracture of the scapula, one at the acromion and one at the scapula spine. The scapula spine fracture was treated successfully with an ORIF, the acromial fracture healed with conservative management.

Furthermore, of the potential cohort of 103, 9 patients had significant complications. 4 of these had low-grade infections, requiring revision operations. 2 patients suffered periprosthetic humeral fractures. 1 patient had a scapula fracture with displacement of the glenoid component, most likely due to severe osteoporosis. 1 patient underwent an operation to the cervical spine following the shoulder replacement. This resulted in a neurological deficit of the ipsilateral upper limb which led to recurrent dislocations of the prosthesis. 1 TSA patient developed a RC tear and underwent revision surgery with conversion to RSA. These patients had to be excluded from the analysis as they were no longer comparable to the rest of the cohort.

Radiological

To assess the ingrowth properties of this novel stem, 74 of these patients were then included in a radiological analysis, after 2 were excluded due to insufficient x-ray quality. First the implantation properties of the stem were analysed. 55 stems had been implanted centred in the medullary canal. Of those not centred, 14 had come to lie in valgus and 5 in varus alignment. The mean average of the filling ratio was 0.54 (range 0.36-0.75). No subsidence or shift of the stem was evident in any cases.

Bony sclerosis around the stem had been previously described by other authors and called "condensation lines"^{31,33}. We observed this process in 14 patients in one or more zones. Interestingly, when sclerosis occurred, there appeared to be a relationship between the alignment of the stem in the proximal humerus and the location of the sclerosis. This suggests that the sclerosis is a reactive process, resulting from forces conveyed to the bone by the stem. We therefore did not adopt the term "condensation lines" and instead named this reactive bony sclerosis.

Bone resorption occurred in 30 patients (40.5%). 22 patients displayed partial resorption and 8 (10.8%) additionally underwent full thickness resorption in one or more zones. The resorption took place in the two proximal zones on the AP radiograph (1 and 5) most commonly, often involving the proximal part of zone 2 when full thickness resorption occurred laterally. Partial resorption was first

noticeable at an average of 16.6 months postoperatively (range 3-40). When complete resorption occurred, this became evident at around 32 months (range 10-49). The average resorption score was 0.84 (range 0-6). A progression from good bone stock postoperatively, to increasing osteopenia and finally collapse of the bone structure was observed and described in our work.

To uncover possible relationships between the findings or influencing factors, a statistical analysis using multiple linear regression was performed. There was a strong relationship between the amount of bone resorption (quantified by the resorption score) and the filling ratio ($p < 0.001$). Graphically this was particularly striking when the filling ratio exceeded 0.55 (see **figure 7** of **publication 2**). When investigating other contributing factors, it became evident that although age and sex had no direct relationship with bone resorption, they were accountable for 51% of the variation in the filling ratio ($p < 0.001$). At this stage of early to mid-term follow-up, there was no correlation between bone resorption and the clinical outcome in terms of the CS ($p = 0.17$). The diagnosis leading to surgery did not impact significantly on the filling ratio ($p = 0.59$) or the resorption score ($p = 0.69$). The prosthesis type also had no impact on the resorption score ($p = 0.47$). Implantation in a varus or valgus alignment rather than a centred position did not influence the formation of reactive sclerosis ($p = 0.93$) or bone resorption ($p = 0.42$). A higher filling ratio explained 8.1% of the variation in the development of reactive bony sclerosis ($p = 0.019$).

To further investigate the causality of the adaptive changes of the bone and the relevance of the factors which were found to be linked, we carried out a hierarchical multiple linear regression analysis. By means of this, the colinear relationships of some factors could be accounted for by correcting for one before testing the effect of the other. In this way we were able to show that age ($p = 0.22$) and sex ($p = 0.95$) do not have a significant direct correlation with bone resorption, once filling ratio is corrected for. The link, which at first seems apparent, between formation of sclerosis and bone resorption ($p = 0.003$) was negated when accounting for the effect of filling ratio first. This led to a narrow insignificance ($p = 0.058$) and only a small effect of sclerosis on variability in resorption (3%). When comparing the remodelling process between RSA and TSA, it seemed that RSA patients underwent more bone resorption. However, the filling ratio was also higher in RSA compared to TSA patients and once this was corrected for there was no significant difference in the resorption score between these two subgroups ($p = 0.70$). Furthermore, a specific comparison for zone 1 between RSA and TSA was undertaken, as the absence of the RC in many RSA patients could lead to different biomechanics here. However, no significant difference in the resorption score in zone 1 between TSA and RSA was found ($p = 0.081$).

Discussion of key findings

The clinical outcomes of these novel second-generation modular short stem shoulder prostheses were overall good and comparable to findings in the literature³⁵. The comparison of functional outcomes when this prosthesis was implanted in its different forms showed some interesting differences. The overall superiority of TSA over RSA and PyC largely matched previously reported results^{2, 15, 17, 19, 39}. We also found, as previously published by others⁹, that the internal rotation of RSA patients was significantly worse than TSA and PyC, despite refixation of the subscapularis tendon in all cases. The subscapularis muscle is the part of the RC which gives rise to internal rotation when contracted. Despite the lack of biomechanical data this suggests a mechanical limitation of the semi-constrained design of the RSA.

Of the comparisons between protheses types those between RSA and TSA, as well as between TSA and PyC are of particular interest. This is because these have the biggest intersections regarding the indications for which they are implanted. TSA is often the implant of choice in degenerative OA. In OA patients TSA outperformed RSA overall in our cohort. However, in a setting with posterior subluxation or extreme wear, many surgeons will consider RSA for OA^{15, 25}. Posterior subluxation is represented by the B types in the Walch classification⁴. In our study population the comparison between RSA and TSA, in the setting of a Walch type B glenoid, showed a larger clinical improvement in the TSA subgroup in terms of the CS. This contrasts what others have found^{15, 25} and would suggest TSA is better for arthritis with posterior eccentricity. However, we grouped all B type glenoids together in our analysis, whereas Iannotti and Mizuno both focussed on more advanced biconcave B2 subtypes. It may therefore be reasonable to conclude, that in early posterior eccentric disease with B1 or beginning B2 morphology TSA is superior, whereas in more advanced B2 or B3 wear RSA should be employed.

Regarding the comparison of PyC and TSA, better clinical results were achieved with TSA overall. However, especially in young patients with little glenoid disease, the decision to replace the glenoid is often difficult, as this is usually the first component to suffer from wear or loosening, leading to failure. Therefore, a good clinical outcome without glenoid replacement is often the goal. Other authors, using traditional cobalt-chrome heads, have reported hemiarthroplasties to be particularly ineffective in the treatment of patients with posterior glenohumeral decentration^{15, 21}. Our comparison showed an equal improvement of the CS with the use of PyC as when TSA is carried out in these cases. Furthermore, our results showed a greater improvement in Walch B than centred A glenoids with PyC. This suggests that the novel pyrocarbon may lead to an improvement in results when a posterior subluxation is present. Additionally, our results suggest that the advantage TSA holds over PyC in type A glenoids is lost in B types, as the centred A types benefit more from the glenoid replacement. Medialisation due to erosion may be reduced by a posterior subluxation, as the head is not engaged centrally reducing the force transmission in dynamic loading. The problem of glenoid wear and medialisation, which causes pain, in hemiprotheses may be less pronounced when using PyC due to the cartilage-like biomechanical properties³², especially in cases with posterior subluxation.

In the radiological assessment, overall a stable anchoring was found to be afforded by these second generation stems, without the problem of periprosthetic loosening as represented by lucent lines in the previous models⁷. However, an alarming amount of bone resorption occurred proximally around some stems. This represents a substantial loss of bone in these cases, which could lead to complications and difficult revision operations in the future. Bone resorption around prosthetic stems is a known problem and has been linked to a high filling-ratio (FR)^{10, 11, 31, 33}. We confirmed this phenomenon to be true of this second-generation stem and showed a strong link between a large filling ratio and the extent of bone resorption. This became particularly evident when the FR exceeded 0.55 in our study. Our analysis of further contributing factors and their interactions showed that the age at the time of operation as well as the sex did not have a direct affect on the bone resorption, although these factors did have a substantial impact on the filling ratio with older females being more likely to have a large prosthesis implanted relative to their own anatomy. This is important to be aware of when planning and operating these cases. With this knowledge the surgeon can be more mindful of the stem size used. This largely built on the data from Schnetzke and Raiss^{31, 33}, who had also reported higher remodelling with a larger FR. In their method however, they measured the endosteal FR (relative to the distance between the inner boundaries of the cortical bone), leading to different measurements for the average FR of patients with low or high

rates of remodelling. Also, their analysis did not differentiate between anabolic and catabolic remodelling processes (sclerosis vs resorption), which was described in more detail in our work.

We were able to explain that a link between bone resorption and the formation of reactive sclerosis was largely an indirect one, mediated by a large FR which correlated strongly with both. A small impact of sclerosis on resorption cannot be ruled out, however, as the marginally insignificant p-value would suggest. In this context a large stem transfers a lot of forces to its distal tip, causing a hardening of the bone here to accommodate the extra load. The proximal metaphysis is then shielded leading to bone resorption. This is stable under normal load, but may lead to fractures in the long run as it acts as a stress riser during trauma.

Other factors such as the type of prostheses (TSA/PyC/RSA), preoperative diagnosis and stem alignment did not have a significant impact on the remodelling process. The exception to this was that RSA patients tended to have a larger FR than TSA and thereby were predisposed to more bone resorption. This seems to be a predisposition which patients who are selected for RSA carry. Interestingly, it did not seem to be reflected in the analysis of preoperative diagnoses, which was insignificant. This could be due to the heterogenic nature of the diagnoses, especially OA, which made up a large subset of TSA and RSA cases. It seems that CTA cases as well as those with advanced and often decentred OA have poorer cancellous bone quality leading to worse stability with a press-fit stem and the relative implantation of large stems. This could be a result of chronically decreased forces from the RC causing osteopenia or due to increased subchondral sclerosis, cyst formation and cancellous osteopenia in advanced arthritis.

Limitations

The main limitation of this work is the retrospective study design. Although the patient selection criteria for each prosthesis type was described in each paper, the reliability of the comparisons are limited as a result of this confounding factor, especially for the clinical analysis. A prospective randomised design would eliminate this problem, but it would be unethical to randomly assign patients with varying types of shoulder arthritis to the prosthesis subgroups, knowing that they may not have a good result. This could only be done specifically for indications where there is uncertainty which prosthesis type is best. For example, TSA vs RSA in OA patients with a posteriorly decentred glenohumeral joint or TSA vs PyC in young patients with an intact RC.

Other factors which limit the weight which can be given to the conclusions of this work include the sample size. Although in comparison to other studies in shoulder surgery this was relatively large, it may still have been too small to detect smaller differences in the clinical outcome or the radiological properties with significance. The FU-rate of >80% for both analyses is good according to accepted standards, although it still leaves a source of weakness, as we cannot be sure that the patients who were not available for FU are adequately represented by those that were. Regarding the clinical investigation, although the subscapularis tendon was repaired in all cases, we did not carry out controls of the success of this repair. This repair, if failed, could be a source of the inferior internal in some patients. Another limitation is the variation in FU length, ranging between 23-55 months, which makes cases less comparable. It may be that some patients with shorter FU, who did not show bone resorption at the time of analysis, could still develop this or progress from partial to full thickness in the coming months. The ubiquitous problem of varying x-ray projection, could have limited the accuracy of the radiographic properties reported. To ameliorate this problem, we only included patients with x-rays of adequate quality where all zone could be reliably analysed and our scoring system, being relatively crude, should have led to reproducible results. The method of describing the zones in which remodelling takes place, which we adopted from previous work, is not

ideal for describing full thickness resorption at the lateral cortex, as this usually takes place at the border between zones 1 and 2.

Overall conclusion

Second-generation modular short stem shoulder prostheses are well anchored 2-5 years postoperatively, seemingly with improvements compared to the previous models. They also lead to a significant improvement in the clinical function of the diseased shoulder as well as alleviating pain.

The most successful results are achieved when implanting TSA, particularly for patients with OA and a Walch A glenoid type. RSA is a reliable alternative for patients with advanced disease or RC lesions, although not usually reaching the same improvements as TSA. Whilst allowing for inherent joint stability the semi constrained design of the RSA appears to limit the range of motion, the effect of which is most pronounced in internal rotation. PyC seems to be a good alternative to TSA, when a glenoid replacement is to be avoided. It gives good clinical improvements in the majority of patients, especially for patients with arthritis resulting from instability, or with OA. Furthermore, it seems that PyC is particularly effective in posteriorly decentred disease. However, patients do not seem to benefit from as much pain relief after PyC when compared to the other prosthesis types, most significantly TSA.

Whilst showing good ingrowth overall with almost no signs of loosening, a substantial loss of bone occurs at the proximal metaphysis of some stems. This is strongly linked to the implantation of large stems with a high FR, which we have defined as > 0.55 . These thick stems are stiff and convey a high proportion of the forces encountered at the joint to their distal tips. This results in stress shielding of the proximal metaphysis leading to bone resorption. Conversely the increased force transmission to the cancellous bone at the tip of the stem often leads to formation of a reactive sclerosis here. Other factors do not seem to have a direct affect on the remodelling process, although female sex, old age and patients being operated with RSA have a higher risk of the implantation of a stem with a high FR. This indirectly predisposes these patients to bone resorption. To avoid this, surgeons should attempt to reduce the stem size required. This can be achieved by autologous cancellous bone grafting, from the resected humeral head. Alternatively, if a stem with a safe FR cannot be implanted in a press-fit technique with adequate hold, cementation should be considered.

Zusammenfassung

Clinical and radiological evaluation of a second-generation uncemented modular short stem shoulder prosthesis with a proximal porous coating

Little is known about radiological ingrowth properties of second-generation short stem shoulder prostheses and factors which may influence this. The clinical outcomes of these prostheses when used in their different modular forms, as a TSA, RSA or PyC, have not been investigated.

For this doctoral thesis, a retrospective cohort study of 76 patients 2-5 years after receiving TSA, RSA or PyC using a second-generation modular short stem prosthesis (FU of 82%), was conducted. Patients were examined preoperatively and at regular postoperative intervals. The range of motion, pain and Constant score were recorded, x-rays were taken. The radiological analysis was undertaken by two examiners independently. 2 of the patients had to be excluded from this due to inadequate x-ray quality. The stem alignment and FR were ascertained and documented. Bone remodelling was noted and the relevant location specified as one of 10 zones. Bone resorption was quantified: Each zone with partial resorption was awarded 1 point and full thickness resorption 2 points. A statistical analysis, comparing pre- vs postoperative clinical function, as well as outcomes between prosthesis types and indications was undertaken. Furthermore, a multiple linear regression analysis of the radiological remodelling process and factors contributing to this was carried out.

All prostheses types brought about a significant improvement ($p < 0.05$) in all measured clinical outcomes. TSA demonstrated a significantly greater improvement in the CS than RSA and PyC ($p = 0.003$ and 0.002 respectively). TSA also showed more improvement in all ROM compared to RSA ($p < 0.02$). RSA improved significantly less than TSA and PyC in internal rotation ($p = 0.0001$ and 0.008 respectively). TSA brought about significantly more pain relief than PyC ($p = 0.02$). TSA patients with Walch A glenoids seemed to improve more than B in the CS, whereas PyC patients with B glenoids improved more than those with type A ($p = 0.03$). The clinical outcome of RSA did not differ between diagnoses, but seemed to improve more in cases with Walch A glenoids. The radiological analysis showed no subsidence or shift of the stems. Only 2 patients showed lucent lines, each of 1mm in zone 1. The average FR was 0.54 (range 0.36 - 0.75). 30 patients (40.5%) displayed some form of bone resorption, first evident at 16.6 months (range 3-40), usually in the proximal zones. This progressed to full thickness resorption in 8 of these patients (10.8%) in ≥ 1 zone after 32 (range 10-49) months. Important predictors of FR were age and sex, accounting for 51% of the variation. Additionally, RSA had a higher FR than TSA patients ($p < 0.001$). A high FR correlated with bone resorption ($p < 0.001$), especially when the FR exceeded 0.55. Other factors, including stem alignment, diagnosis, prosthesis type and reactive sclerosis, did not directly predict the bone resorption score. Reactive bony sclerosis correlated with a high FR ($p = 0.019$) and thus indirectly correlated with bone resorption. Bone loss did not align with the clinical outcome.

In conclusion, these short stems are firmly anchored 2-5 years postoperatively. Nevertheless, substantial bone loss occurs in cases with a high FR (> 0.55) at the proximal metaphysis. Oversizing also leads to sclerosis of cancellous bone. Other factors did not directly affect stem ingrowth. Older females and those undergoing RSA are predisposed to a high FR. Measures should be taken to downsize the stem required. Alternatively, cementation should be considered if a suitably small stem cannot find adequate hold. When these stems are implanted in their different modular forms, TSA achieves the best clinical outcomes overall, particularly when applied for OA with a Walch A glenoid. RSA has an inferior ROM to TSA and PyC, especially in internal rotation, despite refixation of the subscapularis tendon. OA, arthritis resulting from instability and a Walch B glenoid appear to be ideal indications when considering PyC.

Klinisch und radiologische Evaluation einer unzementierten modularen Kurzschaft-Schulterprothese der zweiten Generation mit proximaler Beschichtung

Die radiologischen Einwachseigenschaften von neuartigen Kurzschaft-Schulterprothesen und Faktoren welche diese beeinflussen könnten sind noch nicht umfassend beschrieben. Auch die klinischen Ergebnisse dieser Prothesen, wenn in ihren verschiedenen Versionen (TSA, RSA oder PyC) angewandt, sind noch unklar.

Im Rahmen dieser Dissertation, wurde eine retrospektive Kohortenstudie von 76 Patienten 2-5 Jahre nach Implantation einer Kurzschaft-Schulterprothese der zweiten Generation (TSA, RSA oder PyC), bei einem FU von 82%, durchgeführt. Patienten wurden prä- sowie regelmäßig postoperativ untersucht. Bewegungsumfang, Schmerzniveau, und CS wurden erhoben, Röntgenbilder angefertigt. Die radiologische Auswertung wurde von 2 Untersuchern unabhängig voneinander durchgeführt. 2 Patienten wurden hiervon, aufgrund von schlechter Röntgenqualität, ausgeschlossen. Die Schaftausrichtung und FR wurden bemessen. Knochenumbauvorgänge wurden in 10 Zonen beschrieben. Knochenresorption wurde quantifiziert, indem pro Zone 1 Punkt für partielle- und 2 Punkte für komplette Knochenresorption berechnet wurden. Eine statistische Auswertung zum Vergleich von prä- vs. postoperativer Gelenkfunktion, sowie zwischen Prothesentypen und Indikationen erfolgte. Des Weiteren wurde eine multiple lineare Regressionsanalyse der radiologischen Umbauvorgänge und von möglichen beeinflussenden Faktoren angefertigt.

Alle Prothesentypen erbrachten eine signifikante Besserung aller gemessenen klinischen Variablen. TSA Patienten erzielte eine größere Zunahme im CS als RSA- und PyC-Patienten ($p = 0,003$ und $0,002$). TSA Patienten zeigten zudem eine größere Steigerung aller Bewegungsumfänge im Vergleich zu RSA ($p < 0,02$). Bei Innenrotation hatten RSA Patienten eine geringere Besserung als TSA- und PyC-Patienten ($p = 0,0001$ und $0,008$). Die Implantation einer TSA führte zu mehr Schmerzlinderung als diejenige von PyC ($p = 0,02$). TSA schien bei Walch A Glenoiden eine größere Zunahme im CS hervorzubringen, wohingegen bei PyC Ergebnisse von B Glenoiden überlegen waren ($p = 0,03$). Diagnosen hatten keinen Einfluss auf das klinische Ergebnis von RSA, doch mit einem Walch A Glenoid zeigte sich ein Trend zu einem größeren Anstieg im CS. Die radiologische Auswertung bestätigte kein Einsinken oder Verlagern der Schäfte. Nur 2 Fälle hatten jeweils einen 1mm Saum in Zone 1 um den Schaft. Der Mittelwert der FR war 0,54 (0,36 – 0,75). 30 Patienten (40,5%) entwickelten Knochenresorption, welche zuerst nach 16,6 Monaten und meistens in den proximalen Zonen, nachweisbar war. Diese zeigte bei 8 dieser Patienten (10,8%), nach 32 Monaten (10 – 49), eine Progredienz zu kompletter Knochenresorption in ≥ 1 Zone. Die FR wurde durch Alter und Geschlecht zu 51% beeinflusst. Des Weiteren, hatten Patienten mit RSA eine höhere FR als TSA Patienten ($p < 0,001$). Eine hohe FR korrelierte mit Knochenresorption ($p < 0,001$), besonders bei einer FR von $> 0,55$. Andere Faktoren wie Schaftausrichtung, Diagnose, Prothesentyp und reaktive Sklerose hatten keinen direkten Einfluss auf die Knochenresorption. Knochenverlust korrelierte nicht mit dem klinischen Ergebnis.

Schlussfolgernd sind diese kurzen Schäfte 2-5 Jahre postoperativ fest verankert. Jedoch findet, bei Fällen mit einem hohen FR ($> 0,55$), an der proximalen Metaphyse ein deutlicher Knochenverlust statt. Die Überfüllung bringt auch eine Sklerosierung der Spongiosa hervor. Andere Faktoren beeinflussen das Einwachsverhalten nicht direkt. Ältere Frauen und Patienten die eine RSA bekommen sind zu einer hohen FR prädisponiert. Die Schaftgröße sollte so klein wie möglich gehalten werden. Alternativ sollte die Zementierung in Betracht gezogen werden, falls ein angemessen dünner Schaft keinen adäquaten Halt findet. Wenn diese Schäfte in ihren

unterschiedlichen modularen Arten angewandt werden, erzielt TSA allgemein das beste klinische Ergebnis, besonders bei OA und einem Walch A Glenoid. RSA hat im Vergleich zu TSA und PyC einen eingeschränkten Bewegungsumfang, insbesondere bei Innenrotation, trotz Refixation der Subscapularissehne. OA, Instabilitätsarthrose und Walch B Glenoide scheinen die ideale Indikation für PyC darzustellen.

Veröffentlichungen

Veröffentlichung 1

*RSA, TSA and PyC hemi-prostheses:
comparing indications and clinical
outcomes using a second-generation
modular short-stem shoulder prosthesis*

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RSA, TSA and PyC hemi-prostheses: comparing indications and clinical outcomes using a second-generation modular short-stem shoulder prosthesis

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Abstract

Introduction The goal of this study was to provide an insight into the clinical results after modular short-stem shoulder arthroplasty for various indications.

Materials and methods A consecutive cohort study of 76 patients followed up for 23–55 (mean 31.4) months. 23 anatomical (TSA), 32 reverse (RSA) and 21 hemi-prostheses with a pyrocarbon head (PyC), using a modular short stem with proximal porous coating were implanted. Range of motion, pain and Constant score (CS) were recorded. Comparisons of pre- vs postoperative outcomes, between prosthesis types and indications, were made.

Results All prosthesis types brought about a significant improvement ($p < 0.05$) in all measured outcomes. TSA had a significantly higher increase in the CS than PyC and RSA ($p = 0.002$ and 0.003 , respectively). TSA produced superior gains in all ROM compared with RSA ($p < 0.02$). RSA brought about significantly smaller improvements in internal rotation than TSA and PyC ($p = 0.0001$ and 0.008 , respectively). TSA had greater pain relief than PyC ($p = 0.02$). TSA with Walch A glenoids seemed to improve more than type B in the CS. PyC patients with Walch B glenoids improved more than Walch A ($p = 0.03$). When implanted due to Osteoarthritis (OA), PyC had a comparable final outcome to TSA ($p = 0.95$), although the preoperatively worse TSA patients had a greater improvement in the CS ($p = 0.026$). The outcome of RSA did not differ between indications, but Walch A glenoids tended to improve more.

Conclusions Using a second-generation short-stem shoulder prostheses, TSA achieves the best clinical improvements overall, especially for OA with a Walch A glenoid. Despite refixation of the subscapularis tendon in all cases, RSA has inferior internal rotation than TSA and PyC, suggesting a mechanical limitation. OA, a Walch B glenoid and arthritis caused by instability seem to be ideal indications when considering PyC.

Keywords Short stem · Shoulder arthroplasty · Pyrocarbon · Clinical · Hemiarthroplasty · Modular

Introduction

Shoulder arthroplasty is an increasingly common therapy for osteoarthritis, rheumatoid arthritis, cuff tear arthropathy, osteonecrosis as well as intra-articular fractures of the proximal humerus [1, 2].

Uncemented modular short-stemmed prostheses are still a relatively novel design type in shoulder prostheses and early results have been very positive with good function and low complication rates [3, 4]. A benefit is that one stem can be used in different configurations, as part of a hemi-prosthesis, RSA or anatomical TSA.

Hemi-prostheses are often considered for young patients with predominantly humeral disease, to avoid the complications of a glenoid replacement, subsequent bone loss and difficult revision surgery. However, a major problem when replacing only the humeral joint surface, traditionally with a cobalt-chrome head, is progressive glenoid wear and pain [5, 6]. Consequently, it has been found that TSA has a better outcome and more pain relief than hemiarthroplasty [7]. Pyrocarbon is a novel material thought to have

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biomechanical properties similar to cartilage and is therefore being used in hemi-prostheses in a hope to ameliorate this problem [8]. Clinical results achieved with this new material are yet scarce and to our knowledge no data exist where these are compared to total shoulder replacement.

A recent comparison of elderly patients receiving RSA or TSA for glenohumeral arthritis with an intact rotator cuff was unable to find a significant difference in outcomes [9]. However, other studies have shown TSA to be superior in external rotation [10] and in internal rotation when compared in patients who had contralateral implantation of both RSA and TSA [11].

For cuff tear arthropathy there is a consensus that joint replacement should be performed with RSA. However, for primary osteoarthritis a TSA, RSA or hemi-prosthesis may be used. The choice of which type to implant is based on the patient age, function and disease morphology. The morphology of glenoid wear, as described by Walch and later modified by Bercik [12], has been shown to impact on the outcomes after shoulder arthroplasty. Outcomes of hemi-prostheses were found to be adversely affected by eccentric posterior wear [13]. This trend has also been described for outcomes after TSA, although these still had better results than hemi-prostheses in patients with Walch B2 glenoids [14]. For this reason a trend has emerged to opt for RSA in cases with excessive posterior glenoid wear [15].

The aim of this study was to investigate and compare the clinical outcomes of this second-generation short-stem modular shoulder prosthesis, when used in its different forms (TSA, RSA and PyC) and for different indications.

Materials and methods

Patient population and study design

In this single-centre cohort study, all 103 patients who consecutively underwent shoulder arthroplasty, using a curved titanium short-stem uncemented modular prostheses with a proximal porous coating (Aequalis Ascend Flex™, Wright Medical, Bloomington, USA), between May 2013 and June 2015 at Agatharied hospital, were invited for follow-up at regular intervals. All the operations were carried out by one of two senior surgeons.

Preoperatively the glenoid retroversion was calculated relative to the Friedman line [16], the inclination according to the Maurer angle [17] using X-rays and CT. The prostheses were implanted in three forms: Hemiarthroplasty using a pyrocarbon head (PyC), anatomic total shoulder prosthesis (TSA) and reversed shoulder prosthesis (RSA). Patients were offered prosthesis types best suited to their pathology: Patients with primary osteoarthritis, intact rotator cuffs, a glenoid retroversion of $< 10^\circ$ and a posterior subluxation

of the humeral head of $< 80\%$ underwent anatomical TSA; patients with little or no glenoid pathology, an intact rotator cuff and younger age were offered a PyC hemiprosthesis; lastly patients with rotator cuff pathology, glenohumeral subluxation of $> 80\%$ or a glenoid retroversion of 10° or more were treated with RSA. If the retroversion was $> 10^\circ$, this was corrected with the use of autologous wedge-shaped cancellous bone grafting (wedged BIO-RSA) under the base plate (4 cases). Furthermore, in 2 cases with extreme glenoid wear, BIO-RSA was employed to lateralize the base plate. The subscapularis tendon was repaired in all cases transosseously in double-row technique.

10 Patients were excluded from this study: 1 with a hemiprosthesis with a titanium head (in place of the pyrocarbon due to nickel allergy) and 9 with complications as outlined in the results below, leaving a potential study group of 93. Data from preoperative examinations as well as at most recent follow-up were gathered and analysed. The glenoid morphology was described according to the modified Walch classification [12] from the preoperative CT. We had follow-up data for 76 of the eligible 93 patients (82%). Patients were lost to follow-up for reasons, such as old age and frailty, death (unrelated to the operation or prosthesis), missing data or refusal of follow-up examinations.

Clinical evaluation

Preoperatively and during follow-up appointments clinical outcomes, such as range of movement (ROM) and pain on the visual analogue scale (VAS), as well as the validated Constant Score (CS) [18], were recorded. This and further patient information including the demographics, diagnosis and operations were gathered from the patient records. To quantify internal rotation, this was scored as shown in Table 1.

Statistics

The statistics software SPSS V25.0 (IBM) was used. To assess the significance of changes in pre- and post-operative outcomes, the paired *t* test was calculated; to compare the delta values (difference between pre- and postoperative)

Table 1 Scoring system for internal rotation

Internal rotation score	Level reached with the back of the hand
0	Thigh
1	Gluteal
2	Iliosacral joint
3	Lumbar spine
4	Thoracic spine
5	Scapula

Table 2 Patient demographics and preoperative diagnoses

	Total	TSA	RSA	PyC
Number	76	23	32	21
Age	68.5 (22–84)	70.0 (58–84)	74.1 (65–84)	58.3 (22–84)
Sex	45 female	15 female	26 female	4 female
Follow-up (months)	31.4 (23–55)	31.6 (23–51)	34.3 (23–55)	26.7 (23–38)
Primary osteoarthritis	44	23	6	14
Cuff tear arthropathy	24	0	25	0
Irreparable rotator cuff tear	1	0	1	0
Fracture sequelae	1	0	0	1
Avascular necrosis	3	0	0	3
Arthritis resulting from instability	3	0	0	3

Table 3 Preoperative glenoid morphology according to the modified Walch classification [18]

Glenoid type (Walch)	Total	TSA	RSA	PyC Hemi
A1	14	0	9	5
A2	28	13	11	4
B1	19	6	7	6
B2	11	4	2	5
B3	0	0	0	0
C	0	0	0	0
D	4	0	3	1

between implant types, the *t* test was employed. In each case the significance threshold was set at $p < 0.05$.

Results

Patient demographics

The patient demographics and diagnoses leading to surgery of the study group of 76 patients are shown in Table 2. With the exception of the PyC subgroup, the cohort was made up of more women than men. The PyC contingent was younger and male dominated. The average age was the highest in the RSA subgroup.

Table 3 shows the glenoid morphologies of the patients prior to surgery. TSA patients had mostly A2 glenoids, but also B1 and B2 wear patterns. RSA also had predominantly A type glenoids, but also B and D morphologies. The PyC subgroup contained patients with mixed glenoid types.

Pre- vs postoperative clinical outcomes

The clinical outcomes pre- vs postoperative are displayed in Table 4. All patient groups improved significantly ($p < 0.05$) in all outcomes measured. TSA patients had, on average, the lowest preoperative and the highest postoperative CS. The PyC patients had the highest preoperative CS. All patient groups benefited from pain reduction, reducing from VAS 6.6 pre-change to preoperatively down to 1.0 postoperatively. Abduction increased from 88° to 129°, forward flexion from 93° to 137°. Internal rotation increased from reaching the gluteal area before, to placing the back of the hand on the lumbar spine after the operation. On average, patients also benefited from more external rotation, 21° preoperatively and 40° postoperatively.

Comparison between implant types

To reduce the confounding effect of the demographical differences in the subgroups, delta values (difference between

Table 4 Pre- and postoperative outcomes for the measured variables for the cohort and subgroups

Outcome	Total pre-OP	Total post-OP	TSA pre-OP	TSA post-OP	RSA pre-OP	RSA post-OP	PyC pre-OP	PyC post-OP
CS	38.2	78.3	34.5	84.0	36.9	72.9	44.2	80.3
Pain VAS	6.6	1.0	6.7	0.37	6.8	1.1	6.4	1.5
Abduction°	88.2	129.4	84.3	138.3	88.1	121.7	92.6	131.4
Flexion°	92.5	137.1	87.6	144.3	91.4	128.0	99.5	143.1
Internal rotation (score)	1.4	2.6	1.0	3.1	1.7	2.3	1.2	2.7
External rotation°	21.1	39.6	6.1	40.0	19.8	36.3	17.6	44.3

All comparisons between pre- and postoperative values were statistically significant ($p < 0.05$)

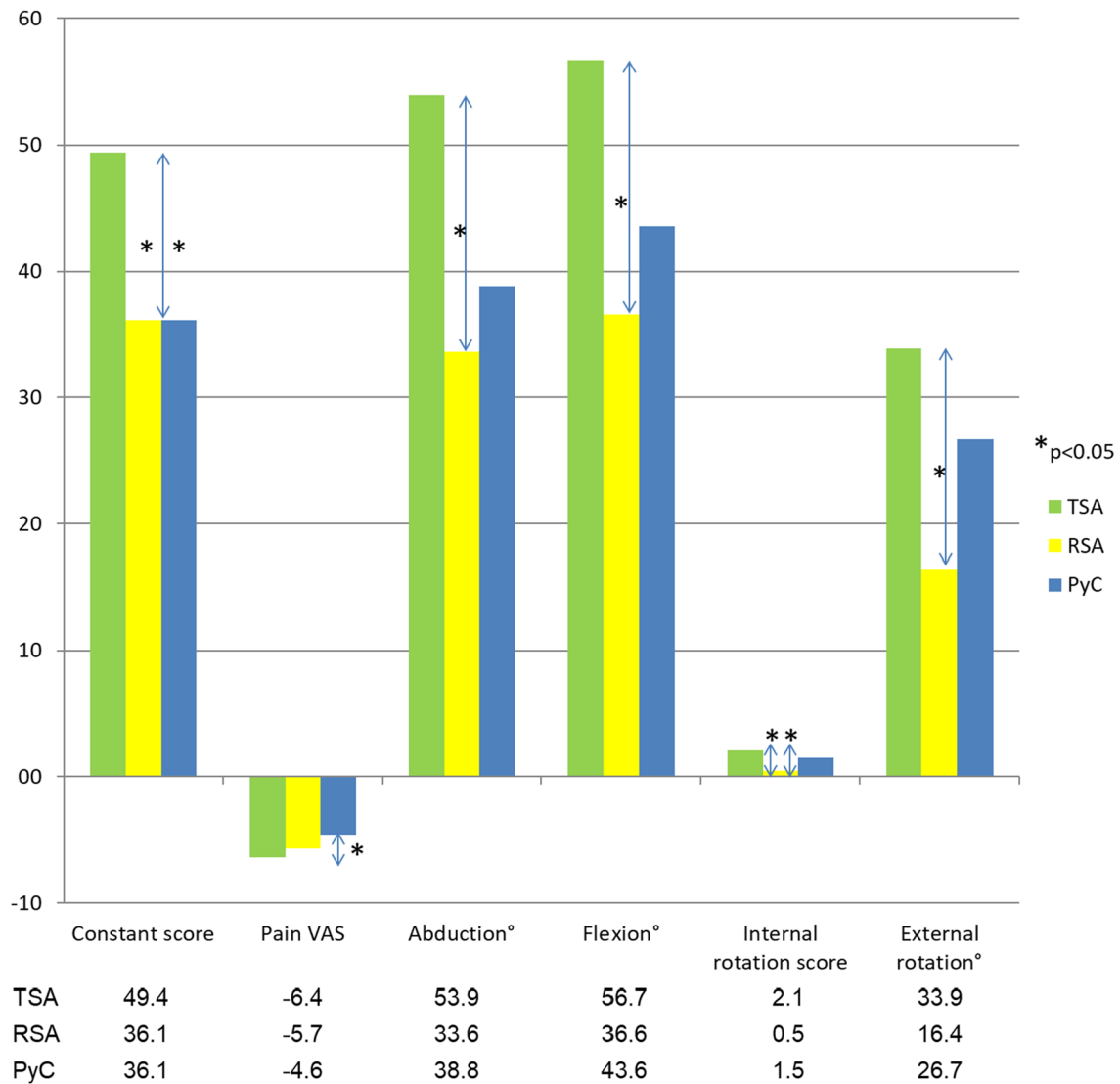


Fig. 1 Delta (postoperative minus preoperative) values for the measured outcomes compared between the implant types. Statistically significant ($p < 0.05$) differences are identified with a *

pre- and postoperative) were compared between prosthesis types (Fig. 1).

Notably, anatomical total shoulder replacements had a significantly higher increase in the CS than the other two types. They also brought about more pain alleviation than the pyrocarbon hemiarthroplasties. In abduction and flexion the RSA had less improvement than the TSA. Both the TSA and the PyC gained more internal rotation than the RSA. Additionally, the TSA had larger improvements in external rotation than the RSA. All other comparisons between the implants were not statistically significant. Nevertheless, the trend emerged that TSA was superior to the other two in all aspects and PyC bettered the RSA in everything but pain reduction.

Given that glenoid morphology is an important predictor of outcome, we investigated the performance of the different prostheses when used in patients of varying glenoid types (see Table 5). Interestingly the final outcome of TSA did not differ between A and B glenoids. However, the improvement achieved with TSA seems to be greater in A than in B glenoid patients, although this was not statistically significant ($p = 0.085$). Conversely, using PyC, patients with B glenoids improved significantly more than those with A glenoids ($p = 0.034$), again achieving the same final outcome. The one patient with a D glenoid in PyC had a poor preoperative function and improved less than A and B patients. When comparing the result with PyC vs TSA in arthritis with B type glenoids, little

Table 5 Comparison of mean constant score by prosthesis type and glenoid morphology

Glenoid type (modified Walch)	Prosthesis type		
	TSA	RSA	PyC
A			
Preoperative CS	28.9	30.4	52.7
Postoperative CS	83.5	71.5	81.7
Delta CS	53.7	41.1	29.0
B			
Preoperative CS	40.6	47.8	39.5
Postoperative CS	84.5	76.6	82.8
Delta CS	43.9	28.8	43.3
D			
Preoperative CS	–	49.7	18.0
Postoperative CS	–	74.0	39.0
Delta CS	–	24.3	21.0

difference is seen in the outcome or the function gained. In patients with type A glenoids, however, a significantly greater improvement was observed using TSA compared with PyC ($p < 0.0001$). Both subgroups reach a similar postoperative CS.

In the RSA subgroup patients with Walch A glenoids appeared to have the greatest improvement, but this was not significant (A vs B $p = 0.091$; A vs D $p = 0.15$). The postoperative CS was comparable between all three glenoid types.

Table 6 differentiates the results achieved when applying the different prosthesis types for the various diagnoses. The comparison for TSA and PyC hemi-prostheses in osteoarthritic shoulders revealed a significantly greater improvement in the CS of TSA patients ($p = 0.026$), which had a lower preoperative function. However, there is no difference in the final outcome of the PyC and TSA subgroups ($p = 0.95$). When comparing RSA with TSA in osteoarthritis patients, TSA has a significantly greater increase in the CS ($p = 0.011$) and a better postoperative CS ($p = 0.002$). When comparing the results achieved for OA, there was no significant difference in the delta CS using PyC or RSA ($p = 0.43$). Although PyC seemed to have a better final result, this was not statistically significant ($p = 0.058$).

Comparing the results for different indications within the PyC subgroup, this showed no significant differences in the delta scores or postoperative CS between any diagnoses ($p > 0.05$). However, patients operated for OA and arthritis resulting from instability seemed to have a greater benefit and a better postoperative outcome than those with avascular necrosis and fracture sequelae. Although not statistically significant (or measurable using a t test), the patient with arthritis resulting from a fracture had the worst postoperative

Table 6 Comparison of mean CS achieved using the different prostheses for the various diagnoses

Diagnosis	Prosthesis type		
	TSA	RSA	PyC
Primary osteoarthritis			
Preoperative CS	34.5	42.5	45.6
Postoperative CS	84.0	74.7	83.8
Delta CS	49.5	32.2	38.2
Cuff tear arthropathy			
Preoperative CS	–	34.8	–
Postoperative CS	–	72.4	–
Delta CS	–	37.6	–
Irreparable rotator cuff tear			
Preoperative CS	–	53	–
Postoperative CS	–	75	–
Delta CS	–	22	–
Fracture sequelae			
Preoperative CS	–	–	50
Postoperative CS	–	–	61.5
Delta CS	–	–	11.5
Avascular necrosis			
Preoperative CS	–	–	41.7
Postoperative CS	–	–	68
Delta CS	–	–	26.3
Arthritis resulting from instability			
Preoperative CS	–	–	38.3
Postoperative CS	–	–	82.3
Delta CS	–	–	44

CS and the least improvement compared to the mean values of the other diagnoses.

In the RSA subgroup patients operated for CTA did not improve significantly differently in the CS ($p = 0.53$), nor did they reach a different outcome according to the CS ($p = 0.72$), when compared with patients with OA. The patient with the irreparable rotator cuff tear, although not statistically testable, also appeared to have an outcome comparable to the other RSA patients.

Complications

In the study group of 76 patients, 2 developed stress fractures: 1 of the scapular spine, which was successfully operated with an ORIF; one of the acromion, which was treated conservatively. 2 patients were revised with evacuations of postoperative haematomas. There were 2 cases of postoperative anaemia requiring a blood transfusion (2.7%) and 4 cases had neurological deficits postoperatively which resolved spontaneously in the months following surgery.

Complications leading to exclusion

9 patients had to be excluded as a result of complications which were recorded in the follow-up of the initial patient cohort of 103 shoulder prostheses, as they were no longer deemed comparable to the rest of the cohort: 4 patients were found to have a low-grade infection (3.88%) and had to be revised. 2 of these were RSA patients, one of whom was 88 years old, the other was a psoriasis vulgaris patient under methotrexate therapy. TSA and PyC had one case of infection each; in the case of the PyC this was a patient who had had a previous operation due to a tubercular fracture. 2 of the 4 infections were caused by *Cutibacterium acnes* (formerly known as *Propionibacterium acnes*). One patient with a TSA developed a rotator cuff tear and was converted to RSA. There were 2 patients with periprosthetic fractures of the humerus (1.94%), one of whom was treated at another hospital. The other fell and fractured twice, she was treated conservatively the first time, the second time she was operated with a single cerclage with a good outcome. One RSA patient with extremely osteoporotic bone suffered a bony dislocation of the glenoid component, despite the use of a long peg base plate and 4 screws. This was revised, the glenoid component removed and as a salvage operation a modular exchange to place an anatomical head on the existing shaft was performed. 1 patient underwent a cervical spine operation in the months after her shoulder prosthesis and suffered a neurological deficit ipsilaterally, involving the deltoid, as a complication of this. This resulted in recurrent dislocations of the shoulder prosthesis and a stress fracture of the scapula spine of the operated side, leading to exclusion.

Discussion

Key results

This patient cohort showed significant improvements in all measured ROM, pain and the CS compared to preoperative values, using a modular short-stem prosthesis with a proximal porous coating 2–4 years postoperatively. This correlates with previous findings using first-generation short-stemmed shoulder prostheses [3, 4, 19, 20]. The overall very positive clinical outcomes achieved with these shoulder prostheses are also, at least, comparable to those described with the use of standard-stemmed prostheses with diaphyseal anchoring [21, 22].

The modular design of this prosthesis has the advantage of individualized assembly to recreate the anatomy of the proximal Humerus and balance tension of the soft tissues. Eccentric head/tray (depending on anatomical or inverse design) components allow the surgeon to adjust the position

of the head/tray by turning it to the ideal position before fixation. In this way ideal coverage without overlap and adjustments of soft tissue tension can be made regardless of the stem position. This is of particular importance in the anatomical prosthesis and may in part have contributed to the successful clinical outcomes.

The hemiprosthesis which was used in this cohort uniformly utilized a novel pyrocarbon head. This material is thought to have a biomechanical profile close to that of cartilage and therefore is hoped to reduce the problem of glenoid wear and pain which complicate traditional hemiarthroplasties [8]. Preliminary results after implantation of these have been encouraging, except in patients with a diagnosis of fracture sequelae (osteonecrosis or secondary osteoarthritis), in a study containing some of the patients from our cohort [23]. Our results equally are encouraging, with improvements in all areas of clinical function. With regard to results in the use for fracture sequelae, we had one patient operated with PyC for this indication, which yielded a poorer result than all other indications, adding weight to the conclusion drawn by Garret et al. [23].

The RSA used in this cohort has a neck shaft angle (NSA) of 145°. This is an intermediate value between the 135° and 155° which inverse prostheses also commonly have. Mechanical studies have shown that a steeper NSA causes earlier impingement in abduction, but reduces glenoid notching and increases joint stability [24]. Computerized models have found a lower NSA (135°) to allow a greater ROM in all motions except abduction [25]. This was also true of internal rotation, although the effect of the lower NSA on internal rotation was negated when the glenosphere had been lateralized. Our cohort demonstrated a successful clinical outcome with this modular tray with a NSA of 145° in terms of the ROM, with no dislocations, suggesting this may be a good compromise between mobility and stability.

The comparison between the different types of this modular prosthesis was interesting, as it showed several differences in their functional characteristics. Overall, though not always statistically significant, the TSA achieved the best outcomes in all measured variables. Kiet et al. have previously described the outcomes of RSA and TSA to be similar, with only better rotation in the TSA group [10]. They, however, did not compare the delta values of the measured parameters. Contradictory to our findings, Flurin et al. described higher outcome scores in TSA but comparatively greater gains in RSA patients [26]. They had implanted the Equinoxe shoulder platform system (Exactech Inc., Florida). Differences in results compared to our study may be due to the implant or differences in the patient cohorts. Trends emerged that patients with PyC heads generally had greater improvements in the ROM than RSA, whilst RSA brought

about more pain relief than PyC. However, the only statistically significant difference between the PyC and the RSA was that PyC had greater improvement in internal rotation. This is mirrored by better internal rotation in TSA compared to RSA patients and is a reproducible finding [10, 27]. As we reconstructed the subscapularis tendon in all prosthesis types, this phenomenon may likely be explained as being a result of a mechanical restriction of the RSAs semi-constrained design.

Comparison between glenoid types

When comparing glenoid types, one important finding was that the final outcome did not differ between TSA patients which had type A or B glenoids. It appears, though, that there may be a greater increase in the CS when operating patients with a centred type A situation. This may be because A glenoids have a purely arthritic problem, which can be solved by replacing the glenoid surface, whereas in the B type situation a soft tissue imbalance complicates the disease. PyC patients with B type glenoids improved more than those with A glenoids, reaching a similar end result. This implies that the presence of a B glenoid does not contraindicate the use of a PyC hemiprosthesis and rather laments that it may be a good indication. It seems that the additional benefit the A types have over B types in TSA is lost in PyC, as the glenoid is not replaced. Strengthening to this is that patients with B glenoids had comparable outcomes when treated with TSA or PyC, whereas type A glenoids improved significantly more when treated with TSA. This does not entirely fit with the findings of Iannotti, who found that both TSA and hemi-prostheses had worse outcomes in a Walch B2 setting, where TSA was still the better choice [14]. This may be because we grouped all B type glenoids together (roughly equal numbers of B1 and B2), whereas they only looked specifically at B2. Also, they used standard cobalt-chrome heads for their hemi-prostheses, so it may be that the new pyrocarbon heads have different clinical properties to these. Perhaps in a type B1 situation with little glenoid wear, the natural glenoid with its labrum is superior to a prosthetic glenoid, giving rise to more clinical improvement when the corresponding arthritic humeral articular surface is replaced. Furthermore, it may be that in a B2 setting with biconcave posterior wear PyC is more effective than standard cobalt-chrome prostheses.

In RSA it appears as if patients with type A glenoids may have the most benefit from the operation. This may be because these are the ones that have cranialized more, rather than posteriorizing and therefore benefit from the distalization of the RSA more. The final outcome appears similar between all glenoid types, including type D, however.

Comparison between Diagnoses

When comparing outcomes between the different types of prostheses in terms of results achieved for osteoarthritis, these mirrored what we found overall when comparing RSA to the other two types. The comparison between TSA and PyC showed a greater improvement in TSA patients with OA, as was the case in the comparison of the entire subgroups for the prostheses. However, the final outcome of the PyC, when only considering OA patients, now matched that of the TSA patients much more closely. In TSA therefore, older patients with worse preoperative function improve more than the on average younger PyC patients. Nevertheless, the function achieved after 2 years when using PyC for OA is equal to that of the TSA.

To allow some insight into what a good indication for the novel PyC hemiprostheses may be, it was interesting to try and compare the results achieved for the various diagnoses. Unfortunately, the group sizes were too small to show any significant differences in this regard. It can be said, though, that there is a trend that OA and arthritis resulting from instability may be the best indications for implanting a PyC hemiarthroplasty.

The improvements and outcomes achieved using RSA seem to be the same irrespective of the preoperative diagnosis. This may be because it has inherent stability due to its semi-constrained design, allows recruitment of the deltoid muscle to substitute rotator cuff function and is limited more by mechanical impingement.

Complications

The infection rate of 3.88% documented in our cohort is comparative to findings of a meta-analysis by Zumstein et al. who found an infection rate of 3.8% in RSA patients [28]. Rates of 1–3.9% have been described for TSA as well [29], whilst it is thought that rates in RSA patients are higher due to haematoma formation in the increased dead space [30]. This is in line with our results. Differences in the reported infection rates are likely to be a result of follow-up and diagnostic differences. Rates of low-grade infections are often likely to be higher than reported as they are difficult to distinguish from aseptic failure [31]. *Cutibacterium acnes* (formerly *Propionibacterium acnes*), which made up half of our 4 cases, has been reported to be present in 18–60% of infections [30]. It is found in the deep tissues around the shoulder, more commonly in men, when using the deltopectoral approach and it has been found in the joint fluid of 42% of patients undergoing primary shoulder arthroplasty and more often still in revision surgery [30, 32, 33].

The rate of periprosthetic humeral fractures in our cohort (1.94%) correlates with 1.6–2.4% described in the

literature for standard shaft prostheses [34]. However, we were able to treat a patient with a recurrent periprosthetic fracture successfully with as little as a single cerclage. This may indicate simpler treatment options for periprosthetic fractures around short-stem prostheses, but clearly more data are required to draw any conclusions regarding this. Regarding the two cases of scapula spine and 1 acromion fracture in the potential cohort of 103 patients, it should be noted that these all occurred in RSA patients. This is unlikely to be a coincidence as reverse shoulder prostheses put a lot of stress on the delta muscle which causes tension and can lead to stress fractures of the scapula. This affect may be exacerbated in this model due to the additional lateralization and distalization brought about by the onlay design of the modular tray.

Limitations and generalizability

The main limitation of this study is the retrospective design and tailored patient selection for the different subgroups, leading to selection bias. The resulting differences in diagnostic indications for arthroplasty and patient demographics in the subgroups limit the extent to which interventions can be reliably compared. Furthermore, the sample size, although when compared with other similar studies in the literature is large, may have inhibited the emergence of further statistical significances in the comparison between the prosthesis's subtypes. The follow-up rate of 82%, which for a mid-term cohort study is satisfactory, could to some extent jeopardize the generalizability of the study. Furthermore, whilst using a single-centre study design increases reliability in a scientific method, it also reduces the extent to which results can be extrapolated to other settings. This must be taken into account when interpreting results. The treatment of this cohort took place before we adopted the use of 3-dimensional planning, so it is not known if and how much correction of version and/or inclination was achieved. Another limitation is that although the subscapularis tendon was repaired in all cases, we did not carry out any controls of the success of this repair.

Conclusions

This study provides an insight into the clinical properties of the different forms in which modular short-stem shoulder prostheses can be implanted and their results for various indications.

When implanted for the diagnoses for which each were conceptualized, it can be said that TSA patients can expect the greatest clinical improvement postoperatively compared

to RSA and PyC. PyC patients seem to have bigger improvements in ROM than RSA patients but may subjectively have less pain reduction. Interestingly, despite refixation of the subscapularis tendon in all prosthesis types, RSA had less improvements in internal rotation than the other two prosthesis types, which suggests a mechanical restriction of RSA.

When comparing the clinical success of these prostheses when used for different glenoid types according to the modified Walch classification, we can surmise that TSA has the same outcome regardless of A or B glenoid type, but possibly with more improvement for type A glenoids. Novel PyC hemiprostheses are a good indication for patients with type A and type B glenoids, with equal clinical outcomes and a greater improvement in B glenoids. In fact, type B glenoids were treated just as successfully with PyC as with TSA.

If OA is the indication for arthroplasty, TSA and PyC achieve a comparable clinical result 2–4 years postoperatively, although the preoperatively worse TSA patients have more improvement. It can be said that if glenoid replacement is to be avoided, for example due to young age, that OA patients or those with arthritis resulting from instability and especially in the presence of a type B glenoid seem to be good candidates for treatment with PyC.

The diagnosis for which RSA is implanted does not seem to greatly affect the outcome, but those with a Walch A glenoid may improve more.

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Compliance with ethical standards

Conflict of interest B. D. Kleim: None. C. Garving: None. U. H. Brunner: Consultant for Wright Medical, has given paid presentations for Wright Medical.

Ethical approval Ethical approval was sought and granted by the ethics commission of the medical faculty of the Ludwig-Maximilians-University Munich (Reference number: 667-15) in advance of study commencement.

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Cementless curved short stem shoulder prostheses with a proximal porous coating: ingrowth properties at 2-5 years of radiological follow-up with clinical correlation

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Abstract

Background

Little is known about the way the newest generation of stems integrate into the proximal humerus and their effect on the surrounding bone. Factors which may influence ingrowth have not been investigated.

Methods

A consecutive cohort study examining 74 anatomical, reverse or pyrocarbon hemi-prostheses, using a curved modular short stem with a proximal porous coating 2-5 years postoperatively (mean 35 months). X-rays were reviewed by 2 examiners independently. Bone loss was scored with one point per zone with partial and 2 points per zone with complete resorption (10 zones). The Constant score was used for clinical correlation. Multiple linear regression was employed to investigate correlations between variables.

Results

No subsidence or shift of the stems occurred. 2 of 74 patients showed 1 zone of periprosthetic lucency of 1mm. The filling ratio averaged 0.54 (range 0.36-0.75). 30 patients (40.5%) displayed bony resorption, first seen at 16.6 months (range 3-40), commonly in zones 1 and 5.

22 patients had ≥ 1 zone with partial resorption and 8 (10.8%) developed full thickness resorption after 32 (range 10-49) months.

One new finding was that female sex and older age accounted for 51% of the variation of the filling ratio. A high filling ratio, especially when >0.55 , correlated with bone resorption ($p < 0.001$). Age, sex and prosthesis type did not directly predict bone resorption. Bony sclerosis correlated with a high filling ratio ($p = 0.019$) and thereby indirectly with resorption. A direct correlation between sclerosis and resorption was narrowly insignificant ($p = 0.058$) once correcting for filling ratio. RSA had a higher filling ratio than TSA patients ($p < 0.001$), resulting indirectly in more bone resorption. The preoperative diagnosis did not significantly correlate with filling ratio ($p = 0.59$) or the resorption score ($p = 0.69$). A varus or valgus alignment did not predict resorption ($p = 0.21$) or the formation of sclerotic lines ($p = 0.93$). Bone loss did not correlate with clinical results.

Conclusions

These short stems are firmly anchored 2-5 years postoperatively. However, significant bone loss, linked to a high filling ratio (>0.55), is observed proximally around these stems. The development of sclerotic lines around the stem indicates oversizing. Other factors were not found to have a significant effect on stem ingrowth. The implantation of stems with a large filling ratio is more common in older females and in patients receiving RSA. Autologous impaction bone grafting could downsize the required stem. If adequate hold is not afforded by a suitably small stem cementation is advisable.

Level of evidence: 3

Key words: shoulder prosthesis, short stem, resorption, remodelling, radiological, pyrocarbon.

Introduction

Uncemented short stems with a proximal porous coating are becoming widely used in anatomical, reverse and hemi shoulder arthroplasties^{9, 11}. Previous short stem prostheses, without the proximal porous coating, have been found to have high rates of aseptic loosening³. The clinical results that can be achieved using this latest implant type have been shown to be at least comparable to standard shafts^{16, 20}. However, the way this newest generation of stems integrate into the bone and their effect on the surrounding bone stock is yet to be examined in detail.

Stress shielding is a reduction of bone density resulting from decreased mechanical stimulation of bone surrounding an implant (Wolf's law). It is a problem which was first described in hip prostheses, but has since been found after shoulder arthroplasty^{7, 17}.

Shortening the humeral component of a shoulder prosthesis brings about a more natural stress distribution⁶, so could ameliorate stress shielding caused by the implant. This is important as bone resorption could affect the long-term clinical function of the prostheses, increase the likelihood of periprosthetic fracture and make revision surgery more difficult.

The filling ratio of the prosthesis in the proximal humerus has been shown to be an important predictor of bone resorption in previous studies^{16, 17, 18, 20}. The filling ratio gives an indication of the size of the prosthesis relative to the patient's bone structure. Larger prostheses are stiffer than thinner ones. The stiffness dictates how much force is conducted to the distal end of the implant. Stiff shafts conduct a greater proportion of load forces to the distal tip of the prosthesis, shielding the metaphysis. Conversely, thin shafts are more flexible and convey more load to the proximal bone, avoiding stress shielding.

Recently other authors have begun to describe the radiological properties of this newest range of short stem prostheses, with a proximal porous coating^{16, 18, 20, 22}. Of these, Schnetzke and Raiss both found, mirroring the findings of the first generation of short stem prostheses, that a high filling ratio was linked to increased bone remodelling. However their analysis did not consider the interaction of different variables such as age, sex, diagnosis and all prosthesis types (RSA, TSA or hemiprotheses) on the remodelling processes observed. Nor did they differentiate between anabolic and catabolic developments (sclerosis vs resorption), the relationship and significance of these are still to be uncovered. Tan et. al. showed a trend to similar levels of stress shielding, but with more medial calcar resorption in the absence of the proximal porous coating when compared to prostheses with the coating²². However, this was a comparison study with small numbers and the findings were not statistically significant. A clear recommendation of how to avoid bone loss due to remodelling when implanting these novel short stem shoulder prostheses has not been made.

The aim of this study was therefore to describe the radiological ingrowth properties of short stem shoulder prostheses with a proximal porous coating. Furthermore, we set out to explain the remodelling processes observed, investigate their interactions with other factors and correlate these with the clinical outcome.

Materials and Methods

Patient population and study design

We conducted a consecutive cohort study of 74 out of 103 patients who were operated with a second-generation modular short stem shoulder prosthesis with a proximal porous coating between May 2013 and June 2015 at Agatharied hospital. Implanted were anatomical (TSA), reverse (RSA) or hemi-prostheses with a pyrocarbon head (PyC) (Aequalis Ascend Flex, Wright medical, Bloomington, USA). All 103 patients were invited for follow-up examinations. Our department had clinical follow-up data for 76 and x-ray images with adequate quality and projection for 74 of these 103 patients 2-5 years postoperatively (mean 35, range 23-60 months). 9 patients had complications leading to revision or rendering them incomparable to the rest of the cohort, the others were lost to follow-up. Reasons for this were old age, inability to travel, refusal of follow-up and death unrelated to the prosthesis. This paper reports on the radiological findings of this cohort using the x-ray images taken at follow-up examinations, investigates interacting factors and correlates these with the clinical outcome.

Prostheses and operative technique

Titanium short stem uncemented modular prostheses with a proximal porous coating (Aequalis Ascend Flex™, Wright medical, Bloomington, USA) were implanted in three forms: Hemi-arthroplasty using a pyrocarbon head (PyC), anatomic total shoulder prosthesis (TSA) and reversed shoulder prosthesis (RSA). Cementless, this stem achieves metaphyseal fixation through bony ingrowth after a press-fit implantation. The oval shaped stem takes the path of least resistance during implantation, which helps to guide this into the natural retrotorsion of the humeral head. The glenoid retroversion was calculated relative to the Friedman line¹⁰, the inclination according to the Maurer angle¹⁵ using the preoperative x-rays and CT.

The operative technique uses the deltopectoral approach. In all cases the subscapularis was taken down in the “peel-off” technique. The humeral head is resected in a manner depending on the type of prosthesis (see below). The proximal humerus was sequentially prepared using a sounder to define the width of the medullary canal and a compactor to check for the definitive implant size. All stems in this series were uncemented. The subscapularis tendon was repaired in all cases transosseously in double row technique.

RSA

For reversed prostheses a cut was made at 132.5° of inclination, using a guide, aiming for a final inclination of 145° when including the 12.5° of the inlay. The height of the resection should place the highest point of the tray at the level of the tip of the greater tuberosity. The glenoid baseplate was implanted with the inferior border flush to the inferior glenoid with $0-10^\circ$ of inclination and a retroversion of $<10^\circ$. If the retroversion was $>10^\circ$ this was corrected with the use of autologous wedge-shaped cancellous bone grafting (wedged BIO-RSA) under the base plate (4 cases). Additionally, in 2 cases with extreme glenoid wear, BIO-RSA was employed to lateralize the long peg base plate. All other RSA patients received the standard base plate with 25 mm or 29 mm diameter, depending on the native glenoid size. The size of the metaglene was 36 for females and 42 for males and this was implanted with an inferior overlap of at least 5mm. The humeral trial with the tray in position 6 and the required inlay was then reduced into the joint. The surgeon checked for deltoid tension, stability, range of motion and impingement. Finally the definitive humeral stem with the reversed head components, assembled on a back table, were implanted.

TSA

For the anatomical prostheses a free-hand resection along the anatomical neck, after removal of osteophytes, was undertaken. The natural inclination was then matched using a prosthesis with 127.5, 132.5 or 137.5° of inclination. Minimal reaming of the glenoid, according to the radius of the curvature of the glenoid, was undertaken and a cemented keeled glenoid was implanted. The humeral trial with the required head was then reduced into the joint and examined as described for RSA above. Finally, the definitive humeral stem with the anatomical head component, assembled on a back table, were implanted.

PyC

The technique for preparation and implantation of the humeral component mirrored that described for TSA. The joint capsule was mobilized and the labrum preserved. In some cases with Walch B1 and B2 glenoids these were treated with minimal reaming (so as to spare as much glenoid bone as possible) and then perforation of any remaining areas of sclerosis with a 1.2 mm Kirschner-wire. The size and rotation of the head was then chosen to maximize coverage of the resected surface whilst avoiding overlap. After trialling, the final stem was implanted and the Pyrocarbon head was mounted in vivo in the optimum rotation with the spring impactor.

Radiological assessment

Two experienced examiners (CG and BK) independently scrutinised the patients' x-rays in 3 planes on a diagnostic monitor in the manner described by Denard et. al.⁷. Where intra observer differences occurred, the cases were discussed and a consensus reached. The location of adaptations found was described in terms of the 10 Zones, as pictured in **figure 1**. The filling ratio was calculated by taking an average of the bone vs prosthesis diameter measured at 4 sites: Proximally and distally in both the AP and axillary views as shown in **figure 2**. In order to better differentiate and quantify bone resorption a novel scoring system

was employed: It was categorised into partial (osteopenia) and complete (full thickness) resorption and scored with one point for every zone with partial and 2 points for every zone with complete resorption.

Clinical evaluation

Patients were examined in our follow-up clinic at regular intervals by experienced examiners. The Constant score⁴ was calculated pre- and postoperatively and used as a quantitative marker for the clinical outcome. Delta values (postoperative - preoperative) were used to allow for a more reliable comparison between subjects.

Statistics

Statistical models using multiple linear regression and hierarchical multiple linear regression were constructed to investigate correlations between the variables. This was performed using the SPSS V25.0 (IBM) software.

Results

The Demographics of the cohort of 74 patients which were analysed for this study are shown in **table 1**.

Implantation properties

55 stems were centered, 14 in valgus and 5 in varus alignment (illustrated in **figure 3**). The filling ratio, as described above, averaged at 0.54 (range 0.36-0.75). No subsidence or shift of the prosthesis was observed in any patients.

Bony adaptations

The bony adaptations which were found are summarised in **Table 2**. An example of reactive bony sclerosis (also called condensation lines) is shown in **figure 4**. 10 of these patients had sclerosis in zone 3, 4 cases in zone 2 and 3 patients in zone 4. 4 patients also had sclerotic reactions in the proximal zones: 3 patients in zone 1 and 1 patient in zone 6. These were accompanied by scleroses in the central distal zone in 3 cases and in zone 2 (lateral distal) in one case. All cases with sclerosis in the proximal zones had prostheses which were centred in alignment. Of those with sclerosis in zone 3 all but one were centred in alignment. Reactive sclerosis in zone 2 was present in cases with centered or varus alignment, never with valgus. 2 patients who developed bony scleroses had a valgus alignment, in both cases scleroses were observed only in zone 4.

Cortical thinning was observed in 30 patients (40.5%). Of these, 22 patients had at least one zone with partial resorption and 8 (10.8%) additionally had one or more zones with full thickness resorption. Partial resorption in zones 1 and 5 were the most common, with 15 and 17 cases respectively. Two patients had partial resorptions in zone 10, one patient in zone 7 and one patient in zone 2. These were first seen radiologically at an average of 16.6 months (range 3-40). The average resorption score, as described above, was 0.84 (range 0-6).

Full thickness resorption was present in two patients in zone 1, three patients in zone 2 (proximal part), two patients in zone 5 and one patient in zone 6. An example of this is shown in **figure 5**. The transition from partial to complete resorption was first seen on average after 32 (range 10-49) months. It can be observed that progressive osteopenia takes place with loss of bone density and cortical thickness. Following this, the bone collapses all the way down to the prosthesis, as shown in **figure 6**.

Statistical correlations

The outcomes of the linear regression analysis are displayed in **Table 3**. There was a strong correlation between a high filling ratio and more bone resorption ($p < 0.001$), especially when the filling ratio exceeded 0.55 (see **figure 7**). Age and sex predict 51% of the variation in filling ratio ($p < 0.001$). A higher bone resorption score did not significantly correlate with the constant score gained ($p = 0.17$). The diagnosis leading to surgery did not significantly correlate with filling ratio ($p = 0.59$) or the resorption score ($p = 0.69$). The prosthesis type had no significant relationship with the resorption score ($p = 0.47$). The presence of a varus or valgus alignment vs a centred one did not correlate with the development of condensation lines ($p = 0.93$). A varus or valgus alignment was also not predictive of increased bony resorption ($p = 0.42$). A higher filling ratio correlated significantly with the development of reactive bony sclerosis ($p = 0.019$), explaining 8.1% of the variation in sclerosis.

In a hierarchical multiple linear regression model, when accounting for the effect of filling ratio first, age ($p = 0.22$) and sex ($p = 0.95$) do not have any significant direct association with bone resorption. The presence of a reactive bony sclerosis seemed to be a significant predictor of bone resorption ($p = 0.003$) when tested independently, however when correcting for its collinearity with filling ratio, sclerosis added little variation to the model (3%) and was an insignificant factor ($p = 0.058$). A comparison of the remodelling processes between RSA and

TSA showed more resorption in the RSA group, as well as a higher filling ratio in RSA patients. Once correcting for the effect of filling ratio there was no significant difference in resorption score between RSA and TSA ($p=0.70$). A specific comparison of resorption in zone 1 in RSA vs TSA patients, which could be different due to absence of the rotator cuff in many RSA patients, did not show a significant difference ($p=0.081$).

Discussion

Larger prostheses carry more forces from the shoulder joint to the proximal diaphysis, shielding the metaphysis and thereby causing bone remodelling. This effect may also be fortified by the loss of intraosseous blood supply¹⁴. Our finding that patients with a filling ratio under 0.55 had few problems with bony remodelling largely fits with the study by Raiss et al. who described an average filling ratio of 0.57 in patients with low levels of bony adaptations¹⁸. In contrast to the method proposed by Denard⁷, Raiss measured the filling ratio using the endosteal bone diameter (a smaller distance, making the ratio compared to the stem larger) and only in the AP projection (where the shaft is thicker). This will be the reason why the average diameter of low remodelling patients was on the upper end of our safe cut-off for patients with little resorption. Also, in addition to describing what filling ratio patients with low remodelling have, we have assessed how large the filling ratio is allowed to be without risking a lot of bony resorption using this stem. The shape of the stem has been found to influence stress shielding and bone remodelling^{1,21,24}, therefore the critical filling ratio may vary when using other short stem prostheses. The pattern of bony resorption is that the proximal medial and lateral zones (1 and 5) are most commonly affected. The proximal area of zone 2 is then involved in the collapse of bone down to the stem, often creating an hour glass like formation.

In our cohort 17 of 74 patients (23%) displayed medial calcar osteopaenia, which is considerably less than the 83% reported by Schnetzke et al. in 2016 for the previous model of this prosthesis¹⁹. This may be a result of the proximal porous coating, which allows more transfer of load to the metaphyseal bone than the previous stem did.

Another adaptation that has previously been described is that of sclerosis of the cancellous bone surrounding the shaft, often around the distal tip, also called “condensation lines”^{18,20}.

A new finding is the appearance of these scleroses at the proximal end of the stem, possibly due to the proximal porous coating, which gives this prosthesis hold in the proximal metaphysis. The formation of sclerosis, we have been able to show, seems not to be directly linked to bony resorption. Instead it mainly correlates indirectly, as it also occurs in patients with a higher filling ratio more commonly. A slight correlation may be present however, given the marginal p-value of 0.058, responsible for 3% of variation in resorption.

The alignment of the prosthesis in the proximal humerus (varus, valgus or centred) does not influence the formation of sclerosis. It does however dictate where sclerosis may occur, as it impacts upon the areas where loads and forces are transferred to and carried by the bone. When bony sclerosis occurs in centred prostheses it is found centrally at the tip of the stem with occasional additional scleroses in the proximal zones- axial load bearing. Patients with sclerotic reactions in zone 2 (lateral to the tip of the stem) have either a centred or varus alignment, never valgus. Finally, a valgus alignment seems to direct a sclerotic reaction medially of the tip of the stem.

Most of the adaptations observed appear in the AP radiograph and therefore occur medial or lateral to the shaft. This may be due to the shape of the shaft, which is thickest and least flexible at this point and could also be influenced by the direction of the forces which are applied during the movement of the shoulder. Despite the proximal porous coating, it seems that when prostheses are large and anchor at the distal tip, forces are not passed on to the proximal metaphysis, resulting in stress shielding and bone resorption here. If the shape of the prosthesis was revised to be thinner at the tip and have a more flexible stem, more force may be shared with the proximal bone.

Female sex and older age were described by a previous study to influence bony remodelling¹⁸, however in our analysis we were able to explain that this relationship is only an indirect one. Age and sex influence the relative size of prostheses implanted, most likely due to poorer bone quality and it is only through this that older patients and those of female sex had more bony resorption.

In our cohort there was no direct relationship between the type of prosthesis implanted and bone remodelling. As TSA and RSA have polyethylene components and PyC does not, it seems that the remodelling processes seen cannot be explained by polyethylene wear, as has been suggested in other settings^{1,2}. Periprosthetic osteolysis is commonly caused by an inflammatory reaction to polyethylene wear particles. Only 2 patients (2.7%) were found to have one zone each of lucency of 1mm in our cohort. This is at a stark contrast with the results achieved using previous models of short stem shoulder prostheses, which have shown rates of lucent lines of 71%³. The low rate of lucent zones in this most recent stem type, when compared to previous models, may be in part a result of the proximal porous coating which integrates into the bone or fills with fibrous tissue²⁴ and may act as a barrier to polyethylene debris matter, as this migrates best along surfaces without a porous coating^{1,24}. Nevertheless, RSA patients did show more resorption than TSA, mediated through a higher filling ratio in this subgroup. Interestingly the preoperative diagnosis did not show a relationship with the filling ratio. This is probably because TSA patients all had primary OA and there were also a lot of primary OA patients in the RSA group. However, the OA patients who were treated with RSA are more likely to have high grade disease with posterior subluxation and therefore a rotator cuff insufficiency. It may be that these and the CTA patients, which are the other big diagnosis group to receive RSA, have a comparatively low cancellous bone density resulting in a larger filling ratio. The increased sheer forces the stems of RSA patients are likely to be

subjected to do not seem to affect the remodelling process significantly, perhaps just replacing the effect of forces from the rotator cuff.

Revision operations in patients with a lot of bone resorption will be challenging. Therefore, as ease of revision is one of the main arguments for the implantation of uncemented prostheses, it must be considered that these are not a good option for patients where the implantation of a small prosthesis does not afford good hold. Preoperatively, this can more likely be expected when operating older female patients, or when planning RSA, according to our findings. A maximum size of prosthesis which can be implanted whilst avoiding over-filling should be calculated. Intraoperatively, it may be necessary to adapt the surgical technique to the bone quality and its resulting hold after impaction, as ascertained using the twist test. If the largest calculated prosthesis which can be implanted without exceeding a filling ratio of 0.55 does not find satisfactory hold in the proximal humerus there are two alternative options. The transfer of autologous cancellous bone graft from the resected humeral head to the humeral metaphysis in order to increase bone stock has been found to be successful at ensuring fixation^{12, 13, 23}. This may enable the implantation of an adequately small prosthesis with sufficient stability. If this is not possible, the implantation of a cementless prosthesis should be abandoned. Cemented prostheses cause a more even distribution of forces to the surrounding bone and allow for the implantation of thinner, less stiff prostheses, as a result of which they cause significantly less stress shielding^{1, 5, 8, 17, 21}. Cementation may therefore be the alternative option to revert to if adequate fixation cannot be achieved with a small stem.

Limitations

The inherently retrospective design of this type of study makes direct comparisons between male/female, old/young and different prostheses as well as diagnoses difficult. As is commonly the case in studies of shoulder surgery, a larger cohort size would have increased

the reliability of our findings further. 29 of the cohort of 103 patients were not able to be analysed for this study, largely due to lack of follow-up data. This reduces the reliability of our findings, as we cannot be sure that the 74 patients analysed fully represent the entire cohort. As the range of development of resorption was 3-40 for partial and 10-49 for full thickness resorption, it is likely that some patients at the lower end of the range of follow-up would have developed further bone resorption in time. The absence of a clinical correlation with bone remodelling is a finding which mirrors what has been described by other authors^{18, 20}. However, as there is only short- to mid-term data available on this thus far, it may be that a correlation is found in long-term studies in the future.

A problem with retrospectively analysed x-ray images is the ubiquitous slight differences in projection. Although only patients with x-rays of adequate quality and projection, where all 10 zones could be reliably analysed, were included, slight rotational differences could have led to decreased accuracy of the results. Having said this, our scoring system for bone resorption is relatively coarse, so does not require perfect images to lead to reproducible results. Also, these are the kind of images which clinicians encounter regularly, making our method transferable to everyday clinical practice. Nonetheless, it may be that a method which accurately measures bone density and volume could uncover relationships between resorption and other factors more sensitively. As the area between zones 1 and 2 is a common site for bone loss, the previously described and used zones are not ideal in describing the adaptations around these prostheses.

Conclusions

Cementless short stem shoulder prostheses with a proximal porous coating are firmly embedded 2-5 years postoperatively, seemingly with improvements in comparison to previous models of this stem. Our findings suggest that the proximal porous coating, which is new to this model of short stem prosthesis, may have the following benefits: Reduced proximal bone resorption, increased fixation in the proximal metaphysis as suggested by the appearance of sclerosis here in some cases and decreased periprosthetic osteolysis.

Overall, large shafts appear to anchor distally, often causing a sclerotic hyperdensity of cancellous bone here. The area where this occurs is directed by the stem alignment. The proximal metaphysis is then shielded from physical stresses, causing resorption. The implantation of a prosthesis with a high filling ratio, in this stem over 0.55, carries the risk of high levels of bone loss. Bony sclerosis is also caused by overfilling of the proximal humerus, but resorption and sclerosis seem not to be directly associated with each other significantly. Formation of sclerosis can be seen as a marker of overfilling in the follow up clinic, which is also likely to lead to resorption. Resorption becomes evident after around 16.6 months in the proximal humeral metaphysis in a substantial proportion of patients. In around 1 in 10 patients in our cohort osteopenia progressed, around two and a half years postoperatively, to full thickness bone resorption in the proximal zones and proximal part of zone 2.

Preoperative diagnosis did not correlate with filling ratio or remodelling in our cohort. Age, sex and prosthesis type are not independent predictors of Bone resorption. However, the filling ratio is influenced by the age and sex of the patient and is also higher in RSA patients. Older and female patients, as well as those receiving RSA, are thereby indirectly at increased risk of periprosthetic bone remodelling.

There is no clinical correlation with bone resorption at this stage. However, there could be a higher risk of periprosthetic fracture in the future and the decreased bone stock will present problems when performing revision operations.

Autologous bone grafting from the resected humeral head to decrease the prosthesis size needed should be considered. Alternatively, cemented implants exhibit little stress shielding and therefore reduce the risk of bone resorption. We therefore propose that it is advisable to revert to the use of cemented prostheses when adequate fixation cannot be achieved with a press-fit implant of a safe size.

Further work

We suggest that large studies with long-term follow up to investigate the clinical and radiological properties of these prostheses are required in the future. Survival rates and contributing factors should be investigated. Furthermore, results after revision surgery are of interest.

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Legends

Figures

1. The 10 Zones around the proximal humerus in the AP and axillary views.
2. Method of determining the filling ratio in 2 x-ray planes.
3. Examples of varus and valgus alignment of the implanted short stem prostheses.
4. Example of bony sclerosis around the tip of a large prosthesis 2 years postoperatively in a 67 y/o female patient.
5. Example of full thickness bone loss in zone one and the proximal part of zone 2, as well as partial resorption in zone 5 in a 70 y/o female patient.
6. Transition from good bone stock postoperatively, to osteopaenia after 24 Months and eventually collapse of the bone down to the prosthesis after 37 months in a 69 y/o female patient.
7. Scatter plot depicting the strong correlation between filling ratio and bony resorption.

Tables

1. Patient population demographics
2. Results of the correlation analysis, showing the effect of independent variables on dependent variables. The extent to which the independent variable influences the variability in the dependent variable is shown as %, the significance in terms of a p-value.
3. Types of bony adaptations observed and number of cases in which these occurred.

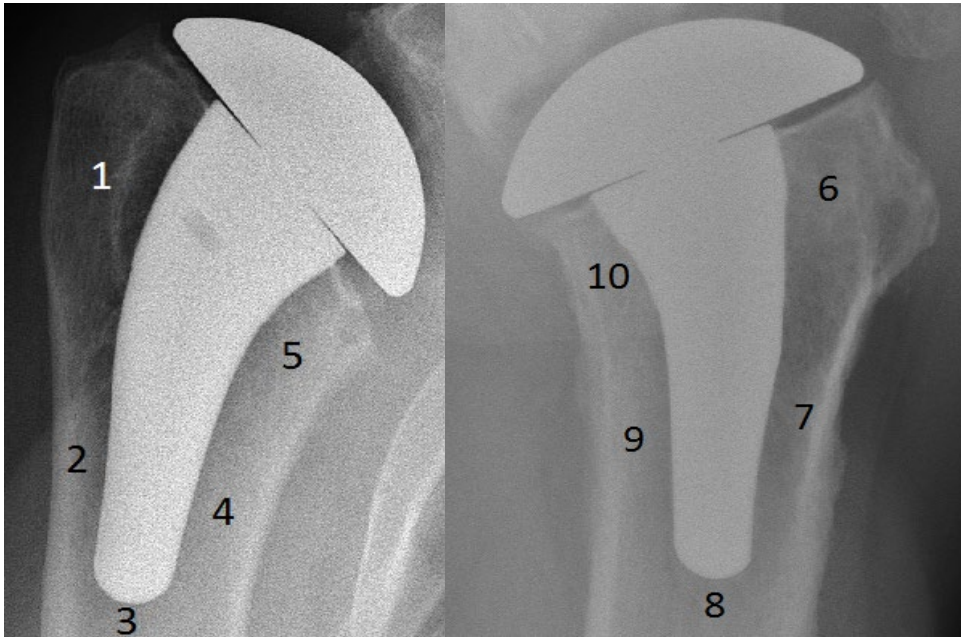


Figure 1: The 10 zones around the proximal humerus, in the AP (left) and axillary (right) views, categorising the site of bone remodelling. In the axillary view the count starts from the proximal ventral zone.

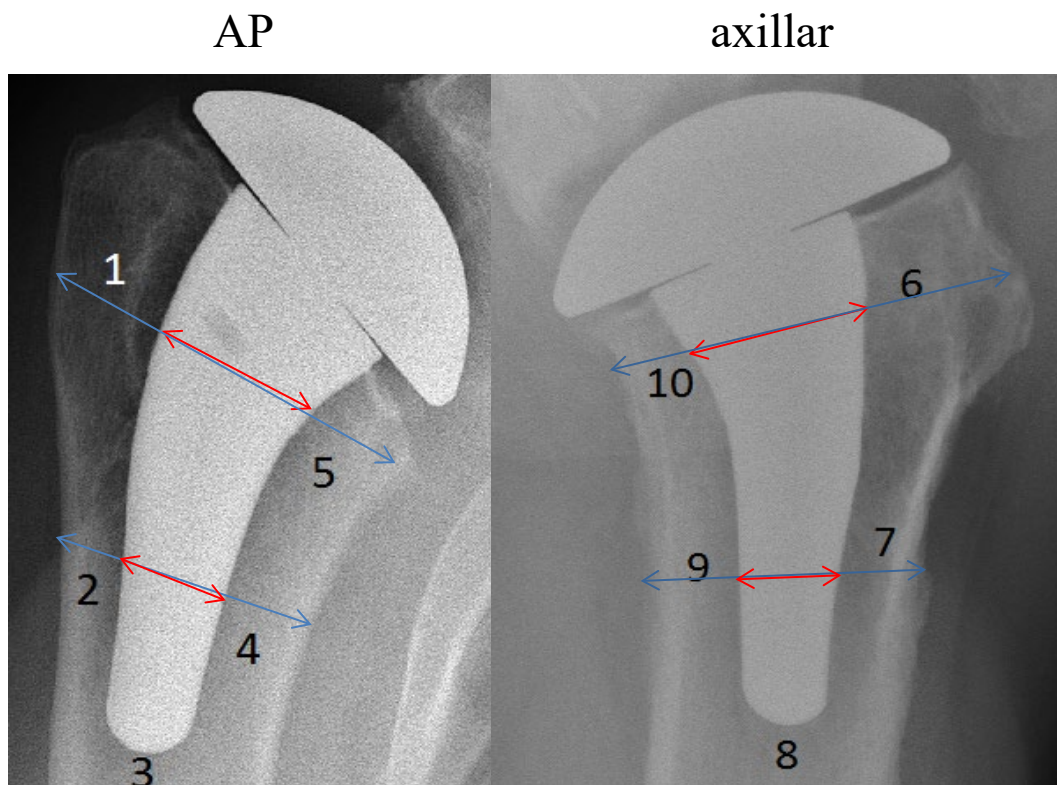


Figure 2: The method of determining the filling ratio in 2 x-ray planes. The mean average of the 4 ratios (red/blue) is taken.

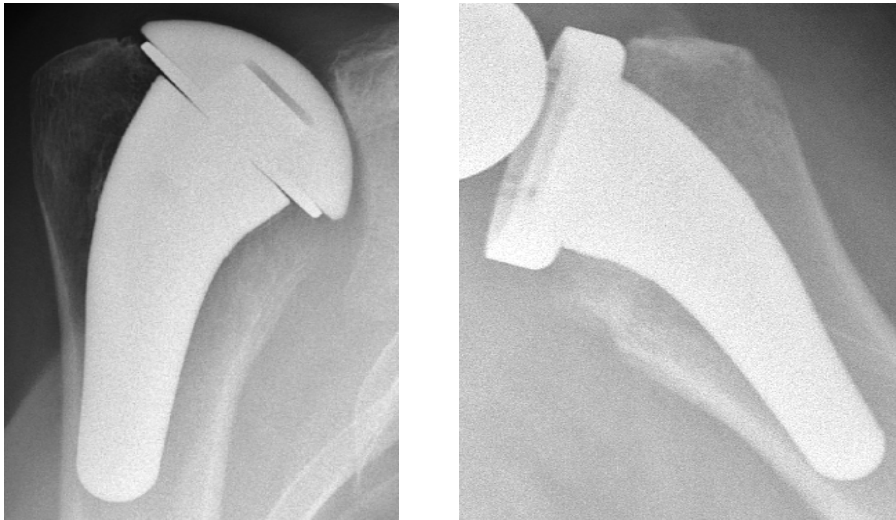


Figure 3: Examples of varus (left) and valgus (right) alignment of the implanted short stem prostheses.

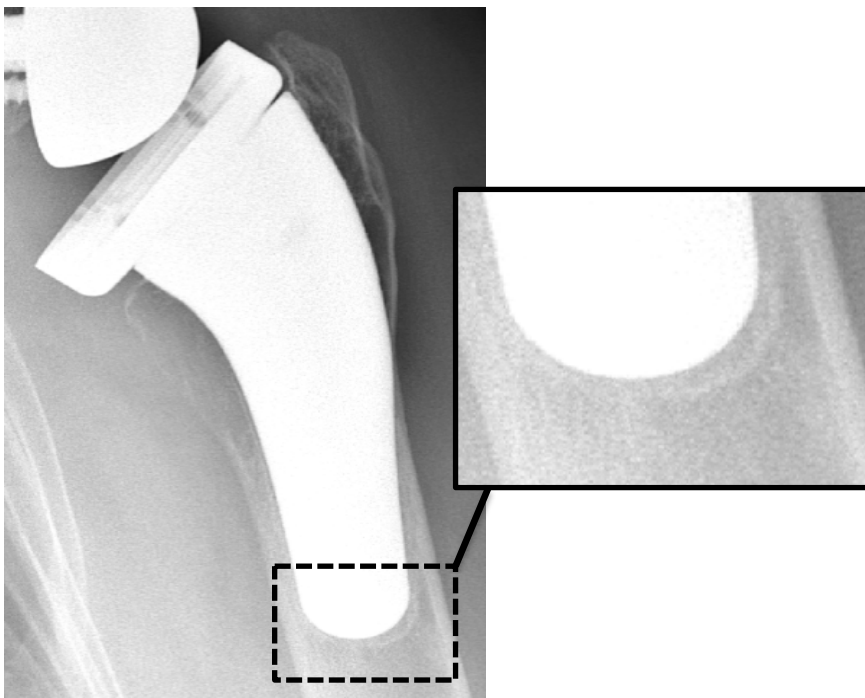


Figure 4: Example of bony sclerosis around the tip of a large prosthesis 2 years postoperatively in a 67 y/o female patient.



Figure 5: Example of full thickness bone loss in zone one and the proximal part of zone 2, as well as partial resorption in zone 5 in a 70 y/o female patient.

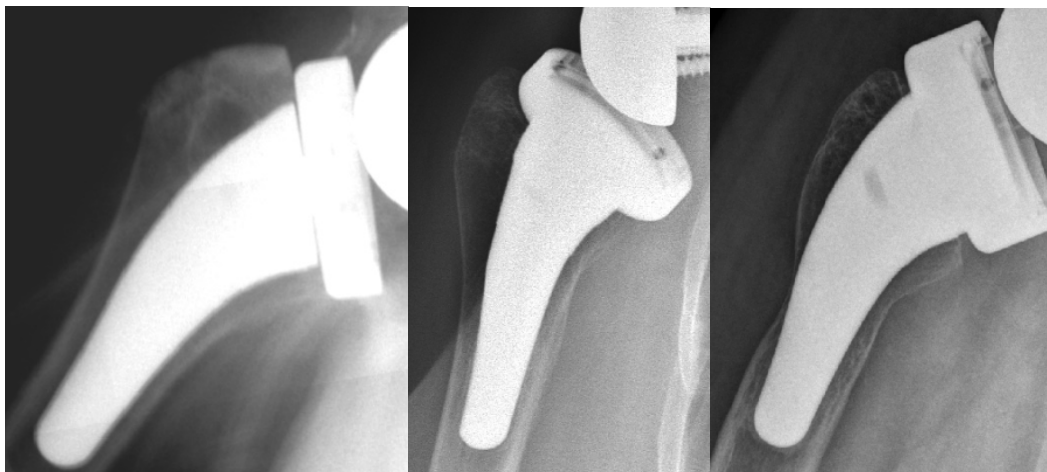


Figure 6: Transition from good bone stock postoperatively (left), to osteopaenia after 24 Months (middle) and eventually collapse of the bone down to the prosthesis after 37 months (right) in a 69 y/o female patient.

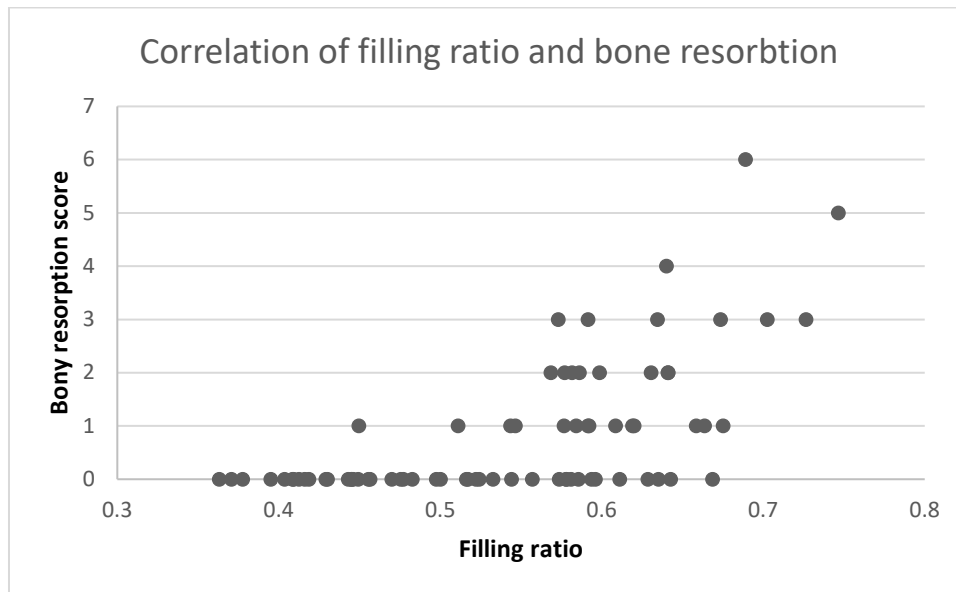


Figure 7: Scatter plot depicting the strong correlation between filling ratio and bony resorption. Noticeable is that at a filling ratio of <0.55 little resorption occurs.

Table 1: Patient population demographics

	Number	Age (years)	Sex	Diagnoses	Follow-up (months)
TSA	21	71.1 (range 62-84)	14 female	21 primary osteoarthritis	34 (range 23-52)
RSA	32	74.1 (65-84)	26 Female	7 primary osteoarthritis, 24 cuff tear arthropathy, 1 irreparable rotator cuff tear	39 (range 23-60)
PyC	21	58.3 (22-84)	4 Female	14 primary osteoarthritis, 1 fracture sequelae, 3 avascular necrosis, 3 arthritis resulting from instability	29 (range 23-48)

Table 2: Types of bony adaptations observed and number of cases in which these occurred.

Bony adaptation	Number of cases
Periprosthetic lucency	2 (each 1 mm in zone 1)
Reactive bony sclerosis	14
Partial thickness resorption	30
Full thickness resorption	8

Table 3: Shows the effect of independent variables on dependent variables. The extent to which the independent variable influences the variability in the dependent variable is shown as %, the significance in terms of a p-value. Age and sex were tested in combination as they are colinear in our cohort (men were younger).

Correlation	variability influenced	p-value
Filling ratio with bone resorption score	39%	<0.001
Age and sex with filling ratio	51%	<0.001
Age and sex with bone resorption score	18%	0.00067
Bone resorption score with constant score	2.6%	0.17
Diagnosis with filling ratio	0.39%	0.59
Diagnosis bone resorption score	0.22%	0.69
Filling ratio with reactive sclerosis	8.1%	0.019
Varus/valgus alignment with reactive sclerosis	0.0016%	0.93
Varus/valgus alignment with bone resorption score	0.89%	0.42
Prosthesis type with bone resorption	0.71%	0.47
Reactive sclerosis with bone resorption score	11%	0.003
RSA vs TSA on resorption score	9.8%	0.021
RSA vs TSA on filling ratio	36%	<0.001
RSA vs TSA on resorption score in zone 1	5.7%	0.081
<i>When correcting for the effect of filling ratio first:</i>		
Age and sex with bone resorption score	1.3%	0.22 and 0.95 respectively
Reactive sclerosis with bone resorption score	3.0%	0.058
RSA vs TSA on resorption score	0.19%	0.70

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Eigenanteil des Doktoranden an den vorgelegten Publikationen

Arbeitsanteil von B. D. Kleim: Hauptuntersucher der Patienten in der regulären postoperativen Schulersprechstunde. Planen der Studie und erweitern des vorhandenen Ethikantrags. Erheben des Großteils der klinischen Daten aus den Patientenakten. 1. Begutachter der Röntgenbilder zur Erhebung der radiologischen Daten. Eigenständige statistische Analyse der erhobenen Daten. Federführender Verfasser der publizierten Manuskripte. Einreichen der Publikationen bei den jeweiligen Fachzeitschriften und Bearbeitung der Manuskripte entsprechend der Fragen und Kommentare der Reviewer.



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