Radiological assessment of bone quality and bone remodeling after primary and revision hip replacement.

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Summary of Ph.D. Thesis

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Szeged, Hungary

2022

1. Introduction

Modern hip arthroplasty has become one of the most successful procedures in terms of pain relief, restoring movement and improving quality of life for patients. As indications have expanded, the proportion of active, young patients with end stage degenerative hip pathology has increased. During primary total hip arthroplasty (THA), the preservation of bone stock has become a priority to facilitate future revisions. The relative number of revision procedures due to the increase of primary operations is also increasing. During the 1990s the previously utilised cemented anchoring techniques gradually gave way to uncemented fixation options where the eventual long-term stability is provided by a biological process where the bone grows onto the implant's surface, using the remodeling capacity of bone. Simultaneously, the materials used for implant manufacture gradually changed from bioinert materials such as steel and chromium alloys to titanium based bioactive alloys. The modulus of elasticity of these alloys with the appropriate implant shape, is close to that of natural bone, thus the micromotion between bone and implant can be minimized, which enables quick osteointegration. The surface preparation of these implants has also changed. Instead of having a polished surface, different coatings have been popularized, such as plasma-spray, porous titanium or hydroxyapatite (HA). Modern implants are more suitable for anatomical reconstruction of the joint, both because of their shape and surface texture. These implants use the structure of the bony bed as a continuously renewing tissue, thus enabling long term stable fixation. Acetabular component usage has largely turned toward uncemented cups for almost all patients, whilst femoral stem fixation is based on bone quality and proximal femoral shape. When using a diaphyseally fixed femoral component, early proximal bone mass loss can often be seen around uncemented implants, this phenomenon is called "stress shielding", which might lead to early bone loss, femoral aseptic loosening (AL), requiring revision. Theoretical advantage of using short metaphyseally fixed stems is the preservation of bone stock in the proximal metaphysis, thus perhaps allowing the use of primary stems during revision. Current revision techniques aim to reconstruct the anatomical parameters of the normal hip, by recreating the biomechanics. A key part of this plan is to restore bone stock, with promoting bone remodeling. Most revision procedures require careful examination of the individual situation including analysing of the remodeling potential of host bone. As these are complicated procedures, there is no universally accepted and used gold standard for these operations. With the use of current technology, such as bioactive materials, special

revision components and bone substitution techniques or their combination, patients can be treated successfully in most cases.

1.1. Osteointegration and osteoconductive materials

The process of the osteointegration begins immediately after primary implantation. The ossification process begins in the first months with formation of a cancellous bone construct which turns the parallel fibre structure into cortical bone in about 1-2 years. This process is strongly dependent on various factors. The primary press fit between the bone and the prosthesis facilitates the „contact form" of osteointegration on the implant's surface, which is a faster process than the „distance form" which starts with a fibrin mesh. The close connection allows micromotion and microfracture formation at the interface, in just the right amount during loading, in woven bone as well. The material makeup and the surface characteristics of the implant have an important role in osteointegration. The titanium became the „gold standard" material of the manufacturing of uncemented implants because of its bioactive properties. An extra material such as HA is intended to increase the osteoconductivity of the titanium alloy and gives the basic building element for bony remodeling.

1.2. Difference between osteointegration of primary and revisional cases

We have to differentiate between the bony bed created during primary THA and the often egg-shell like, compromised, poor bone seen during revision procedures. The available bony bed during revisions often has segmental defects which decreases the integration potential, thus increasing the time required for biological fixation of revision implants. The slightly rough surfaced titanium alloys remain to be the gold standard amongst revision implants and can be used in various settings.

In the case of primary THA, for patients with normal bone quality, the components are fixed within the periacetabular cancellous bone and the metaphyseal bone of the proximal femur. During the implantation of conventional femoral stems, the proximal diaphysis is also prepared in addition to the metaphyseal area, and these areas will share load transfer duties. For this reason, osteolysis and periprosthetic femoral fracture (PFF) can affect both areas, compromising the available revision techniques. Young patients, who might require multiple revision procedures in the future, might benefit from using shorter femoral implants, allowing for femoral revision using conventional primary stems.

Revision procedures are the biggest challenges in lower limb arthroplasty. Despite the longer survival provided by the development of newer primary implants, improved bearing surfaces

and highly porous coatings, in Hungary, the premature failure and loosening of hip implants is an integral part of everyday orthopaedic practice. Significant pain is often a late symptom, thus without regular follow-up patients might present with large, sometimes untreatable defects. The AL of both components is the most frequent diagnosis, necessitating hip revision. The patients involved require thorough assessment and meticulous surgical planning, along with the knowledge and application of advanced surgical techniques. Preoperative computer tomography (CT) complemented by 3D reconstruction is a crucial part of the planning, because it provides a more detailed description of bone defects than conventional radiographs.

Establishing a timely diagnosis is the first key element of initiating early treatment of acetabular defects. Relatively small defects might be treated with devices that are similar to primary implants. Large cavitary or segmental defects require augments and the use of materials and bone graft that stimulate bony remodeling. In lower limb arthroplasty the initial weight bearing ability of the implanted construct is important. Obtaining allograft is an alternative, either in freeze-dried or lyophilized grafts can be used for bone substitution. Adequate preparation, correct sizing of the bone graft is required for successful integration and long-term incorporation.

In the case of pelvic discontinuity, the fixation of the revision implant is only possible in biologically viable bone away from the native acetabulum (ilium, ischium or pubic rami). The bony acetabulum is no more than a thin cortical rim, where the available bone has little integration potential. The posterior acetabular wall, even in these dire situations, might be suitable for supporting a cage. Using this characteristic, a two-flange bridging spherical anti-protrusion cage (APC) can be an option, with screw fixation in the ilium and the ischium, complemented by screws through the inside of the cage and into the pubic rami and the supraacetabular bone.

The AL of the femoral component might also be diagnosed late, when a low energy injury creates a proximal femoral fracture. Timely diagnosis of femoral loosening might prevent some of these fractures. Vancouver B2 and B3 fractures dominate, where the compromised lytic proximal femur is unable to support a conventional primary stem. Diaphyseally fixed, taper fluted stems are anchored in the isthmical part of the diaphysis, bypass the damaged metaphyseal bone. At this part of the bone, if straining forces are applied, these do not cause stress shielding, on the contrary, the forces can promote the formation of a new bony structure.

2. Aim

Evidence based medicine that provides protocols and clear treatment algorithms is gaining popularity in various medical subspecialities. Despite this, choosing the appropriate implant in lower limb arthroplasty is still often based on surgeon's preference. Similarly, evaluation of patients is still often based on scores that are surgeon reported outcome measures. Well-structured follow-up plan of arthroplasty patients is still lacking in many countries. Our main aim was to present the short- and medium-term results of some modern techniques and implants used in primary and revision THA. We also present the objective radiological assessment of femoral remodeling after femoral revisions for PFF and AL.

2.1. Hypotheses

1. The bone preserving Proxima uncemented metaphyseal short stem provides excellent radiological and clinical results in the medium term.

2. The use of an APC with bone grafting in the cases of pelvic discontinuity (Paprosky 3B) provides a stable construct that allows patient to fully weight bear.

3. Severe femoral AL (Paprosky 2, 3A and 3B), and PFF requiring a revision (Vancouver B2 és B3) can be satisfactorily treated with the Wagner SL stem.

4. The recovery of bone stock around the Wagner SL stem takes place reliably for both AL and PFF patients, but the timeframe varies considerably.

5. Quicker bone stock recovery is associated with better clinical results.

7. The Wagner SL stem can subside, but with appropriate technique this is not significant and does not influence clinical results and complication rate.

3. Methods

3.1. Methods of the study with the Proxima stem

In our follow-up study we prospectively followed the first 86 cases of implanting the Proxima metaphyseal stem (DePuy, Leeds, UK) in two independent centres. The patients under 70 years old were recruited between September 2006 till May 2011, and were followed for a minimum of 7 years. The basic demographic data (age, gender, weight), indications were collected. Patients' Preoperative diagnosis included: avascular necrosis of the femoral head (AVN), primary osteoarthritis (OA), secondary OA due to previous mild dysplasia or previous trauma. The operations were performed by two experienced arthroplasty surgeons, after preoperative planning A minimized anterolateral exposure was used, with the patient in the supine position. The postoperative thromboprophylaxis and rehabilitation sequences were the same for all patients. A thorough clinical and radiological follow-up was performed, for an average of 111

months (range 84-140). The patients were seen at 6 weeks, 6 months, 1 year and yearly thereafter. A radiograph was performed at all follow-up visits.

Radiological analysis included the assessment of subsidence, malposition, loosening and proximal stress shielding. Radiological loosening was deemed to be present when we observed a radiolucent zone bigger than 3 mms or if the implant has either vertically or horizontally moved more than 2 mms, accompanied by radiolucent zones. The position of the stem was designated normal if its axis was no more than 5 degrees of the long axis of the femur. Deviations of 6-10 degrees were assessed as varus or valgus, and if the malposition exceeded 10 degrees, the stems were deemed to be in severe varus or valgus. The overall survivorship of the stems was also determined.

Clinical assessment included a routine physical examination, and the calculation of the Harris Hip Score (HHS), with examination for thigh pain. Patients were also asked to provide their perception of being satisfied with the surgery. All complications were noted, and followed in detail.

3.2. Methods of the study with the anti-protrusion cage

Our second study involved the follow-up of patients treated for pelvic discontinuity by using the Anti Protrusio Cage (DePuy Protrusio Cage – DePuy Orthopaedics, Inc, Warsaw, IN), with impaction bone grafting. These severe AL cases (Paprosky 3B) were closely followed up, with an emphasis on assessing the incorporation of the graft and the reconstitution of the periacetabular bone stock. A clinical and radiological surveillance was performed.

Our retrospective study included 5 AL cases complicated by pelvic discontinuity that were operated on between 2016-2017. The minimum follow-up was two years. Clinical and radiological assessment was performed at 6 weeks, 3 months, 6 months 1 year postoperatively and yearly thereafter. The radiological follow-up included an AP pelvis, an AP and a lateral view of the affected hip. Due to the severe pelvic defects measurements according to the Sutherland method (Köhler-line) were not possible, thus the vertical and horizontal position along with the abduction angle of the APC was determined in relation to the obturator line. A 5mm and 5 degree was determined as margin of error. In addition, the appearance of radiolucent lines of more than 2 mm, and bone resorption around the screws was also examined. Bone graft consolidation was studied in the DeLee-Charnley I-III zones at the graft-host and graft-cage interfaces. The appearance of trabeculae was deemed as a definite sign of integration, whilst radiolucent lines of more than 2mm was considered definite loosening.

In terms of clinical assessment, a routine musculoskeletal examination of the hip and adjacent joints was performed, and the use of walking aids was noted. OHS and VAS self-assessing tests were filled. Patients who had surgery for pelvic discontinuity using other surgical methods were not included.

3.3. Methods of the study with the Wagner SL stem.

Our study included THA revision cases operated between January 2015 and December 2017 using the Wagner Self-Locking (Wagner SL, Zimmer, Warsaw, IN) monoblock stem, which is a tapered and fluted titanium stem, well suited for use in both AL and PFF cases, where there is some remaining intact diaphyseal bone.

From our prospectively collected database we selected all patients who had a minimum of two years of follow-up and fell into one of two categories in term of indication for surgery. One group included patients undergoing revision for severe aseptic loosening (AL group), the other were patients requiring a stem revision due to PFF, where the femoral component becomes loose (Vancouver B2-B3), which was designated the periprosthetic fracture group (PFF group). Demographic data was collected for all patients, such as age, gender, weight, height, body mass index (BMI). In terms of clinical data, length of surgery, type of anaesthesia, intraoperative blood loss, transfusion requirement and length of stay were noted.

A thorough radiological and clinical follow-up was performed at 3, 6, 12 and 24 months after surgery and yearly thereafter.

The radiological follow-up included an AP pelvis, an AP and a lateral view of the affected hip. As the primary outcome measure, the bone remodeling adjacent to the Wagner SL stem was determined using several objective scoring systems. Four independent doctors performed the measurements providing a blinded radiological assessment. Intra- and interobserver variability was determined. The changes in bone remodeling in the proximal femur was determined by using the Global Radiological Score (GRxS). The GRxS is an objective scoring system, that unifies the Secondary Bone Stock (SBS) and the Osteointegration and Secunder Stability (O-SS) scoring systems. Both systems score the bone bed and prosthesis anchorage in the specific Gruen Zones. Finally, we compared the results we measured in the different timepoints. The measurements were performed on our picture archiving and analysing software GEPACS (General Electric Company Healthcare, Chicago, Illinois, USA).

During clinical follow-up, a routine musculoskeletal physical examination was performed, whilst pain was subjectively assessed with the VAS. All patients at all follow-up appointments filled out our preferred patient reported outcome measure, the OHS.

All procedures included in the study were performed by the same revision hip surgeon. The procedures were carried out under a general anaesthetic, in the lateral decubitus position, utilizing a posterolateral approach. The appropriate sizing and component position was verified using an image intensifier. An endofemoral approach was used in all AL cases, no extension, such as an ETO was performed. With the PFF cases a prophylactic cerclage wire was used on the distal, intact femur. If the fracture pattern allowed, first a provisional reduction of the proximal fragments was performed. The final osteosynthesis was performed after the implantation of the final revision component. If provisional fixation was not suitable, then the distal femoral piece was prepared and the proximal fracture fragments were only reduced onto the final stem.

Antibiotic prophylaxis, thromboprophylaxis and the rehabilitation after the procedure was carried out as the same protocol for all patients. Patients receiving alternate implants or having a different preoperative diagnosis from AL or PFF were excluded. Patients requiring an ETO or other femoral osteotomy, or where extensive impaction bone grafting was used, were also excluded to give as homogenous group as possible. A detailed statistical analysis was performed from our results. GRxS values and discrete grouped results were compared. Intra- and interobserver reliability was evaluated. We evaluated the comparison of GRxS results at different time points. Subsidence, OHS and VAS values were compared, correlation between the GRxS and OHS/VAS results was examined.

With every test we performed, the determined level of statistical significance was $\alpha=0,05$.

All of our tests were performed using the R software (version 3.6.2; The R Foundation for Statistical Computing, Wien, Austria).

4. Ethical permission

All patients provided written consent to be included in the studies and our clinical and radiological follow-up plan was supported by the approval of the Clinical Research Coordination Office of the University of Szeged with the number of permission: 3/2019-SZTE.

5. Results

5.1. Results of the study with the Proxima stem

A total of 86 procedures were carried out with the Proxima short stem on 81 patients, during the 5-year study period. The average age was 50 years (32-65 years), meaning a relatively young patient group for a hip arthroplasty procedure. Preoperative diagnoses included four different groups: AVN (44 cases), primary OA (31 cases), developmental dysplasia of the hip (DDH) (8 cases) and post-traumatic OA (4 cases). Our follow-up was an average of 111 months long (range 84-140 months). During follow-up, two patients died, but all patients were included in the complication and radiological analysis.

5.1.1. Radiological follow-up

We performed the alignment measurements. According to our criteria most stems were implanted in a normal position. The stem position was defined as varus (5-10°) in 8 cases and as severe varus (>10°) in 2 cases. The overall malalignment rate reached 12% for all cases.

There was only one case which had radiologically significant subsidence.

We investigated the bony ingrowth. We found perfect bone contact around the stem in every cases immediately after the procedure. The bony integration continued, and was maintained for all cases, except one. Loosening, instability and a radiologically significant subsidence was visible after two years in this case.

5.1.2. Functional outcomes

The improvement in function was measured with the HHS. We found an average increase of 51 points between preoperative test and last follow-up. No patient exhibited symptoms of thigh pain during the follow-up. All patients said that they would be happy to undergo the same procedure again.

5.1.3. Complications

We did not have any infections, deep vein thrombosis or pulmonary embolism related to the operation. We have only one case where the stem was undersized. It eventually loosened, subsided, became unstable, so we required to perform a revision.

We experienced 3 PFF, which all occurred in the first 20 cases. One of them eventually needed a stem revision. The PFF rate was thus 3.5 % in our study cohort. We noted only one dislocation, due cup malposition. Eventually a cup revision was performed, but the stem was left in situ. Our overall survivorship at the end of the study (at an average of 9.3 years) was 98.8% (83 of 84), with failure due to AL as the end point. A 7-year Kaplan–Meier survival rate of 97.6% was determined of stem revision for all cause.

5.2. Results of the study with the anti-protrusion cage

In the study period we had 5 cases of APC. All the patients had a Paprosky 3B acetabular defect with pelvic discontinuity, confirmed with 3D CT reconstruction. The diagnosis was reenforced with the intraoperative findings. The defects encountered were filled with cancellous bone graft using the impaction bone grafting technique. The cages were fixed with 6-8 screws. Transacetabular screws are crucial, and one or two was used in all cases.

5.2.1. Radiological measurements

The follow-up examinations were performed at 3,6, 12 months and yearly thereafter. The minimum follow-up time was 24 months.

We found an adequate cage-graft and cage-host contact in all cases. With the radiological analysis satisfactory trabeculae formation was observed at the graft–host interface. Significant graft absorption was not observed. On two occasions there was loosening of the ischial screws, not affecting the overall stability of the implant. The potential migration never reached margin of error of 5mms and/or 5 degrees.

5.2.2. Functional outcomes

OHS improved from an average preoperative value of 10 (3–16), to 29 (24–32) at the last follow-up. VAS values improved from a preoperative value of 8 points (5–10), to 3 points (0–7) at the latest appointment. All patients had significant improvements in both VAS and OHS values. At the last follow-up two patients used a cane and three patients arrived with no walking aids.

5.2.3. Complications

Other than the blood loss, and transfusion requirement, we experienced one case of wound healing issues, requiring readmission. Cultures were negative and the wound eventually healed. There was no further surgery required during the follow-up period.

5.3. Results of the study with the Wagner SL stem

Twenty patients were included in our study. All of them had a minimum follow-up of two years at the end of the study period. 10 patients formed the AL group and the other half was put into the PFF group. Between the two groups, the basic demographic data was similar, except for postoperative length of stay, because of a more conservative rehabilitation protocol, that was requested for the PFF cases. Perioperative blood transfusion rate was required 65%, nine of these were intraoperative events.

5.3.1. Radiological results

5.3.1.1. Inter-/Intraobserver reproducibility

To verify the reproducibility of our measurements we calculated intra-observer agreement with ICC analysis for numerical variables with a “very good” result (ICC 0.89; $p < 0.001$; 95% CI 0.84–0.93). Weighted Cochen-Kappa was calculated for categorical results with a „very good” qualification (Kappa 0.84; $p < 0.001$) as well. The interobserver comparison was made for the four independent examiners who performed the measurements. We found a „good” result for both the numerical GRxS values (ICC 0.68; $p < 0.001$; 95% CI 0.57–0.77) and for the categorical values (Fleiss-Kappa 0.548; $p < 0.001$) as well.

5.3.1.2. Results of GRxS

As the primary outcome of our study, we examined the bone remodeling around the revision stem. GRxS results of the both groups were compared statistically. None of the cases was evaluated „Very Good” at the preoperative measurement. Every case that was originally designated as a „poor” eventually improved classification by the end of the follow-up. The GRxS group classification of every case improved from the preoperative value to the latest timepoint. We analysed the GRxS measurements between the different timepoints statistically. We found a significant difference between the results at each 5 timepoints (Friedman $x^2 = 70.812$; $p < 0.001$; KendallW = 0.88515/large/). For the pair-wise comparisons we used paired Wilcoxon signed-rank test. Except immediately after the operation, we found a significant difference between the two groups at each timepoint. We observed 89% (17.7/20 points) of bony architecture remodeling after 6 months in the PFF group, whilst the AL cases needed 2 years to reach almost this level of reconstruction (86%, 17.1/20 points).

5.3.1.3. Subsidence

As part of our radiological assessment, we paid close attention to early and late subsidence of the stem, as this was proven to be an issue with the initial design, potentially causing instability. The average subsidence in our 20 patients was 3.5 mms (range 0-10). 13 patients had a subsidence of no more than 5mms, with 6 patients having no measurable subsidence. There was no further subsidence beyond the 6-month follow-up. There was no significant difference between the two groups in terms of subsidence, the average was 3mms for the AL and 4mms for the PFF group. ($p= 0.4813$; 95% CI -3.921214-1.921214*)*. Stem diameter inversely affected the subsidence, although this did not reach statistical significance (Spearman's rank correlation; rho= -0.3017466; p=0.09801). There was no correlation between stem length and subsidence (Spearman's rank correlation; rho= -0.1191173; p= 0.3085).

5.3.2. Functional outcomes

Clinical status assessment consisted a physical status examination and a self-assessing test before the operation and at every follow-up timepoint.

5.3.2.1. OHS

The average OHS results increased significantly in the AL group (Wilcoxon rank sum test with continuity correction; $p = 0.005857$). We did not find a significant difference between the two groups latest follow-up values (Wilcoxon rank sum test with continuity correction; $p = 0.2892$).

5.3.2.2. VAS

In terms of the VAS scores, we found a significant difference between the preoperative (average 7.3 points) and the latest (average 2.6 points) follow-up results (Wilcoxon signed rank test with continuity correction; $p = 0.005603$). Patients in the PFF group marked an average of 1.9 points (0-7 points) on the VAS. A comparison was made between the AL and PFF groups (Wilcoxon rank sum test with continuity correction), with no significant difference seen ($p = 0.7017$).

As the final analysis, we investigated the relationship between the GRxS and functional results. We performed a Spearman's rank correlation test. We were not able to demonstrate a significant correlation of GRxS results with either the OHS, or with the VAS (rho = − 0.2 and − 0.1; $p > 0.05$).

5.3.3. Complications

We noted a 100% stem survival at the end of the follow-up period. We had no reoperations.

A closed reduction was required in one case of early dislocation. This patient had no further instability and scored an almost perfect OHS at the latest follow-up.

We observed an intraoperative greater trochanter fracture, treated conservatively without any further intervention. 6 months follow-up radiograph confirmed the fracture union.

6. Discussion

6.1. Discussion of the study with the Proxima stem

Initially there was apprehension regarding metaphyseally fixing short stems. This was due to the long and difficult learning curve observed, and the frequent intraoperative fractures, along with the difficulties of optimal positioning, resulting in undersizing or varus placement. With further evidence and longer-term follow-up, more and more papers emerged showing a similar revision rate as conventional stems, with some theoretical advantage.

In our present study we observed a 97% survival rate at a minimum of 7 years. This result currently fulfils NICE guideline requirements, which recommends a less than 5% revision in 10 years for the best benchmark. By using a short metaphyseal stem can potentially achieve

decreased longitudinal strain and better rotational stability, meaning that it can provide close to physiological load transfer and decreases the chance for stress-shielding. The more anatomical load transfer might also potentially prevent thigh pain which can be common with some more conventional designs. With the Proxima stem no thigh pain was observed in our study.

The intraoperative and early PFF rate in our study was 3.5 % (3 cases). All fractures occurred in the first 20 cases. Our findings are comparable with the international 0.3-5% fracture rate. This major complication can be largely reduced with the appropriate sizing and positioning of the stem. Malposition of the stem is not infrequent with short stems, meaning that a more than 5-degree valgus or varus position does occur in 14-20%. Our series had an incidence of 12 % for malposition. Summarized the findings, the use of an image intensifier is recommended during the learning curve period.

The short-term follow-ups showed a decreased stress-shielding rate with excellent remodeling. We observed a similar pattern. The bony integration was unproblematic, and the bone-stem contact was excellent, except for one case. This undersized stem eventually showed peri implant osteolysis at two years postoperatively, where a revision was required due to AL, which equates to a 98.8% survival rate at an average of 9.3 years postoperatively. Our cumulative, all diagnosis revision rate was 2.4% which is similar to the reported rates in the literature. The problems seen in the first 20 cases can be attributed to the „learning curve".

The overall patient satisfaction rate was 100%, whilst the HHS improvement was on average 51 points.

Our study does have some weaknesses, namely there was no control group. Our patient group was a very young active patient group, which is perhaps a strength. Adding older patients with various diagnoses, with co-morbidities would have added a lot of heterogeneity to our relatively small patient group with potential anatomical variations. Despite this our study is one of the longest follow-ups with this particular stem design, with our results comparable to well-established conventional uncemented stems, despite a very young patient group.

6.2. Discussion of the study with the anti-protrusion cage

There is no gold standard treatment method in terms of treating large segmental bone defects. For Paprosky 3B defects with pelvic discontinuity preoperative preparation in terms of diagnostics and surgical planning is paramount for achieving successful results. Plain radiographs with Judet views our essential and are well supplemented by a CT scan with 3D

reconstruction. Obtaining these ensures adequate preparation and choosing the suitable surgical method, taking into consideration local expertise, and availability of implants and instruments. Using an APC with impaction bone grafting is one of the most accessible techniques for bridging a severe segmental bone defect with pelvic discontinuity.

The advantage of bone graft is the potential to re-establish the bony acetabulum, which if a further revision is required, primary acetabular components might be implanted.

In our case series, the APC – bone graft composite gave good results in the first two years when treating Paprosky 3B defects with pelvic discontinuity. The bony remodeling was continuous in all cases. Significant graft absorption, collapse, cage-graft or cage-host interface bone resorption was not observed. There were no radiolucent lines or decrease of supporting surface. The detected screw loosening in the ischial flange did not cause any major symptoms or implant instability. However, it has been reported that the ischial flange and/or screws can cause long term sciatic nerve irritation and/or palsy. The Burch-Schneider cage prevents this problem by using a flange that is designed to be within the ischium, into a bony trough.

The APC-graft technique can be utilised even in very severe cases of osteolysis, and good functional results can be achieved. Its disadvantage is that the bony remodeling can suffer from various issues, such as graft resorption, graft collapse and infection.

The relatively rare indication and the short follow-up time is an obvious weakness of our study. To further understand the technique, we would need to enrol more patients, and carry out a longer follow-up. This technique allows for the treatment of pelvic discontinuity, and provides a stable system, with eventual full weight bearing.

6.3. Discussion of the study with the Wagner SL stem

The basic principles in revision hip arthroplasty have undergone a paradigm change during the last two decades. The cemented techniques have given way to monoblock or modular taper fluted stems, when stem revision is considered. The monoblock taper fluted design has been gaining popularity, due to its lack of a rigid coupling and modulus of elasticity that is close to that of bone. Nonmodular stems avoid having the potential for coupling failure, and bony integration is quicker.

We have demonstrated that proximal femoral bone remodeling reliably happens around a monoblock, taper fluted, grit blasted titanium revision stem (Wagner SL) both in cases of AL and PFF. The process of remodeling was analysed at five follow-up points, where the AL and PFF cases could be compared. Except for the immediate postoperative assessment, we found a

significant differences in the results of the two groups. The process is much faster with PFF cases, where 90% of bone stock is re-established in 6 months. The same process takes roughly two years when AL is the diagnosis. Our results validate some of the previous findings with similar implants and patients, although such comparison with these objective scores was lacking. In multiple articles PFF cases were treated with the addition of an ETO, and bone healing was observed at 4-6 months. Another paper demonstrated satisfactory bony remodeling in Paprosky 2 and 3 AL cases, at two years following surgery.

Initial fears of subsidence of nonmodular, taper fluted stems were confirmed by previous publications which reported an incidence of significant subsidence (>10 mms) of 4-21%. Recently, with more experience and improved design, much lower rates have been described. Our average subsidence was 3.5 mms, with only one of 20 patients (5%) having more than 10 mms of stem migration. Subsidence occurs in the first 6 months. We found no correlation between stem size (diameter and length) and the incidence of subsidence. There was no difference between the groups (PFF and AL).

Clinical follow-up included the OHS, and VAS tests. There was no significant difference in the measured outcome of the two groups at the final follow-up. We observed significant improvement in both scores in the AL group.

In our study we did not find a statistically significant relationship between radiological and functional results, perhaps because of the relatively small number of patients.

The assessment of bony remodeling is relatively subjective. GRxS is a method where remodeling can be assessed in a more objective and reproduceable way. Our findings of 4 blinded independent observers, where we measured the inter- and intra-observer correlation, rated „good” and „very good”, thus supporting this statement.

In the cases of AL, the proximal femoral bone stock that has already been compromised and become egg-shell like. Despite this, the bony remodeling still occurs around a titanium taper fluted stem, although this process is relatively slow. Patients with PFF, where a near anatomical reduction of proximal femoral fracture fragments supplements the revision procedure, the remodeling process is very quick. Preserving the blood supply of proximal fragments can accelerate this process even further. The callus that forms allow an even larger surface where the shear forces and load transfer can occur, improving the endofemoral bone formation.

According to our knowledge this is the first study that compares PFF and AL indications for stem revisions and assesses the bone remodeling around the Wagner SL stem.

Our work is unique in the sense, that it assesses the remodeling speed in the two most frequent femoral revision indications, where the surgical technique is uniform. Our main weakness is the relatively low number of patients. Including more patients and subdividing them according to the Paprosky and Vancouver classifications, perhaps more detailed information can be gathered in the future. Another is of interest for future research is comparing monoblock and modular taper fluted stems and establishing the reasons for delayed bone remodeling.

7. Conclusions

The characteristics of bone remodeling is less well understood in case of component malposition or in case of severe osteolysis. Our work focused on a patient group where bone salvage was paramount and bone remodeling was of utmost importance for sustainable long-term results. The patients involved represented cases which require detailed surgical planning. A close and regular follow-up is mandatory and allows real time surveillance of bone remodeling. We have proven in our work that without additional radiation, bone remodeling can be assessed accurately in everyday orthopaedic practice, thus the success of the procedure can be evaluated. The bone preserving Proxima uncemented metaphyseal short stem provides excellent radiological and clinical results in the medium term. To our knowledge this is the longest follow-up of this particular metaphyseal stem. Our review of the use of an APC with bone grafting in the cases of pelvic discontinuity (Paprosky 3B), we found that the device provides a stable construct that allows the patients to fully weight bear. The impacted bone graft with the help of the bridging function of the cage shows good remodeling, and the reestablishment of the bony continuity of the pelvis. Severe femoral AL (Paprosky 2, 3A és 3B), and PFF requiring a revision (Vancouver B2 és B3) can be satisfactorily treated with the Wagner SL stem. The Wagner SL stem can subside, but with appropriate technique this is not significant and does not influence clinical results and complication rate. The recovery of bone stock around the Wagner SL stem takes place reliably for both AL and PFF patients, but the timeframe varies considerably. Quicker bone stock recovery is associated with better clinical results. Although we were not able to show a statistically significant difference between the groups, this is mainly due to our relatively small number of patients. According to our knowledge, this was the first such study, which objectively compared the bone remodeling around the Wagner SL stem, in the two major femoral revision categories, AL and PFF. We feel that our findings are novel. Further studies with larger patient groups are required to elevate the evidence level of our findings.

8. Acknowledgements

First of all, I would like to express my heartfelt gratitude towards my mentor and scientific supervisor, Dr. Krisztián Sisák. I am utterly grateful to him for the immeasurable amount of advice he has given me, and his invaluable guidance on my thesis. I am utterly indebted to him for having given me the opportunity to be a member of his team in the operating theatre, and having shared his invaluable knowledge, experience and approach with me.

I would like to thank all of my senior colleagues in the Orthopaedic Department, especially Dr. Ferenc Greksa; Dr. Gellért Sohár; Dr. László Mécs; Dr. András Gyetvai; Dr. László Tajti; Dr. Ildikó Fiszter; Dr. Ernest Nagy and Dr. Katalin Rattay for having set a fully professional and medically knowledgeable example for me.

I would like to thank all of my young colleagues in the Orthopaedic Department, especially Dr. Hristifor Gálity; Dr. László Levente Arany; Dr. Zsolt Szerényi; Dr. András Bozó; Dr. Melinda Ugocsai and Dr. Mihály Márk Zsikó for their inspiring enthusiasm with what they carry out their everyday work in our Department.

I would like to render special thanks to Dr. Csaba Gombár for his technical and theoretical advices. Without his selfless contribution I would not have been be able to complete my scientific investigations.

I would like to express my gratitude to the auxiliary staff (nurses, administrative colleagues) in the Orthopaedic Department for their help and patience during the examinations of the patients.

I am very grateful to the colleagues and co-authors in the Radiological Department, especially Dr. Ilona Polyák and Dr. Ádám Brzózka for spending time with preparing radiological archives and performing the measurements of our studies.

Furthermore, I would like to pay special thanks to Dr. Ádám Brzózka for his selfless help with the statistical evaluation of our datasets.

Finally, I wish to express my deep gratitude and love to my beloved wife, Dr. Zsófia Együd and our beloved little daughters, Zoé and Lea. I am utterly indebted to them for their endless love, support and patience while I had to be away from them because of the extra work and research time during working on my theses.

9. List of publications

9.1. Publications related to the thesis

I. Friebert Gábor; Gombár Csaba; Bozó András; Polyák Ilona; Brzózka Ádám; Sisák Krisztián: Differences between proximal bone remodeling in femoral revisions for aseptic loosening and periprosthetic fractures using the Wagner SL stem. BMC MUSCULOSKELETAL DISORDERS, 22 (1), ISSN 1471-2474, IF: 2,362, SJR rank: Q2 (2021)

II. Gombár Csaba; Janositz Gabor ; Friebert Gábor; Sisák Krisztián: The DePuy Proxima (TM) short stem for total hip arthroplasty. JOURNAL OF ORTHOPAEDIC SURGERY, 27 (2). ISSN 1022-5536, IF: 1,095, SJR rank: Q2 (2019)

III. Friebert Gábor, Gombár Csaba, Sisák Krisztián: Kiterjedt acetabularis csontdefektusok (Paprosky 3B medence diszkontinuitással) kezelése impaktált csont allograft és ilioischialis cage használatával. MAGYAR TRAUMATOLÓGIA ORTOPÉDIA KÉZSEBÉSZET PLASZTIKAI SEBÉSZET 63 : 1-4 pp. 17-23. , 7 p. (2020)

9.2. Publications not-related to the thesis

I. Sisák K, Gombár C, Friebert G, Koós Z. Modern Treatment of Recurrent Patellofemoral Instability - Combined Medial Patellofemoral Ligament Reconstruction and Tibial Tubercle Transfer. Acta Chir Orthop Traumatol Cech. 2020;87(6):396-403. English. PMID: 33408004. IF: 0,531; SJR rank: Q4 (2020)

10. Co-author certification

1.sz. melléklet

Társszerzői lemondó nyilatkozat

Co-author certification

Alulírott Dr. Gombár Csaba PhD. (felelős társszerző) kijelentem, hogy Dr. Friebert Gábor (pályázó) PhD értekezésének tézispontjaiban bemutatott - közösen publikált - tudományos eredmények elérésében a pályázónak meghatározó szerepe volt, ezért ezeket a téziseket más a PhD fokozat megszerzését célzó minősítési eljárásban nem használta fel, illetve nem kívánja felhasználni.

2022. 05. 12.
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dátum

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szerző

A pályázó tézispontjaiban érintett, közösen publikált közlemények:

Gombár C, Janositz G, Friebert G, Sisák K. The DePuy Proxima™ short stem for total hip arthroplasty - Excellent outcome at a minimum of 7 years. J Orthop Surg (Hong Kong). 2019 May-Aug;27(2):2309499019838668. doi: 10.1177/2309499019838668. PMID: 30939986.