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

Gábor Friebert M.D.

Ph.D. Thesis

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1. List of publications

1.1. 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)

1.2. 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)

2. Summary

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. 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. 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. 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. Thorough surgical planning is crucial in these cases and a Computer Tomography (CT) is often required.

Aim: 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 and acetabular remodeling after primary and revision THA.

Methods: In our first study we prospectively followed the first 86 primary THA cases treated with the Proxima metaphyseal short stem between September 2006 till May 2011. The basic demographic data and indications were collected. A thorough clinical and radiological follow-up was performed at 6 weeks, 6 months, 1 year and yearly thereafter for a minimum of 7 years. All complications were noted. Radiological analysis included the assessment of subsidence, malposition, loosening and proximal stress shielding. Harris Hip Score (HHS) was assessed at every follow-up.

Our second study involved the follow-up of patients treated for severe aseptic loosening (AL) of the acetabulum (Paprosky 3B) with pelvic discontinuity by using the Anti Protrusio Cage, with impaction bone grafting. Our retrospective study included 5 rare cases that were operated

on between 2016-2017. The minimum follow-up was two years. Follow-up was carried out at 6 weeks, 3 months, 6 months 1 year postoperatively and yearly thereafter. Radiological assessments were performed for stability of the cage, graft and component loosening, and for bony remodeling on the graft-host/cage-host/cage-graft interfaces. Main functional outcomes were the Oxford Hip Score (OHS) values. Complications were noted.

Our third study included revision THA cases operated between January 2015 and December 2017 using the Wagner Self-Locking (SL) monoblock stem, which is a tapered and fluted titanium stem, well suited for use in both AL and periprosthetic femoral fracture (PFF) cases of the proximal femur. A thorough follow-up was performed at 3, 6, 12 and 24 months after surgery and yearly thereafter. Main radiological result was an objective evaluation of bone stock via Secondary Bone Stock (SBS) and Osteointegration and Secunder Stability (O-SS) scores merged in Global Radiological Score (GRxS). Functional status followed by OHS.

Results: We found perfect bone contact around the Proxima stem in every cases immediately after the procedure. The bony integration continued, and was maintained for all cases, except one. The overall malalignment rate reached 12% for all cases. A 7-year Kaplan–Meier survival rate of 97.6% was determined for stem revision. HHS increased an average of 51 points between preoperative test and last follow-up.

Around the anti-protrusion cage (APC) we found contact at the graft and the host bones, and satisfactory trabecular formation was observed at the graft–host interface after 24 months. On two occasions there was loosening of the ischial screws, not affecting the overall stability of the implant. OHS values increased significantly.

With the use of Wagner SL stem, we found a significant difference between the GRxS results at each 5 timepoints (Friedman $x^2 = 70.812$; $p < 0.001$; KendallW = 0.88515/large/). Except immediately after the operation, we found a significant difference between the PFF and AL 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). There was no difference in functional outcomes between the groups.

Conclusions: 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 re-establishment of the bony continuity of the pelvis. Severe femoral AL (Paprosky 2, 3A and 3B), and PFF requiring a revision (Vancouver B2 and B3) can be satisfactorily treated with the Wagner SL stem. The Wagner 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.

3. List of abbreviations

3 Dimensional (3D)
Anteroposterior (AP)
Anti-Protrusion Cage (APC)
Aseptic loosening (AL)
Avascular necrosis of the femoral head (AVN)
Body Mass Index (BMI)
Burch–Schneider Cage (BSC)
Computer Tomography (CT)
Confidence Interval (CI)
Developmental dysplasia of the hip joint (DDH)
Extended Trochanteric Osteotomy (ETO)
Global Radiological Score (GRxS)
Haematocrit (htc.)
Haemoglobin (hgb.)
Harris Hip Score (HHS)
Hydroxyapatite (HA)
Icc (ICC)
Low Molecular Weight Heparin (LMWH)
Morpho-cortical index (MCI)
Osteoarthritis (OA)
Osteointegration and Secunder Stability (O-SS)
Oxford Hip Score (OHS)
Periprosthetic fractures (PFF)
Secondary Bone Stock (SBS)
Self-Locking (SL)
Standard deviation (SD)
Thrombo-Embolus Deterrent Stockings (TEDS)
Trabecular Metal (TM)
Total hip arthroplasty (THA)
Visual Analog Scale (VAS)

4. Table of contents

5. 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 [1]. The relative number of revision procedures due to the increase of primary operations is also increasing [2].

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. [3] The modulus of elasticity of these alloys with the appropriate implant shape, is close to that of natural bone. [4], thus the micromotion between bone and implant can be minimized, which enables quick osteointegration [5]. 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) [6, 7]. 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. [3, 8].

The historically used, age-based, arbitrary decision-making algorithms that determined the use of cemented or uncemented fixation have largely become obsolete. 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. In our previous work [9], we analysed the preoperative radiographs of 130 patients who underwent primary THA in 2013. We used a scoring system that is based on age, gender, radiological anatomical characteristics of the proximal femur (Shing-Index, Morpho-Cortical Index (MCI)) to create a score. We found that the uncemented femoral component usage could have been 3.1 times more, than the actual practice. According to Wechter et al. [10], more than 90% of hip replacements were carried out in North America using uncemented implants. Similar trends could also be seen in Western

Europe and the United Kingdom. [5, 11] Similarly at our Department, the use of a cemented femoral component is limited to situations where uncemented fixation is unlikely to succeed.
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 [12]. 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. As 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.

5.1. Osteointegration and osteoconductive materials

The process of the osteointegration begins immediately after primary implantation. The haemostatic processes have the main role in the first hours. A continuous blood clot is created in this phase between the bone and the implant surfaces. Due to reaming of the bone the clot is rich in bone stem cells and macrophages. In the first days after the operation a fibrin rich mesh evolves around the prosthesis which gives a structure to the mesenchymal stem cells to adhere to the surface of the implant. After this initial phase, proliferation starts and differentiation of the cells begin, with the formation of fibrotic tissue. After a few weeks the main extracellular component of this system is Type I collagen and various proteoglycans. The ossification of this matrix 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. Further bony remodeling is facilitated by this close contact. 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. Titanium is hydrophilic, which promotes the adhesion of proteins and cells on its surface. Moreover, titanium alloys have good corrosion resistance and elastic modulus which is very similar to that of bone. Titanium triggers the white blood cells in the blood clot to start secreting the initializing factors of the inflammatory like processes. These cytokines include growth factors. Titanium facilitates the adhesion and proliferation of osteoblasts as well. Last, but not least the roughness and porosity of the implant’s surface are other important factors of osteointegration. Surface modification of the implants improves their osteoconductivity. There are lot of physical, chemical and biological techniques which help mimic the micro and nano topography of host bone. Physical grit blasting, additive manufacturing, vapordeposition and plasma spraying are the most commonly used methods. These are safe and effective procedures to increase the surface of the implant and thus an extra material layer can be added to the implant. 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. There are many studies investigating the features of additional coatings that improve the osteointegration process. Currently, there is only one material on the joint reconstruction market that has better mechanical, antimicrobial properties and superior osteoconductivity than titanium-based products. This material is, tantalum, trabecular metal (TM), which is a highly porous material with lots of potential benefits. Mostly utilised as a material for acetabular revision cups, although not used in huge numbers due to its premium price [8, 13].

5.2. Difference between osteointegration of primary and revisional cases

The remodeling potential of bone is not a static property. 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 devices that we plan to implant, can have widely variable properties.

The slightly rough surfaced titanium alloys remain to be the gold standard amongst revision implants and can be used in various settings. The time for osteointegration can be reduced with the use of materials on the surface of the implant. One of the most frequently used materials is HA, which increases surface porosity, thus can provide a supporting scaffold and raw material for achieving a close connection between bone and implant. The integration of HA coated implants is faster [14].

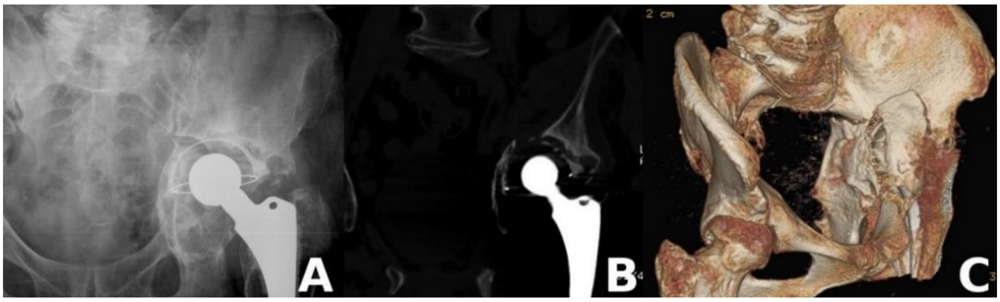
In the case of primary hip replacement, for patients with normal bone quality, the components are fixed within the periacetabular cancellous bone and the metaphyseal bone of the proximal femur.

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 fracture 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. One of the stems utilised in our Department, is such a device, which is fixed only in the proximal metaphyseal bone (Proxima - Depuy, Leeds, UK). Due to its relative novelty, the long learning curve, and the limited indications, there are only a few medium-term results for this implant.

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. The debris created by wear of the components activates inflammatory processes, eventually leading to progressive bone loss and a change in force distribution around the implant. The long-term effect can be the development of large volume defects [15]. Regular follow-up can aid early diagnosis and the development of a treatment plan which preserves as much remaining bone as possible, and allows for reconstructive options that have the best possible functional outcome [16, 17]. Significant pain is often a late symptom, thus without regular follow-up patients might present with large, sometimes untreatable defects [15]. The underlying chronic osteolytic process can eventually result in pelvic discontinuity of the acetabulum, with or without significant trauma. The AL of both components is the most frequent diagnosis, necessitating hip revision [11]. The patients involved require thorough assessment and meticulous surgical planning, along with the knowledge and application of advanced surgical techniques [18, 19]. Conventional radiographs, even with additional views only achieve about 40-70% sensitivity in accurately describing periprosthetic acetabular defects. Even with the use of multiple views, there can be obscure areas masked by metal implants. Preoperative computer tomography (CT) complemented by 3-Dimensional (3D) reconstruction provides a more detailed description of bone defects, increasing the sensitivity to 74–98% [15] *(Figure 1).*

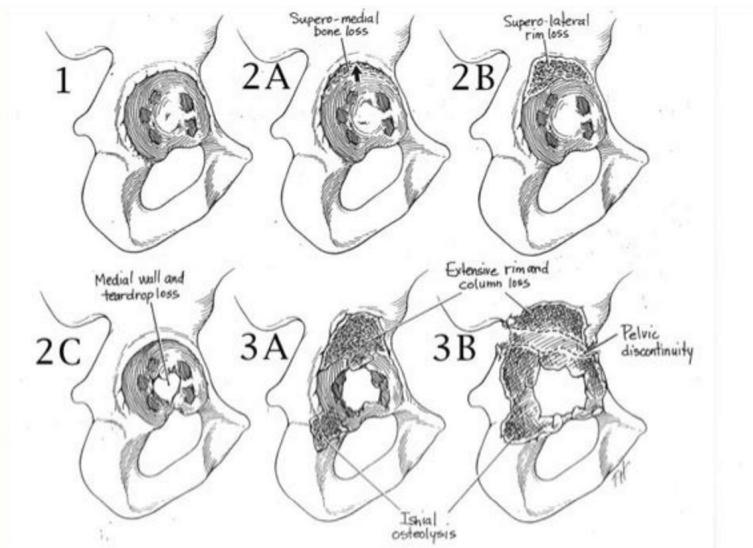
Figure 1*: Preoperative diagnostical images:*

A: *antero-posterior (AP) radiograph shows the medio-cranial migration of the cup and the pelvic discontinuity;* ***B:*** *CT scan shows the proper position of the bony pieces and the prosthesis components;* ***C:*** *3D CT reconstruction helps further evaluation.*



Generally, the loosening of the acetabular component is more frequent, if compared with loosening of the stem [20]. The most widely used classification of acetabular defects is the Paprosky classification *(Figure 2),* which is a reproducible, validated system, that actually helps choosing the appropriate reconstruction technique [21-23].

Figure 2*: Paprosky Classification for periacetabular pelvic bone defects [24].*



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. Amongst such augments, the ones that are made of TM, have the longest and most reliable track record, although their financial implications make them second tier implants. Despite, the relatively quick incorporation of these TM augments, additional screw fixation is required, into relatively well-preserved bony areas. In addition, their use, does not necessarily mean that the acetabular floor will eventually regain its bony architecture. In lower limb arthroplasty the initial weight bearing ability of the implanted construct is important. Synthetic bone substitutes are expensive and their osteointegration takes a long time. The amount of autograft that can be harvested is limited, and the consequently created second incision is a point of potential local complications and symptoms. 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.

Meticulous planning is mandatory with large segmental acetabular defects. In the case of pelvic discontinuity (incidence ~ 0.9%, [25]) the fixation of the revision implant is only possible in biologically viable bone away from the native acetabulum (ilium, ischium or pubic rami). For such purposes jumbo cups, trabecular metal shells +- augments alone are rarely suitable.

In the most severe cases the bony acetabulum is no more than a thin cortical rim, where the available bone has little integration potential nor enough structure for supporting screw fixation (Paprosky 3B). 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. In cases where off the shelf APCs are not suitable, custom-made implants might be an option, although their manufacture is both lengthy and expensive. The implantation of APCs requires extensive exposure to uncover the fixation sites in the ilium and the ischium. The posterolateral approach is the ideal approach for exposing the back of the acetabulum. The adjacent cavitary defects can be filled with bone graft or with augments if necessary. The bearing surface (polyethylene cup/insert) is cemented into the prepared and well-fixed cage [26]. Other options include the bi- and triflange of the shelf cages. Their outer surface is usually covered by bioactive material such as HA or high porosity titanium, which helps cage-graft fixation and facilitates integration. In the case of poor bone quality and inadequate contact area or due to infection, HA can dissolve from the surface prior to achieving integration, which might cause third body wear and loosening. Thus, roughened surface titanium remains the preferred material for these types of cages.

The AL of the femoral component might also be diagnosed late, when a low energy injury creates a periprosthetic proximal femur fracture (PFF). There is often radiological evidence of long-standing loosening of the femoral components. Timely diagnosis of femoral loosening might prevent some of these fractures [27].

The AL around the femoral component is also classified according to Paprosky *(Figure 3)*. The classification system is based on radiological parameters [28]. There are 4 main groups from I to IV, based on the severity and extent of proximal osteolysis. Diaphyseally fixed, taper fluted stems are anchored in the isthmical part of the diaphysis. If this area is also affected by the lysis, such as with Paprosky IV defects, where the thinned cortices create a wide cylinder, revision stems of a different philosophy are required, such as the interlocking long revision stems.

Figure 3*: Paprosky Classification of periprosthetic femoral bone loss [29].*

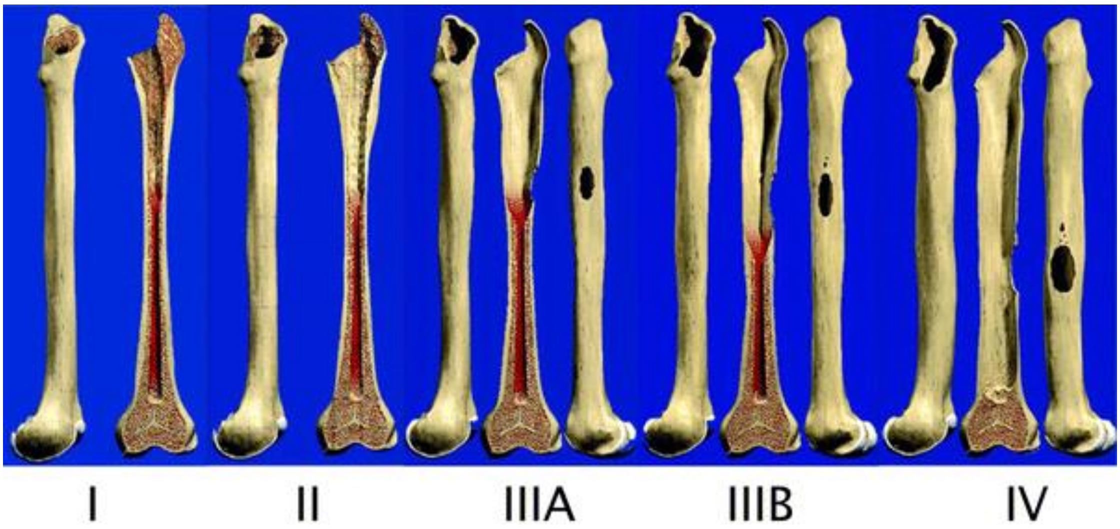
I *Minimal metaphyseal bone loss.*

II *Extensive metaphyseal bone loss, minimal diaphyseal bone loss.*

IIIA *Extensive metaphyseal and diaphyseal bone loss, ≥ 4 cm intact diaphyseal bone.*

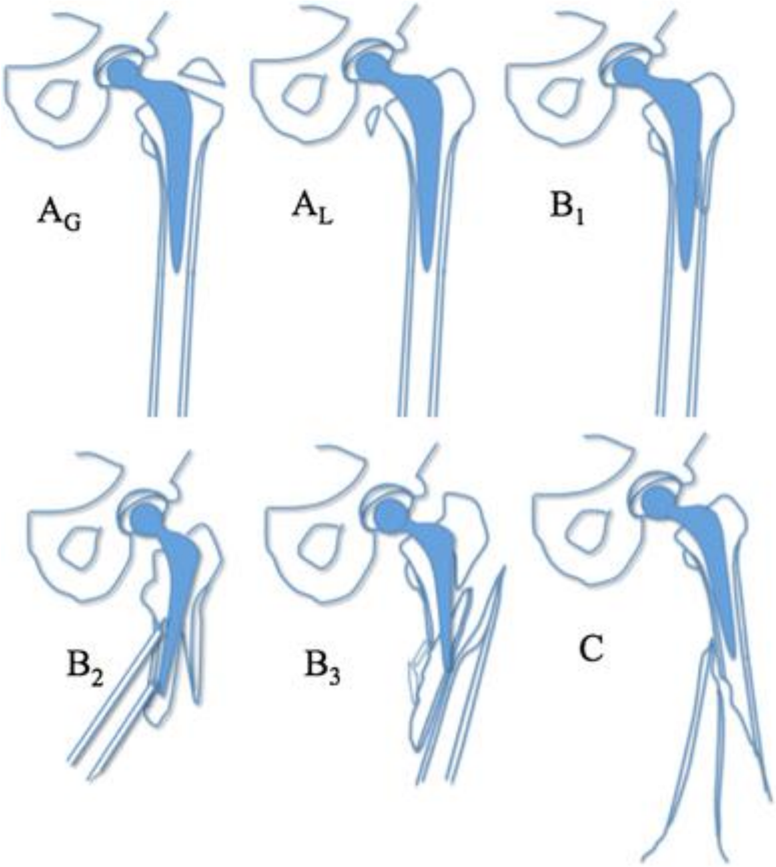
IIIB *Extensive metaphyseal and diaphyseal bone loss, < 4 cm intact diaphyseal bone.*

IV *Extensive metaphyseal and diaphyseal bone loss, nonsupportive isthmus.*



The most commonly used classification system of PFF is the radiograph-based Vancouver classification *(Figure 4)* [30, 31]. The location, the extent of the fracture and the surrounding bone quality are all considered when classifying these fractures. The treatment strategy can be determined on the basis of the classification, with decent certainty. A CT is often required for surgical planning, and to distinguish between B1 and B2 fractures [32].

Figure 4*: Vancouver Classification of PFF [33].*
AG *fracture of the greater trochanter.*
AL *fracture of the lesser trochanter.*
B1 *fracture at the level of the stem, prosthesis remains stable.*
B2 *fracture at the level of the stem with unstable prosthesis.*
B3 *fracture at the level of stem with unstable prosthesis as well as comminution/poor bone stock.*
C *fracture below the stem, prosthesis remains stable.*



B2 and B3 fractures dominate, where the compromised lytic proximal femur is unable to support a conventional primary stem. The diaphyseally fixed revision stems bypass the damaged metaphyseal bone. At this part of the bone, if straining forces are applied, these do no cause stress shielding, on the contrary, the forces can promote the formation of a new bony structure [34, 35]. The subject of our investigation was the Wagner Self-Locking (Wagner SL, Zimmer, Warsaw, IN) monoblock stem, which is a tapered and fluted titanium stem which is well suited for use in both AL and PFF cases, where there is some remaining intact diaphyseal bone [36, 37]. The monoblock design gives a similar modulus of elasticity as the native femur. The rigid coupling of the modular stems might slow down bony remodeling. The eight longitudinal lamellae provide rotational stability, whilst the tapering distally provides axial stability after adequate preparation. Subsidence of the stem can be avoided by using image intensifier control and gaining experience of the preparation and trailing process [34].

6. 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 PPF and AL.

6.1. 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 anti-protrusion cage 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 and 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 stem can subside, but with appropriate technique this is not significant and does not influence clinical results and complication rate.

7. Methods

7.1. 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 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 under 70 years old with severe degenerative disease were recruited to receive the Proxima stem. 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. 9 implant sizes were available in both standard and high offset versions. The Duraloc ™ (DePuy, Leeds, UK) porous coated, cup was used, with a 10-degree lipped liner and 28 mm inner diameter, using metal or ceramic heads. A minimized anterolateral exposure was used, with the patient in the supine position. Image intensifier was not used during the primary surgery. The thromboprophylaxis was the same for all patients using Low Molecular Weight Heparin (LMWH) for 42 days. Postoperatively the patients were allowed to partially weight bear on the day after surgery. After partial weight bearing for 4 weeks full weight bearing was allowed.

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. The potential migration of the stem was assessed according to Martell et al. [38], whilst stability was determined according to Engh et al. [39]. 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 [40]. 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) [41], with examination for thigh pain. Patients were also asked to provide their perception of being satisfied with the surgery (on a scale).

All complications were noted, and followed in detail, including periprosthetic fractures, revision for any reason, neurovascular injury, and general complications such as myocardial and thromboembolic events.

Selection criteria for this particular stem meant that patients with severe dysplasia, advanced osteoporosis, patients after previous proximal femoral osteotomy, or other acquired deformity (too small MCI (MCI<3; MCI: diameter of the femur minus the diameter of the femoral canal 10 cm below the lesser trochanter, divided by the diameter of the femur at the same level, times 10). Patients whose weight was above 100kgs and would require a size 1 or 2 stem (according to preoperative templating).

7.2. 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 *(Figure 5 and 6)*. 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.

Figure 5*: **A**: All procedures were performed under a general anaesthetic, in lateral decubitus position of the patient, utilizing a posterolateral approach. The photograph shows a final APC with a cemented polyethylene liner. The cage is fixed with screws to the posterior column of the acetabulum. Sciatic nerve is signed (▲), its intact status was checked on the end of the procedure. **B**: The position of the cage and all screws were checked with an x-ray intensifier.*

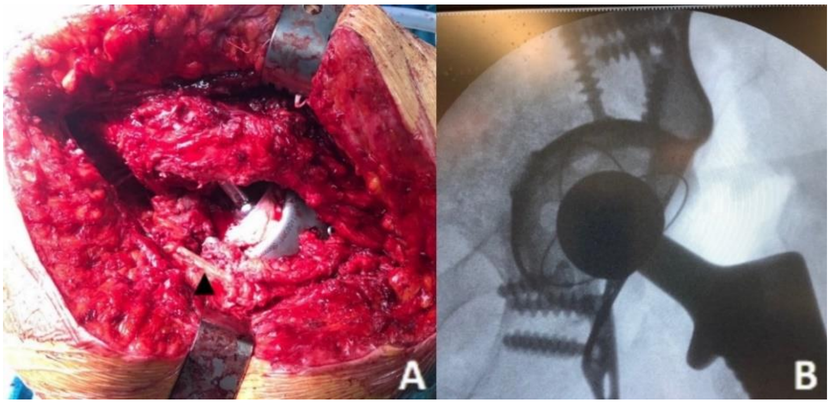
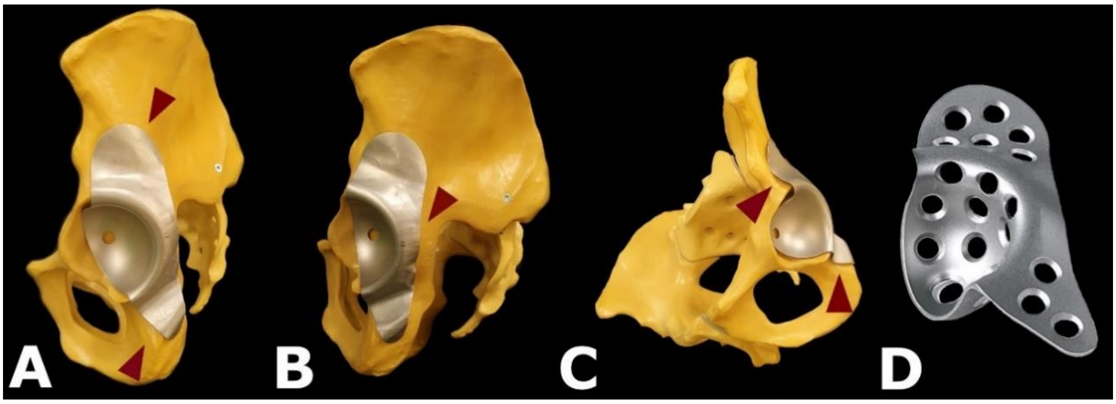


***Figure 6**: Sawbone model of the pelvis with a component trial. **A** and **B**: The APC device bridges the acetabular defect and it is supported on the iliac, ischial bones and the posterior column of the acetabulum; **C**: Accurately chosen device fills the acetabulum and the flanges are fitting perfectly on to the iliac and ischial bones. **D**: The final APC differs just from the trial in its screw holes.*



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. The follow-up 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, [42] thus the vertical and horizontal position along with the abduction angle of the APC was determined in relation to the obturator line [43]. Due to small differences in the magnification and brightness of the radiographs, a 5mm and 5 degree was determined as margin of error [44]. 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 [45].

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. Patients who had surgery for pelvic discontinuity using other surgical methods were not included.

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

Our study included total hip revision arthroplasty cases operated between January 2015 and December 2017 using the Wagner SL revision stem. 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 AL (AL group – *Figure 7*), the other were patients requiring a stem revision due to periprosthetic fracture of the proximal femur, where the femoral component becomes loose (Vancouver B2-B3), which was designated the PFF group *(Figure 8)*.

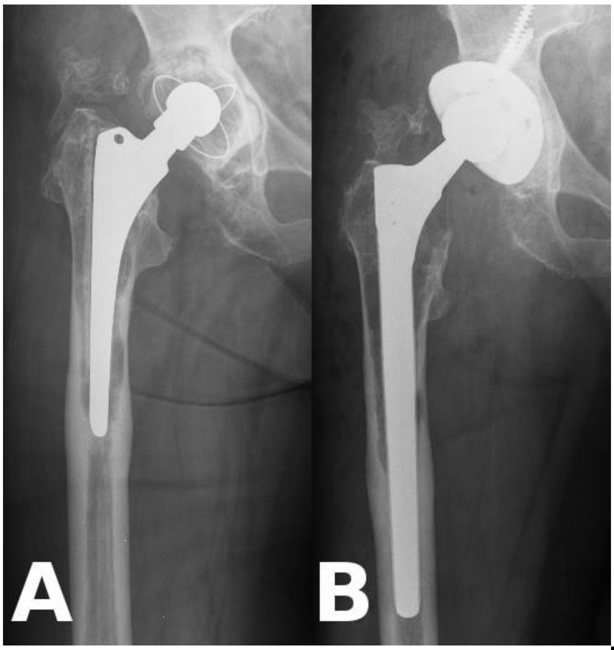


***Figure 7**: Pre- and postoperative radiographs of an AL case (Patient 11)*

***A**: Preoperativ radiograph shows Paprosky 3B type loosening.*

***B**: Wagner SL stem fixed in the healthy diaphysis. Bone grafting or Extended Trochanteric Osteotomy (ETO) was not performed.*

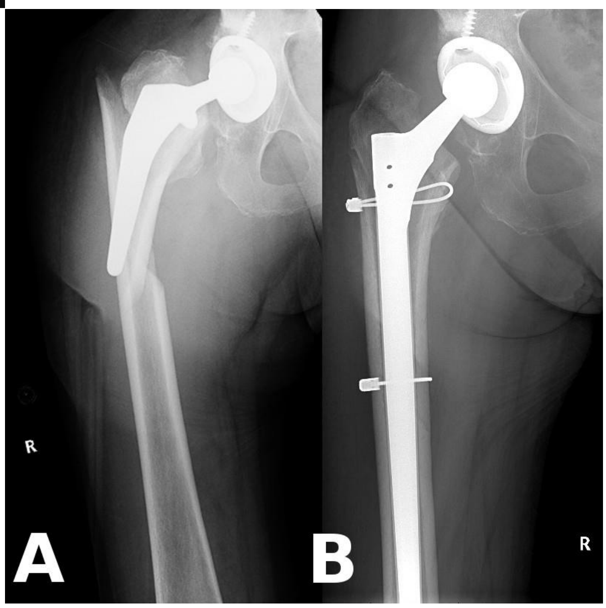


***Figure 8**: Pre- and postoperative radiographs of a PFF case (Patient 10)*

***A**: Preoperative radiographs shows Vancouver B2 fracture type;*

***B**: Anatomical reduction with two cables around a Wagner SL stem.*

The preoperative classification was performed in all cases, which was then verified during surgery. The AL cases were classified according to the well-established Paprosky classification whilst the PFF cases were categorized according to the Vancouver classification. PFF cases were also classified according to the Paprosky classification, as many of the fractures happened around already loose stems.

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. Measurements were taken on standardized AP pelvic radiographs, which were focused on the symphysis. Four independent doctors performed the measurements, a Consultant Arthroplasty surgeon, an Orthopaedic Registrar, and a Consultant radiologist along with a Radiologist Registrar. The assessors were not involved in the operations, did not know the patients, and the radiological images were provided in a random order, thus providing a blinded radiological assessment. Measurements were repeated. Intra- and interobserver variability was determined.

Postoperative radiographs were compared to ones taken at 3, 6, 12 months and yearly thereafter. The changes in bone remodeling in the proximal femur was determined by using the Global Radiological Score (GRxS) [46]. The GRxS is an objective scoring system, that unifies the Secondary Bone Stock (SBS) [47] and the Osteointegration and Secunder Stability (O-SS) [48] scoring systems. Both systems scores the bone bed and prosthesis anchorage in the specific Gruen Zones, zone 1, 2, 3, 5 and 6 Gruen [49] *(Figure 9)*.

The SBS aims to quantify the cortical width, bone density and the presence of lytic areas in the five mentioned Gruen zones. The point designations are the following: + 4 points = no damage or complete regeneration (density and thickness). + 2 points = moderate damage, meaning decreased thickness or density or defects that are < 10 mms. 0 points in the zone means severe damage, that translates to decreased thickness and density or defects that are > 10 mms. Finally, if there is a major damage in density and thickness or cortical lysis in the examined Gruen zone, we subtract -2 points. The SBS score summarized value can be between -10 and +20. SBS between 18 and 20 is very good, from 14 to 16, it is good, from 10 to 12 it counts as average and under 10 points the bone stock is poor.

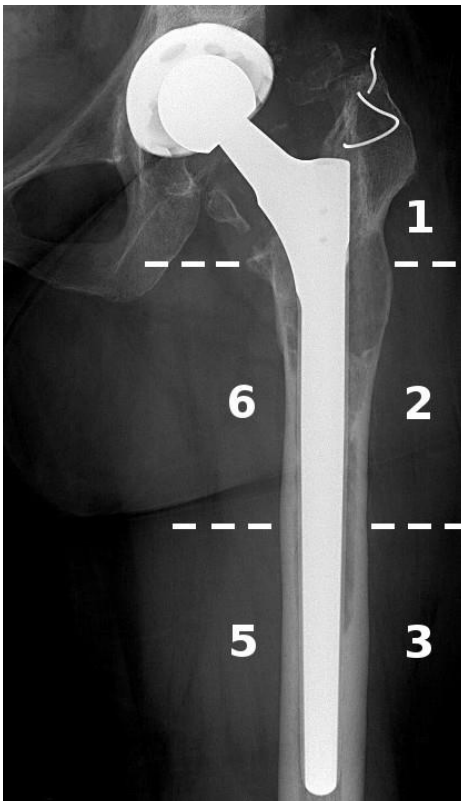


Figure 9*: Postoperative radiograph (Patient 18) shows the evaluation of the modified Gruen zones around the revision stem*

The proximal femur around the stem is divided to a proximal (Gruen zone 1, 2 and 6) and a distal (Gruen zone 3 and 5) part by the O-SS score. It examines the two parts separately, then it adds them together. O-SS counts with radiolucent lines: if there is not any radiolucent line, we give 10 points. If the visible radiolucent line does not reach 50% of the examined part, we give 7 points. But if there is a huge lysis in the cortical bone and the radiolucent line is longer than the 50% of the examined part of the femur, it counts only 4 points. After qualifying of the both parts the score system makes some corrections depending on the quality of the proximal part. If there is a good bone-stem contact proximally, but some radiolucency is evaluable on the distal part, then 1 more point can be added. But we need to deduct 3 points, if there is a significant lysis in the proximal part regardless of good distal stem fixation. After the correction we get the O-SS score, which is divided to 4 different levels: very good (20–18), good (14), average (11) and poor (5–8).

To get the final GRxS we need to convert the SBS and the O-SS scores, as we just give each very good a 10, good an 8, average a 5 and poor a 2.

GRxS is very good (20), good (18–16-15), average (13–12) or poor (≤10).

In some cases, an inverted view was very helpful to easier to evaluate the bony defects and bone-stem contact.

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 Visual Analog Scale (VAS). All patients at all follow-up appointments filled out our preferred patient reported outcome measure, the Oxford Hip Score (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. After the removal of the loose implant a thorough debridement of all granulation tissue and/or cement was performed to provide a clean healthy bone bed for the implantation of the revision implant. The femoral cavity was prepared gradually using hand reamers. Power reaming was used on some occasions, but the preparation of the final size was always hand reamed. The appropriate sizing and component position was verified using an image intensifier. As the Wagner SL stem is a straight stem with no bow, the distal tip can abut to the anterior cortex of the femur, especially if the normal anatomical anterior bow of the femur is increased. Rarely, this can lead to partial or complete perforation of the anterior cortex. This can be avoided with routine imaging, using a lateral view of the distal tip of the stem. An endofemoral approach was used in all AL cases, meaning that implants and cement were all removed from „the top" – from the proximal femur, through the routine posterior approach, no extension, such as an ETO was used. With the PFF cases a prophylactic wire was used on the distal, intact femur [50]. If the fracture pattern allowed, first a provisional reduction of the proximal fragments was performed with large reduction forceps and/or cables or cerclage wires and the preparation was performed similarly from the top. The final osteosynthesis was performed after the implantation of the final revision component. If the fracture pattern or fragments did not allow provisional fixation, then the distal femoral piece was prepared with the hand reamers, and the proximal fracture fragments were only reduced onto the final stem. Fixation was again performed predominantly with wires and cables. With these cases, additional plate osteosynthesis (hook plate) or the use of a strut graft was not required.

Prophylactic antibiotics were started within 30 minutes of the start of the procedure (1.5 grams of cefuroxime), and continued for 24 hours, with two more doses of 750 mgs of the same drug. Thromboprophylaxis was initiated six hours after surgery, using LMWH, for 30 days after discharge. This was supplemented with the use of Thrombo-Embolus Deterrent Stockings (TEDS).

Mobilisation was started on the first postoperative day with passive range of movement exercises. Active exercises were introduced gradually. Typically, touch toe weight bearing was allowed for the first six weeks, which was increased by 15kgs weekly if the patient tolerated weight bearing well.

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. At first, we examined the demographic homogeneity of AL and PFF groups. For continuous variables like age, time to revision, length of surgery, blood loss, BMI and length of stay we used Student's two sample t-test, for discrete variables as gender and cup revision rate we performed a Fisher's exact tests. We compared subsidence between the groups with Student's two sample t-test. Comparison between stem parameters and the extent of subsidence was assessed with the Spearman's rank correlation test.

The OHS and VAS values were compared with a two sample or a signed design of the Wilcoxon test as required. Correlation between the GRxS and OHS/VAS results was examined with Spearman's test.

GRxS values and discrete grouped results were compared as well.

Intra- and interobserver reliability was evaluated with the intraclass correlation coefficient (ICC) test for numerical and Cohen's-Kappa for intraobserver and Fleiss-Kappa for interobserver reliability for the categorical GRxS results.

We used the Friedman test with calculation of KendallWand Wilcoxon signed-rank test as post hoc analysis to evaluate the comparison of GRxS results at different time points.

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

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

8. 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.

9. Results

9.1. 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. Our follow-up was an average of 111 months long (range 84-140 months). 79% of the patients were male (68/86) and 21% were female (18/86). The average age was 50 years (32-65 years), meaning a relatively young patient group for a hip arthroplasty procedure. 44 of the hips were left, whilst, 42 were right.

The indications – preoperative diagnoses included four different groups. Most of the patients had AVN of the femoral head (44 cases) or primary OA (31 cases). 8 patients had developmental dysplasia of the hip (DDH). The remaining 4 cases were post-traumatic OA. The percentage of the various diagnoses is depicted in *Table 1*.

Table 1*: Percentage distribution of the indications.*

Indication	**%**
AVN	51%
Primary OA	36%
DDH	9%
Posttraumatic OA	4%

During follow-up, two patients died of an acute coronary event unrelated to the surgery, leaving 79 patients and 84 hips who completed the study, but all patients were included in the complication and radiological analysis.

9.1.1. Radiological follow-up

We performed the alignment measurements of the stem on the postoperative radiographs. 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 (10/86 cases).

Subsidence is one of the most important factors and indicators of stem instability. We measured the stem displacement at every timepoint. 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 *(Figure 10).*

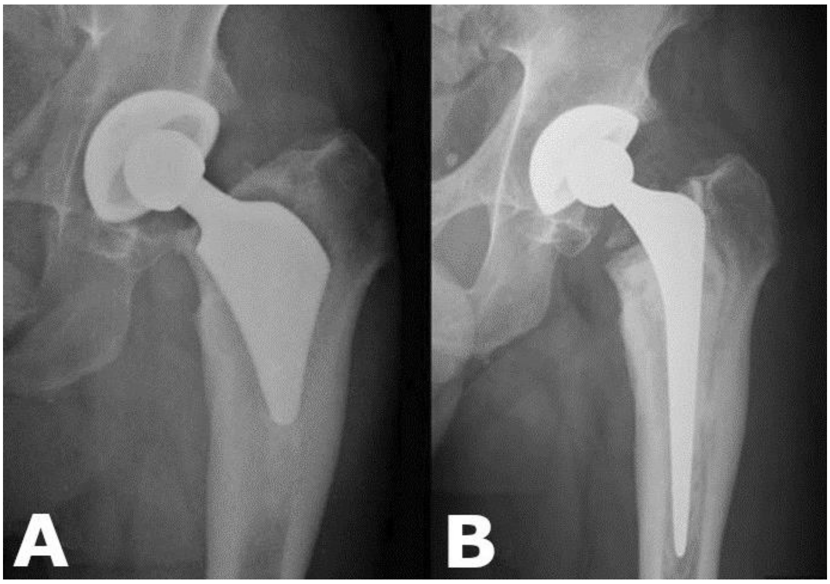


***Figure 10**:*
***A**: Subsidence of the Proxima stem and proximal symptomatic osteolysis eventually indicating a revision procedure.*
***B**: The revision was carried out with use of a primary polished tapered stem (Exeter stem).*

9.1.2. Functional outcomes

The improvement in function was measured with the HHS. Tests were filled out preoperatively, at the 6-month follow-up, one year follow-up and at the latest follow-up. The average preoperative value was 40 points (7-95 points, standard deviation (SD): 17 points). We found an average increase of 51 points at the last follow-up. The outcomes are demonstrated in the *Table 2.*

***Table 2**: HHS values during the study at different time-points and changes in HHS values (difference between preoperative score and at latest follow-up).*

HHS	**Preoperative**	**6 months**	**12 months**	**Latest follow-up**	**Changes in HHS**
Average HHS	40	77	89	91	+51
SD	17	16	12	12	
Minimum value	7	44	53	50	+43
Maximum value	95	98	99	100	+5

No patient exhibited symptoms of tight pain during the follow-up. The patient's satisfaction rate was perfect at the end of the study, all of them said that they would be happy to undergo the same procedure again.

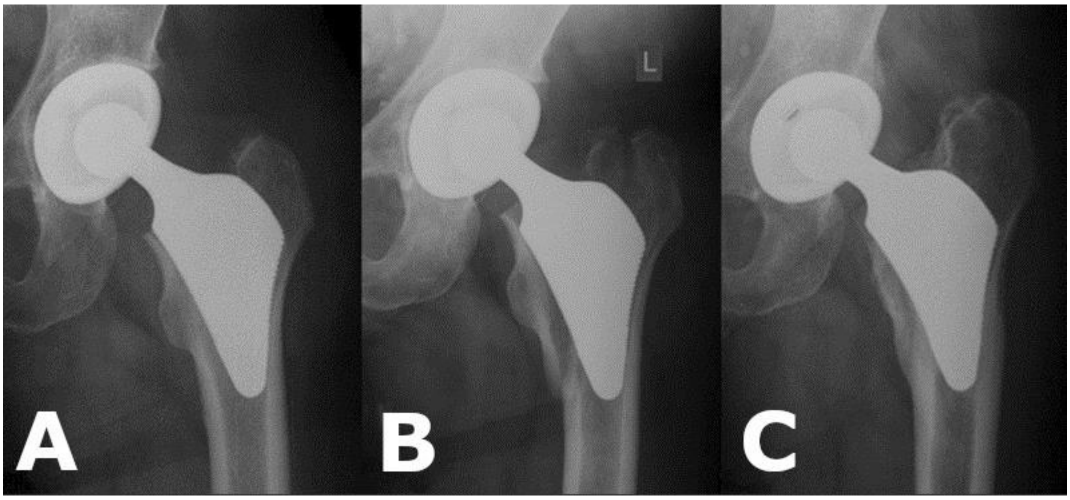
9.1.3. Complications

We did not have any infections, deep vein thrombosis or pulmonary embolism related to the operation.

The key to long-term stability of an uncemented anatomical femoral component is implant sizing. We have only one case where the stem was undersized. It eventually loosened, subsided, became unstable, so we required to perform a revision with a cemented Exeter stem two years after the primary procedure *(Figure 10)*.

We experienced 3 PFFs, which all occurred in the first 20 cases. Two of them were intraoperative iatrogenic fractures of the proximal femur, treated with open reduction and internal fixation. One of them eventually needed a stem revision. The third PFF was a postoperative Vancouver B1 fracture. The fracture occurred after adequate trauma 3 weeks after the THA. It was treated conservatively and the fracture healed uneventfully *(Figure 11)*.

***Figure 11**: **A**: Immediate postoperative radiograph after the procedure. **B**: The patient suffered a Vancouver B1 PFF after adequate trauma 3 weeks postoperatively. **C**: With conservative treatment the fracture healed, after 7 years remodeled bone structure and a stable stem can be seen. Excellent function was seen during the physical examination.*

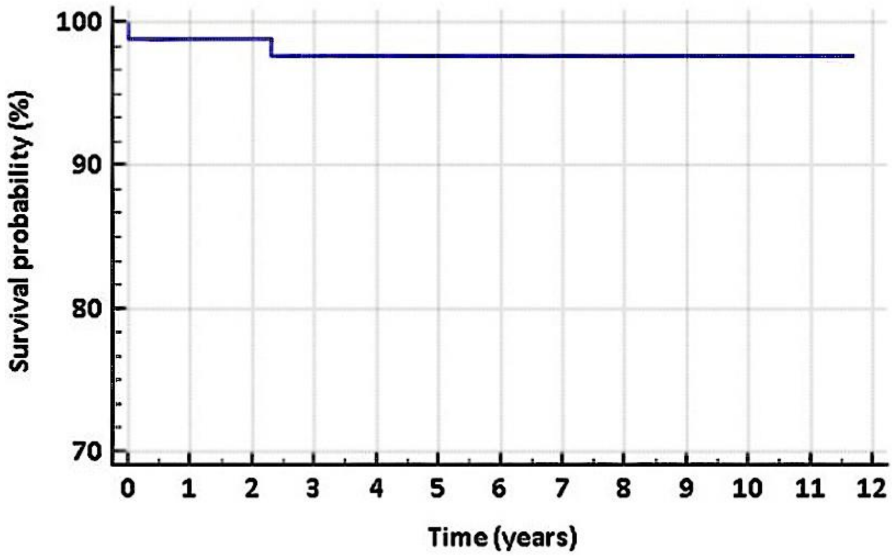


Although there were a few millimeters of subsidence observable, the patient's functional results were very good at the latest follow-up (HHS: 91 points). In summary, the PFF rate was thus 3.5% in our study cohort.

We noted only one dislocation. The cause of instability was the cup malposition in this case. Eventually a cup revision was performed, but the stem was left in situ.

We performed the survival analysis of our cohort with the Kaplan-Meyer test. Our overall survivorship for the Proxima femoral component 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. The all-cause stem revision rate at the end of the study was 2.4% (2 of 84). A 7-year Kaplan–Meier survival rate of 97.6% was determined for Proxima short stems *(Figure 12).*

Figure 12*: Kaplan-Meyer analysis of survivorship of the Proxima short stem in our study.*



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

In the study period we had 5 cases of APC. All patients were female, with an average age of 68 years (53–76 years) at the time of surgery, the average BMI was: 27.5 kg/m² (min.: 23.7 kg/m², max.: 29.4 kg/m²). 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 APC revision was the first revision in two, second revision in two, and third revision in one case. The underlying diagnosis was AL in four cases, and a low energy trauma causing a comminuted insufficiency fracture of the acetabular floor, with discontinuity.

The average survivorship of the previous implant was 114 months (5–196 months). The distribution of the previous components is shown in *Table 3*. The average length of surgery was 172 mins (160–180 mins). All stems were left in situ as they were deemed stable. The defects encountered were filled with cancellous bone graft using the impaction bone grafting technique. We used 2-7 lyophilised half femoral heads. The cages were fixed with 6-8 screws (on one occasion six, on three occasions seven, and one occasion eight screws). The potential screw placement options were planned with the help of the available CT images. Transacetabular screws are crucial, and one or two was used in all cases.

The average blood loss during these relatively long operations was 480 ml (300–700 ml). Only two patients required a transfusion, whilst the others although had a drop in the haemoglobin level, did not develop symptomatic anaemia. In one patient (patient four) the transfusion happened late in the postoperative period using two units. This patient had the longest hospital stay (23 days). The other transfusion case (patient five) was an intraoperative event which had to be repeated on the fifth postoperative day. The length of stay for this patient was 11 days. This patient was excluded from the perioperative blood loss calculations. The average haemoglobin drop for the first four patients was 44 g/l (33-51 g/l). The total perioperative blood loss was calculated with the Nadler-formula [51]. The average blood loss of the first four patients was 1.7 liters (1.3–2.2 l), with no major outlying value (σ=0.413). The postoperative length of stay was an average of 13 days (8–23 days).

***Table 3**: previous acetabular components of our patients.*

Previous component	
Primary cemented cup	2
Revisional uncemented cup	2
Single flange cage	1

9.2.1. 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 trabecular formation was observed at the graft–host interface *(Figure 13)*.

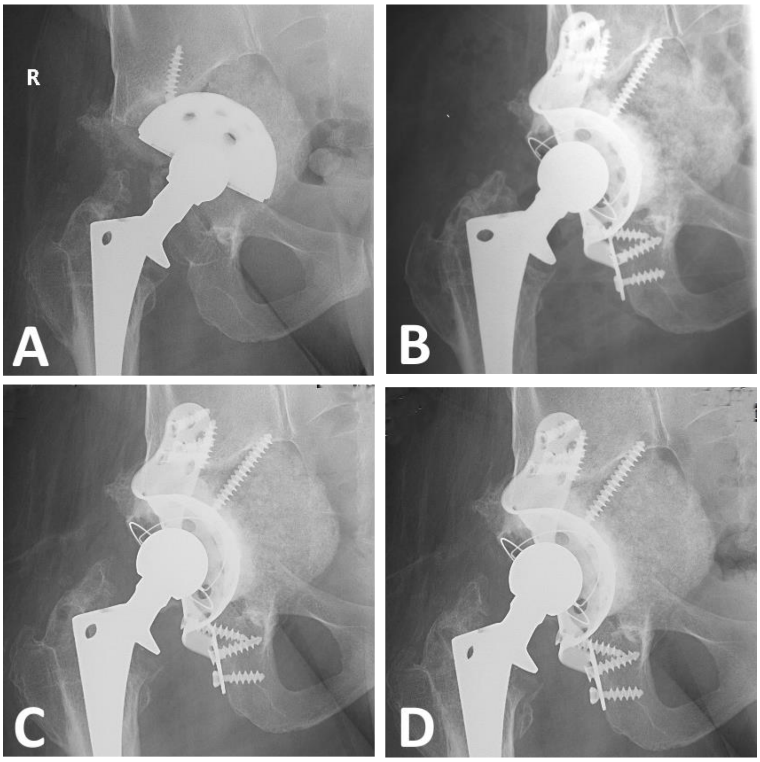


Figure 13:

A: *Preoperative radiograph, previous cup is in malposition, screw has broken;*

B: *Immediate postoperative radiograph;*

C: *Follow-up at 6 months;*

D: *Follow-up at 2 years.*

Significant graft absorption was not observed. On two occasions there was loosening of the ischial screws, not affecting the overall stability of the implant *(Figure 14).*

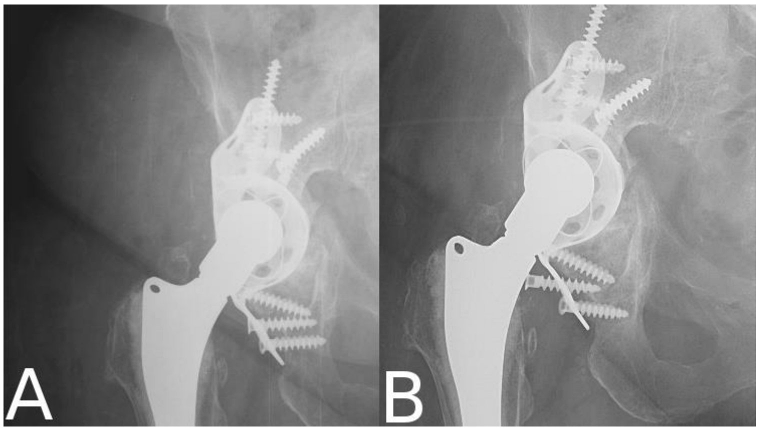


Figure 14:

A: *Immediate radiograph after the operation.*

B: *6 months follow-up radiograph, sciatic screw loosening is clear, but the device is still stable.*

The potential migration of the cages was assessed on AP views of the implants. None reached our preoperatively designated margin of error of 5mms and/or 5 degrees [44].

9.2.2. Functional outcomes

The clinical assessment included an OHS, which 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.

9.2.3. Complications

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

9.3. 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. At this timepoint we had 39 cases in our prospectively collected hip prosthesis revision database, where a Wagner SL stem was used.

The cases of our study cohort were divided into two different groups by indication of revision THA. 10 patients formed the AL group and the other half was put into the PFF group.

11 patients were female (55%), the reminder nine patients were male. The mean age was 66 years (41-78). The mean BMI was 31.3 kg/m^2 (17.8-44.3). The mean time to revision was 144 months (3-316). An acetabular revision was required in 65% (13/20) of our cases. The mean length of the procedures was 175 minutes (100-260). The mean blood loss was 800 ml (0-1800), In the case of 0 ml blood loss we used a CellSaver. The mean length of stay after the surgery was 12 days (6-23). 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. The exact demographical details between the groups are depicted in *Table 4*.

In most cases (15/20), the revision was a first revision, whilst in three cases it was the second revision, and the remaining two operations were performed a third revision of the affected hip.

Perioperative blood transfusion was required in 13 cases (65%), nine of these were intraoperative events.

We had an even distribution of sides in the 20 patients, with half having a right, and half a left sided procedure.

The 10 patients, who formed the AL group, were classified as Paprosky 2 in two cases, as 3A in two cases and as 3B in 6 cases. The fractures of the PFF group were evaluated by the

Vancouver classification as B2 in 7 cases and as B3 in 3 cases. The PFF group's radiographs were classified according to Paprosky as well. Seven cases were deemed Paprosky 3A and three cases were classified as 3B. One case of the Vancouver B2 cases, and two of the B3 cases were defined as Paprosky 3B.

Table 4*: Perioperative data and demographics of AL and PFF cases.*

	Sum. Mean	**AL**	**PFF**	**p-value**	**95% CI**
Age (years)	66 (41-78)	65 (41-78)	66 (51-78)	0.873	9.815; 8.415
Gender (Female)	55% (11/20)	35% (7/20)	20% (4/20)	0.369	0.030; 2.464
BMI (kg/m^2)	31,3 (17,8-44,3)	34.1 (27.2-44.3)	28.5 (17.8-40.6)	0.063	0.341; 11.661
Time to revision (months)	144 (3-316)	173 (75-316)	115 (3-264)	0.098	-11.762; 127.162
Surgery length (minutes)	175 (100-260)	163 (100-245)	187 (120-260)	0.191	59.897; 12.897
Cup revision (Y/N)	13 / 7	9 / 1	4 / 6	0.057	0.948; 684.423
Bloodloss (mls)	800 (0-1800)	600 (0-1500)	1000 (300-1800)	0.062	-822.036; 24.036
Length of stay (days)	12 (6-23)	9 (6-13)	15 (10-23)	0.0005	-8.997;-3.002

9.3.1. Radiological results

9.3.1.1. Inter-/Intra-observer 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% confidence interval (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.

9.3.1.2. 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.

The preoperative and last follow-up GRxS categorisation differences between the AL and PFF groups are depicted in *Table 5 and 6.*

Table 5*: Preoperative GRxS values of both groups.*

Preop.	**AL**	**PFF**
Poor	9	6
Average	1	2
Good	0	2
Very Good	0	0

None of the cases was evaluated „Very Good" at the preoperative measurement.

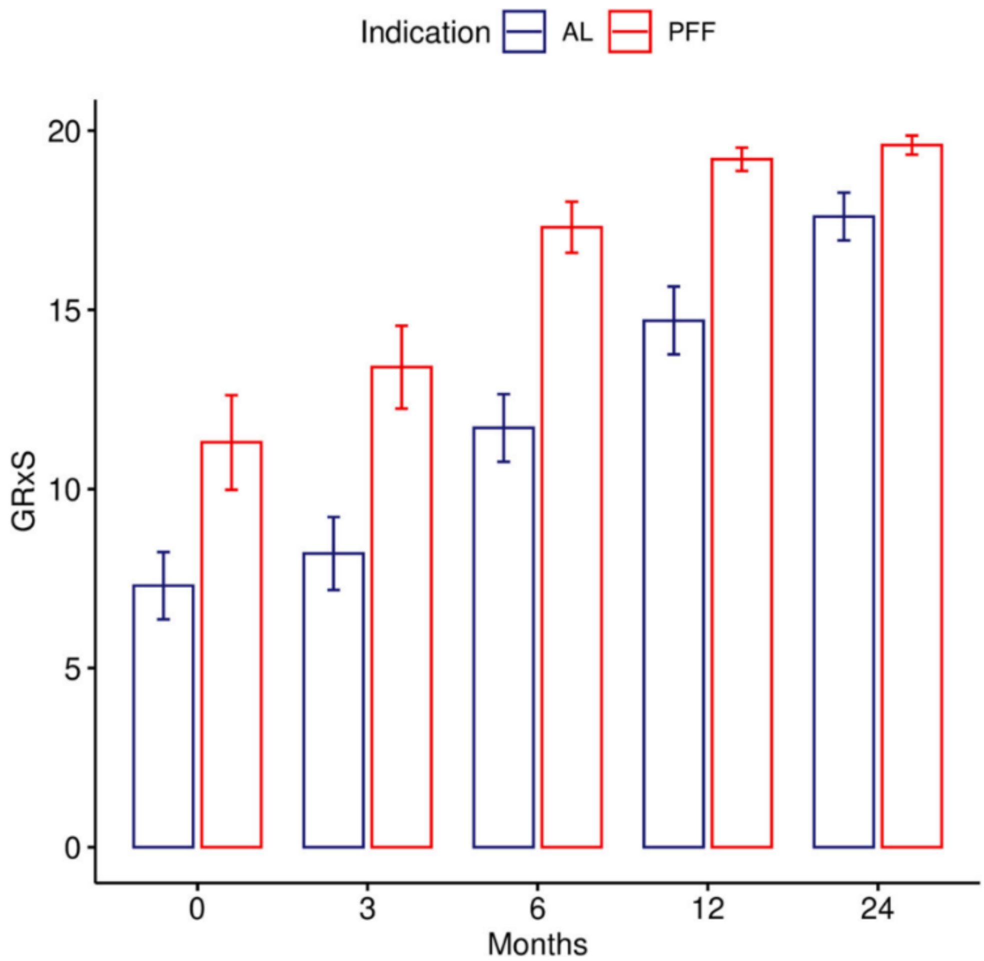
Table 6*: GRxS values of both groups at the latest follow-up.*

Last Follow-up	**AL**	**PFF**
Poor	0	0
Average	1	0
Good	7	2
Very Good	2	8

Every case that was originally designated as a „poor" eventually improved classification by the end of the follow-up.

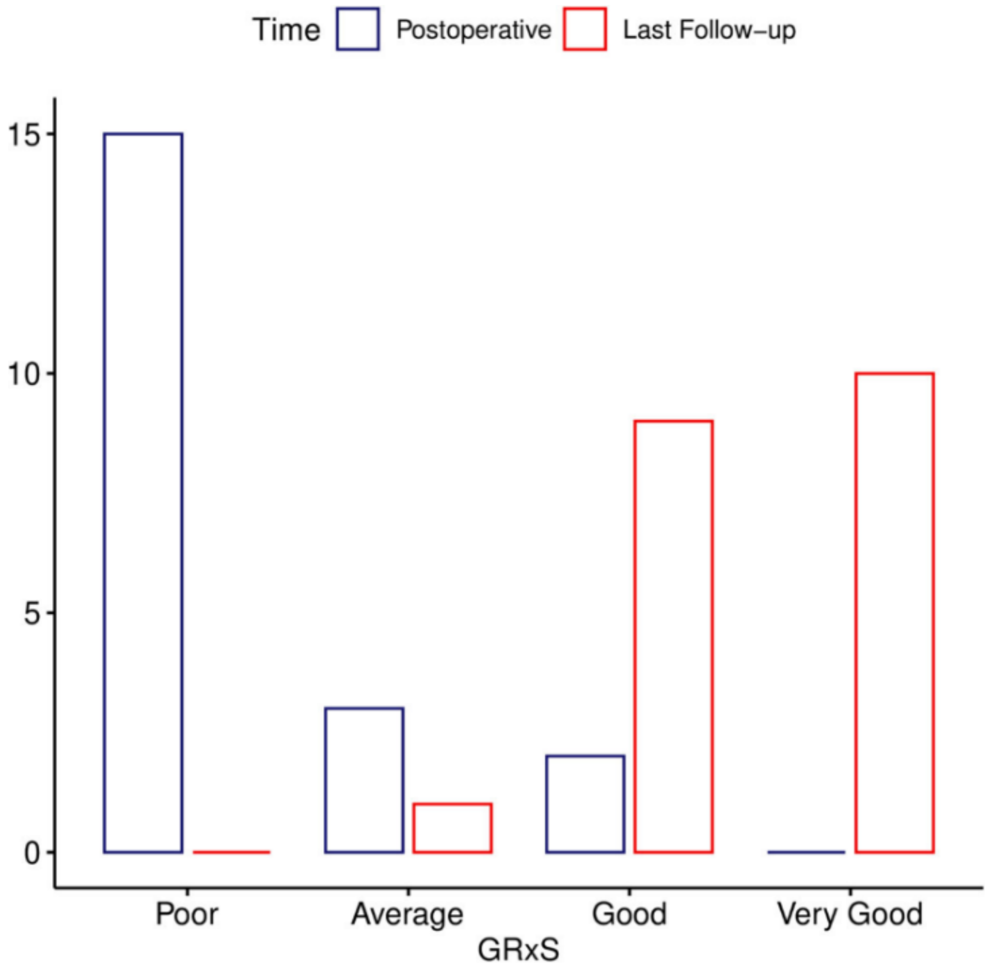
The relationship between the groups is shown in *Figure 15* at each follow-up timepoints.

Figure 15*: The GRxS means of AL and PFF groups at the follow-up timepoints. There is a significant difference between the results of the groups at each timepoint (except immediate after the operation) with paired Wilcoxon signed-rank test (0 = immediate after the operation (p-value = 0.08198), after 3 months (p-value = 0.03412), 6 months (p-value = 0.008492), 12 months (p-value = 0.0213), and 24 months (p-value = 0.01788)).*



The GRxS group classification of every case improved from the preoperative value to the latest timepoint, as is demonstrated in *Figure 16.*

***Figure 16**: Changes of GRxS group classifications between immediate postoperative and last follow-up measurements.*



The changes in the bony structure are illustrated with radiographs with an example of each group *(Figure 17 and 18)*.

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).

***Figure 17**: Example for AL case (Patient 17). **A**: Postoperative radiograph after revision. Obvious proximal femoral lysis. **B**: After 12 months there is mild subsidence, and continuous bony remodeling. **C**: Almost complete reconstitution of bone stock at 2 years.*

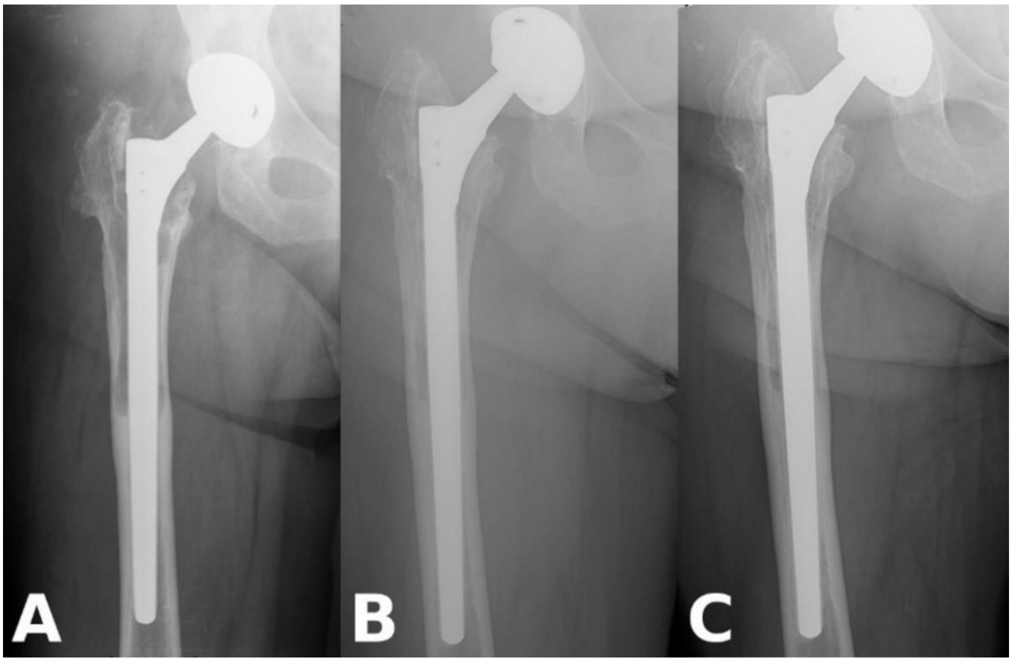
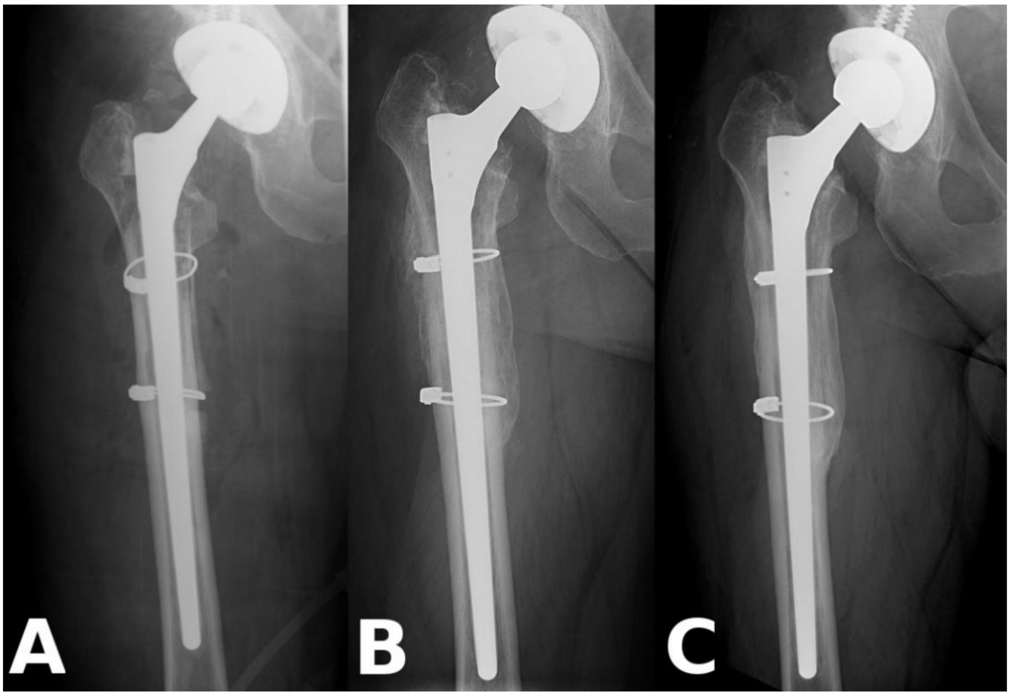


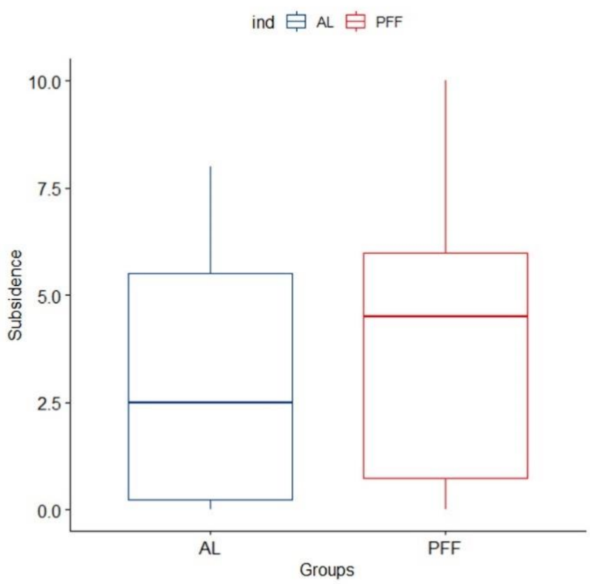
***Figure 18**: Example of a PFF case (Patient 07). **A**: Immediate postoperative radiograph after revision. The poor quality of the proximal bone stock is unequivocal. **B**: obvious new bone formation seen at 6-month follow-up. There is some subsidence. **C**: Radiograph 2 years after the operation. Complete reconstitution of bone stock.*



9.3.1.3. Subsidence

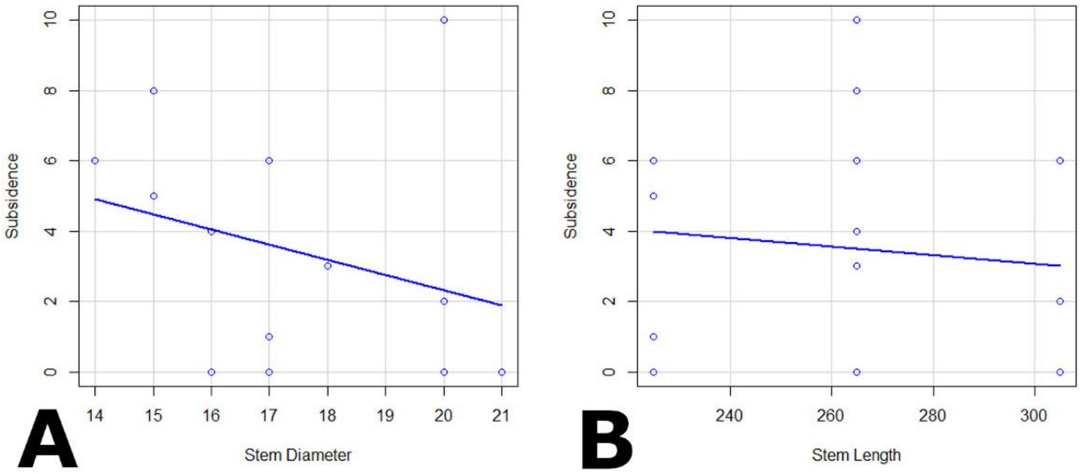
As part of our radiological assessment, we paid close attention to early and late subsidence of the stem, as this was proven to be an issue with the initial design, potentially causing instability. The average subsidence in our 20 patients was 3.5 mms (range 0-10). 13 patients had a subsidence of no 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) *(Figure 19)*.

Figure 19*: Difference of subsidence between AL and PFF groups.*



The stems used, had a diameter range from 14-21 mms, and length from 225 to 305 mms. The most frequently used component diameter was 17mms, with a 265mms long stem utilized most often. Previous studies have shown that stem diameter inversely affects subsidence, i.e., a thicker stem leads to less subsidence [52]. We found a similar tendency, although this did not reach statistical significance (Spearman's rank correlation; σ = -0.3017466; p=0.09801) *(Figure 20/A)*. There was no correlation between stem length and subsidence (Spearman's rank correlation; σ = -0.1191173; p= 0.3085) *(Figure 20/B)*.

***Figure 20**: Subsidence statistics. **A**: Correlation between subsidence and stem diameter; **B**: Correlation between subsidence and stem length.*



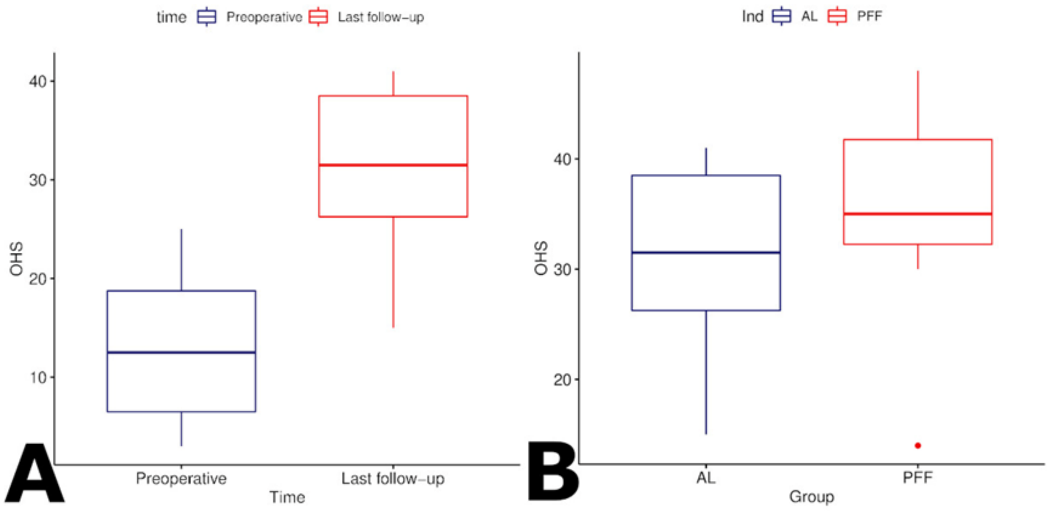
9.3.2. Functional outcomes

In addition to the radiological follow-up, we assessed the clinical status of our patients as well. It consisted a physical status examination and a self-assessing test before the operation and at every follow-up timepoint. Patient reported outcome measure was the OHS and the severity of the pain was measured on VAS. Preoperative and latest follow-up's results were compared. In case of patients with a fracture the preoperative OHS tests were not performed because of the pain and of the severely decreased ability to move.

9.3.2.1. OHS

The average OHS results increased significantly in the AL group (Wilcoxon rank sum test with continuity correction; $p = 0.005857$). Preoperative OHS values (3-25) with an average of 13 points increased to the last follow-up to 15-41 points (average: 30 points). Patients in the PFF group reached at the final examination 14-48 points with an average of 35 points, we did not find a significant difference between the two groups latest follow-up values (Wilcoxon rank sum test with continuity correction; $p = 0.2892$) *(Figure 21)*.

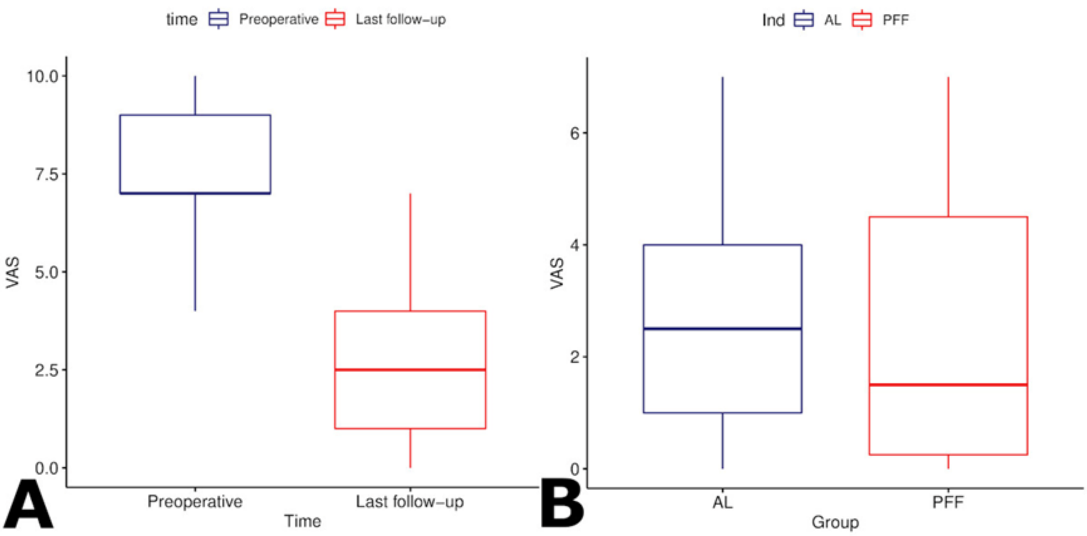
Figure 21*: OHS statistics.* ***A****: AL group preoperative and last follow-up OHS results;* ***B****: Last follow-up OHS results between AL and PFF groups.*



9.3.2.2. VAS

In terms of the VAS scores (similar to the OHS values) we found a significant difference between the preoperative (4-10 points; average 7.3 points) and the latest (0-7 points; 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) *(Figure 22)*.

Figure 22*: VAS statistics.* ***A****: AL group preoperative and last follow-up VAS results;* ***B****: Last follow-up VAS results between AL and PFF groups.*



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 ($\sigma = -0.2$ and -0.1; $p > 0.05$).

9.3.3. 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.

10. Discussion

10.1. 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. Conventional uncemented stems generally have an excellent long term survivorship and a low complication rate, which makes further improvement very difficult [53]. 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 [54].

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 [55].

Bieger et al. [56] showed that by using a short metaphyseal stem one 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 [57]. The more anatomical load transfer might also potentially prevent thigh pain which can be common with some more conventional designs [54]. Banerjee et al. compared multiple short stem designs in 2013, and found an overall incidence of [58] 0.4% in terms of thigh pain. Conventional uncemented stems might have as large as 1 in 8 patients having thigh pain [59]. With the Proxima stem, which is a so called „lateral flare" design, no thigh pain was observed.

The intraoperative and early (within 30 days postoperatively) PFF rate in our study was 3.5 % (3 cases). All fractures occurred in the first 20 cases. Watt et al. [60] described a 0.3-2.5% fracture rate. Whilst Berry et al. [61] showed a 5% fracture rate during primary procedures. This major complication can be largely reduced with the appropriate sizing and positioning of the stem. The right neck cut, in terms of level and angle is crucial for this, as the neck cut with this stem design is much higher, and the angle is much flatter, then with conventional stems, thus providing a broader entry surface during the introduction of the broaches and the stem. If a conventional cut of the neck was performed Ender et al. [62] reported a more frequent revision rate with the use of CUT™ (ESKA Implants, Lübeck, Germany) stem.

Malposition of the stem is not infrequent with short stems, meaning that a more than 5-degree valgus or varus position does occur. Banerjee et al. [58] found that this happens in one in five cases. The Proxima stem showed a 14% malposition with the lateral flare design. Our series had an incidence of 12 % for malposition.

A varus position might contribute to the distal tip of the stem abutting to the lateral cortex, which might be a factor in causing a PFF. In addition, malposition might decrease longevity by altering biomechanics, with an obvious change in offset, thus changing the abduction force, thus creating increase loads in the proximal femur. 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 [57, 63, 64]. 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, with subsidence and varus migration. This was our only case 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 [65, 66].

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 50 points. Thorey et al., Ghera S and Pavan L. [66, 67] demonstrated a similar overall improvement in function.

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.

10.2. 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 [68].

The recommendation from the Mayo Clinic is to either consider the „pelvic distraction" technique, the so called „a la carte reconstruction" with the use of TM augments, cups and/or the cup-cage method. [69].

Migaud et al. [68] compares the TM techniques with the Burch-Schneider Cage (BSC) technique. He reports an overall BSC survival rate of more than 85% at 18 years, which is bettered by the TMs better than 90% survival rate, although this is reported at only 10 years. The infection rate of the BSC technique is lower (3.3% - TM: 4.9%). Because of the infection rate (extremely difficult TM removal) and the higher costs, he only recommends the TM reconstruction if there was an APC-graft failure.

In a meta-analysis from 2019 Szczepanski et al. [70] compared the four techniques. Short-, medium- and long-term follow-ups, mechanical complications were reported in only 5% of the cases with the use of custom-made cages. With the cup-cage construct this was 7%, with the TM techniques 12%. The worst results were reported with the APC – bone graft combination with 24%, although the most experience and the longest follow-up is available with this technique.

López-Torres et al. [71] compared 84 cases of either TM or BSC in the medium term (7.5 years). They were not able to find any significant differences in terms of re-revision rate, bone consolidation rate or infection rate. However, during the clinical assessment, TM patients were superior in terms of overall satisfaction, walking aid usage, and patient reported outcome measures.

The advantage of bone graft, contrary to TM augments, that there is the potential to re-establish the bony acetabulum, which if a further revision is required, primary acetabular components might be implanted [72].

Kawanabe et al. performed biomechanical tests, where they proved that biflange cages bridge the lytic lesions, thus distributing the forces and load more evenly. This property prevents graft collapse and improves the remodeling potential [73, 74].

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. Wedemeyer et al. followed 36 revisions for Paprosky 2C, 3A or 3B acetabular defects. During the 7-year period, 2 re-revisions were required because of resorption of the bone graft [43].
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 BSC cage prevents this problem by using a flange that is designed to be within the ischium, into a bony trough. The down side of this design that there is often ischial lysis, which prevents the flange from having any significant hold, additionally there is no screw fixation option.
Regis et al. reported perhaps the longest follow-up of the BSC-graft combination at an average of 11.7 years, demonstrating 87.5 % survivorship with almost 90% good bony remodeling in Paprosky 3A and 3B defects [75]. Berry et al. reported a similarly long term follow-up but only 76% survivorship of the same design [76].
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.

10.3. 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 [77] have given way to monoblock [78-80] or modular [81] taper fluted stems, when stem revision is considered.
The monoblock taper fluted design has been gaining popularity [78, 80], 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.

Canovas et al. based their radiological assessment algorithm on Engh’s work [82], and developed an objective, reproducible and accurate scoring system. The GRxS [46] combines the SBS and O-SS scores. The SBS score which is based on bone quality and the size of lytic areas [47], whilst the O-SS score [48] quantifies the radiolucent lines around the implant.

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 [37, 80, 83]. Sandiford et al. [36] demonstrated satisfactory bony remodeling in Paprosky 2 and 3 AL cases, at two years following surgery.

Canovas et al. [46] reviewed AL cases treated with the modular taper fluted porous coated stem (Revitan, Zimmer, Warsaw, IN). They did not use bone grafting, but an ETO was part of exposure/implant removal in two thirds of the cases. They reported a significant correlation between GRxS scores and functional results.

Gutierrez et al. [37] found a significantly more pronounced bony remodeling in PFF cases treated with the Wanger SL stem, supplemented by an ETO, then in cases were femoral lytic lesions were treated with the same implant. They found a 92.3% survival of the stem, with stem revision as the endpoint and their major issues included mechanical complications, such as subsidence and dislocation.

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% [36, 37, 80, 84-89]. Recently, with more experience and improved design, much lower rates have been described. Hancock at al. reported in their paper no cases with subsidence over 8 mms [52]. 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, in terms of patient reported outcome measure, the OHS, and for pain the VAS. 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. We found mean increase of 17 points in OHS in the AL group after minimum two years. Our results are similar to the 18.3 points improvement reported by Kjaergaard et al. [90] 6 months after primary THA. Scott et al. [91] in their prospective study followed patients under the age 65 years 1 year after revision THA. The patients who returned to work showed an improvement of 17.5 points, whilst those who did not return to work showed a lower, 14.5-point increase in OHS.

Similar excellent functional results have been reported previously using Wagner-type stems [36, 50, 84, 85, 87, 89, 92-96].

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 bony incorporation of uncemented stems can only be proven with either invasive processes such as a histological examination (biopsy) [14] or with costly CT scanning which also evolves additional radiation [97, 98]. These methods are not suitable for patient surveillance and follow-up. A simple, reproducible, relatively non-invasive method is required. In everyday orthopaedic practice a radiograph-based follow-up remains the routine. The assessment of bony remodeling is relatively subjective [82]. Canovas et al. [46] formulated 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 by stress shielding is further damaged by the osteolytic processes. Only a small amount of cancellous bone remains proximally, whilst the cortices normally atrophize, and become egg-shell like. Despite this, the bony remodeling still occurs around a titanium taper fluted stem, although this process is relatively slow and can be measured in months not in weeks. Patients with PFF, where a near anatomical reduction of PFF 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 allows an even larger surface where the shear forces and load transfer can occur, improving the endofemoral bone formation. The fracture pattern and the quality of bone does influence the appropriate fixation method that is used for osteosynthesis [99].

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

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 (same approach, same surgeon, same surgical technique, identical postoperative rehabilitation). In addition, the measurements were performed by blinded independent professionals, on multiple occasions.

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.

11. Conclusions

Bone remodeling is well researched and mostly understood process. Bone remodeling is affected by various internal and external factors, and can suffer disturbances. The use of osteoconductive materials is popular. 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 re-establishment of the bony continuity of the pelvis.

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

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14. Annex

I.

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Article

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The DePuy Proxima™ short stem for total hip arthroplasty – Excellent outcome at a minimum of 7 years

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Abstract

Purpose: Metaphyseal, proximally anchored uncemented stems for total hip arthroplasty provide bone preservation and decrease the incidence of proximal stress shielding and thigh pain. Our study investigated the clinical and radiological outcome of the DePuy Proxima™ short stem at a minimum of 7 years. **Methods:** Eighty-one consecutive patients (86 procedures) under the age of 70 undergoing primary total hip replacement at two arthroplasty centres were enrolled. Follow-up was clinical (Harris Hip Score (HHS), thigh pain and satisfaction) and radiological (subsidence, malalignment and loosening) at 6 months and yearly thereafter. **Results:** Average age was 50 (range 32–65) with 79% (68 of 86) being male. Preoperative diagnosis included primary osteoarthritis (OA) 36%, avascular necrosis of femoral head 51%, dysplasia 9% and post-traumatic OA 4%. HHS improved 51 points at latest follow-up (from 40 to 91). We had 3.5% (3 of 86) peri-prosthetic fractures, one requiring revision. We had one dislocation, no infections and no thigh pain. Malalignment rate ($\geq 5^\circ$ off neutral) was 12% (10 of 86), not affecting clinical results. **Conclusion:** Overall stem survival was over 97% at 7 years. The DePuy Proxima provides excellent clinical results at a minimum of 7 years post-operatively.

Keywords

arthroplasty, bone preserving, hip, minimally invasive surgery, proxima, short stem

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Introduction

Total hip arthroplasty (THA) is arguably the most successful orthopaedic intervention performed in large numbers today. The indications for surgery have expanded to patients who are young and active and are suffering from debilitating degenerative disease of the hip.[1] Using cementless fixation has gained popularity in the last two decades and is undoubtedly the fixation of choice in the United States today (≥90%). In the United Kingdom, fully uncemented THA has overtaken fully cemented THA in 2008, as the most popular fixation combination, while hybrid fixation has recently gained popularity.[2] Using an uncemented stem carries the risk of exposing the patient to potential thigh pain, the incidence of which is variable, depending on stem design, but can be more than 11%,[3,4] and proximal stress shielding, which is frequently seen with stems which load in the diaphysis. Avoiding the above issues and preserving bone stock for potential future revision procedures have led to the development of short metaphyseal stems that offer a more proximal fixation in the metaphyseal cancellous bone. These stems have the advantage of potentially allowing for a future revision using conventional primary stems.[5] As most of these short stems are relatively new, there is little evidence regarding their

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medium-term clinical and radiological outcome. A recent review has found that less than a quarter of the studies reporting on metaphyseal stems have a follow-up period exceeding 5 years.[6]

We report our medium-term results with the use of the Proxima™ stem in THA, clinically evaluating our first 86 consecutive cases. We hypothesized that medium-term Proxima stem results are comparable with traditional uncemented stems without thigh pain and frequent major complications.

Materials and methods

Consecutive patients undergoing total hip replacement (THR) in two large regional arthroplasty centres were enrolled in our study. The study began in September 2006 shortly after the introduction of this particular lateral flare design stem and lasted till May 2011. Patients required to fulfil inclusion criteria to be considered for the use of the Proxima (DePuy, Leeds, UK) short stem. The Proxima stem is made of forged titanium alloy, with a Duofix™ (DePuy, Warsaw, Indiana, USA) hydroxyapatite (HA) (porous coating and HA) surface coating. Nine sizes of standard as well as high-offset stems for each side are available. Cementless Duraloc™ (DePuy, Leeds, UK) porous-coated cups (DePuy) with 10° lipped polyethylene liners and 28-mm metal or ceramic heads were used in all cases.

Patients met inclusion criteria if they were relatively young (age less than 70 years of age), were active (working part- or full-time), were not suitable for a resurfacing procedure and had one of the following diagnoses in their hip: hip primary osteoarthritis (OA), avascular necrosis (AVN) of the femoral head, secondary OA due to mild-to-moderate hip dysplasia or previous trauma.

Exclusion criteria were preoperative templating showing small stem size (size one or two) for patients whose weight was over 100 kg, severe hip dysplasia, previous hip osteotomy or other acquired femoral deformity, a cortical index (diameter of the femur minus the diameter of the femoral canal 10 cm below the lesser trochanter, divided by the diameter of the femur at the same level, times 10) less than 3 and severe osteoporosis.

Basic demographics were collected, including age, gender and weight. All patients were followed up clinically and radiologically at 6 weeks, 6 months, 1 year and yearly thereafter. Clinical follow-up included recording all complications (acute myocardial infarction, deep vein thrombosis, pulmonary embolism, periprosthetic fracture, dislocation, neurovascular injury, etc.). Patient outcome was documented using the Harris Hip Score (HHS)[7] and potential thigh pain was also noted separately. Radiological assessment was performed with the use of standardized pre- and post-operative radiographs. Radiological examination focused on established issues, such as subsidence, implant malposition, loosening, proximal stress shielding and implant survivorship. Implant migration was assessed according to Martell et al.[8] Implant stability was evaluated according to Engh et al.[9] based on the radiological features of the bone–implant interface. Criteria for radiological loosening of the implant were defined as a radiolucent zone greater than 3 mm or a horizontal and/or vertical migration greater than 2 mm with an adjacent radiolucent zone.[10] Stem alignment was rated as normal if its deviation from the axis of the femoral shaft was 5° or less. A deviation of 6–10° was rated as 'varus' or 'valgus' and a deviation exceeding 10° was rated as 'severe varus' or 'severe valgus'. All procedures were performed by two experienced arthroplasty surgeons, using the same (supine) position, and utilizing an anterolateral approach, with a minimized exposure, using a routine operating table, with no image intensifier. Patients received the same low molecular weight heparin for 42 days post-operatively as the method of thromboprophylaxis. Patients were allowed to partially weight-bear, using crutches from the first post-operative day, and were allowed to fully weight-bear after 4 weeks post-operatively.

Table 1. Basic demographic data.

Gender	Male: 68	Female: 18
Average age (years)	50 ± 8 (range 32–65)	
Side	Left: 44	Right: 42
Average follow-up time (months)	111 (range 84–140)	

Results

During the 5-year period, 81 patients undergoing 86 procedures met our inclusion criteria. Basic demographic data can be found in Table 1. The majority of patients either had primary OA (36%; 31 of 86) or AVN of the femoral head (51%; 44 of 86), with the remainder having mild dysplasia (9%; 8 of 86) or post-traumatic OA (4%; 3 of 86). Functional outcome was assessed with the use of the HHS. Preoperative and post-operative HHS values are demonstrated in Table 2.

Complications

During the study, two patients died of an acute coronary event unrelated to surgery, leaving 79 patients and 84 hips who completed the study, but all patients were included in the complication and radiological analysis. In terms of complications, we did not observe any infections, deep vein thrombosis or pulmonary embolism. We had two intraoperative periprosthetic fractures, requiring open reduction and internal fixation with a plate. One of these cases eventually required a revision. One patient had a post-operative Vancouver B1 periprosthetic fracture after adequate trauma. This fracture was treated conservatively, and the fracture healed uneventfully (although with a few millimetres of subsidence), with the patient being very happy

Table 2. HHS values during the study.

HHS	Preoperative	At 6 months	At 12 months	At latest follow-up (range 84–140 months)	Changes in HHS (difference between preoperative score and at latest follow-up)
Average HHS	40	77	89	91	+51
SD	17	16	12	12	
Minimum value	7	44	53	50	+43
Maximum value	95	98	99	100	+5

HHS: Harris Hip Score; preop: preoperative; SD: standard deviation.

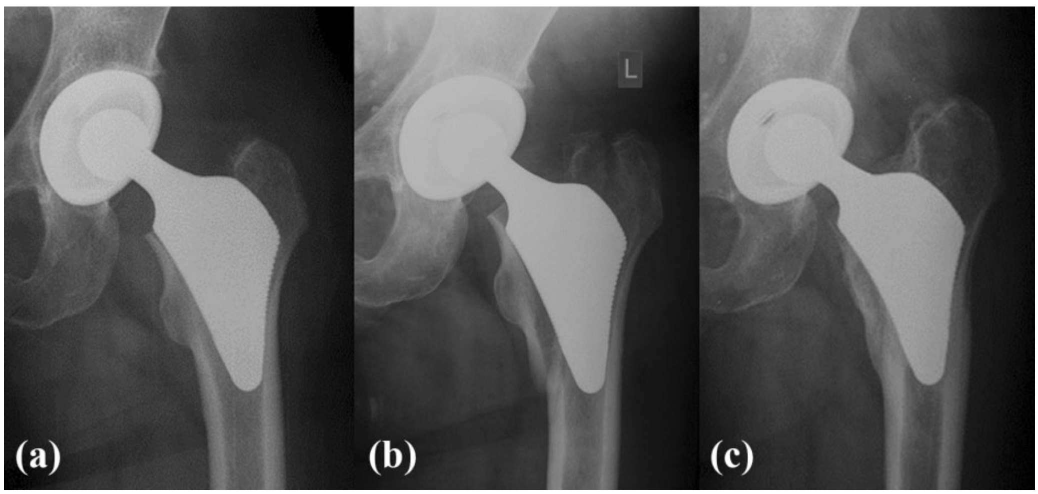

Figure 1. (a) Immediate post-operative XR of left hip following uncemented THR using the Proxima short stem in a 48-year old male patient. (b) Three weeks after THR patient had a fall and suffered a Vancouver B1 periprosthetic femoral fracture. The fracture was treated conservatively. (c) At latest follow-up, 7 years after THR. The fracture has fully healed and remodelled. The hip function is excellently. THR: total hip replacement.

with the result at 9.3 years post-operative, with an HHS of 40 preoperative and 91 at last follow-up (Figure 1(a) to (c)). The overall periprosthetic fracture rate was thus 3.5% (3 of 86). All fractures occurred in the first 20 cases. We had one dislocation, due to a cup malposition, where the cup required eventual revision, with the stem staying in situ. We did not observe any patients with thigh pain, during the study. At the latest follow-up all of the patients said that they would be happy to undergo the same procedure again.

Radiological follow-up

We had one case of subsidence, where the reason for the change in the position of the stem was an undersized implant. This patient eventually required a revision procedure (Figure 2(a) and (b)). The main coronal alignment of the Proxima stem was found to be in severe varus (>10°) position on two occasions, while another eight stems were measured to be in varus (5–10°), giving an overall malalignment rate of 12% (10 of 86). The rest of the stems were in a normal position, as per our criteria. Other than the one subsided stem requiring revision, there was no femoral component loosening around our femoral components.

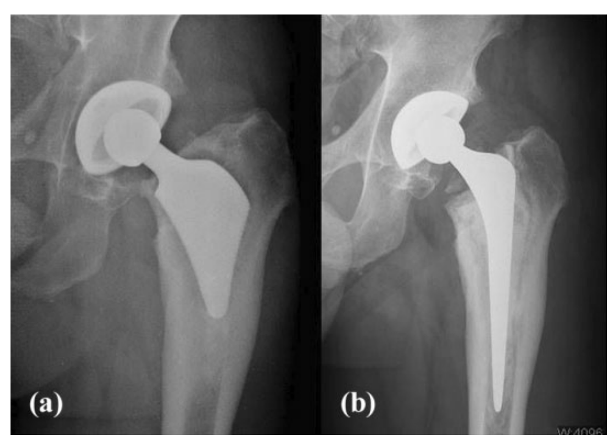

Figure 2. (a) Two years after THR subsidence and osteolysis are visible around the Proxima stem in a 50-year-old male patient. (b) The uncemented short stem was revised to an Exeter stem. Patient is asymptomatic with excellent function. THR: total hip replacement.

Our overall survivorship for the Proxima femoral component at the end of the study (at an average of 9.3 years) was 98.8% (83 of 84), with failure due to aseptic loosening as

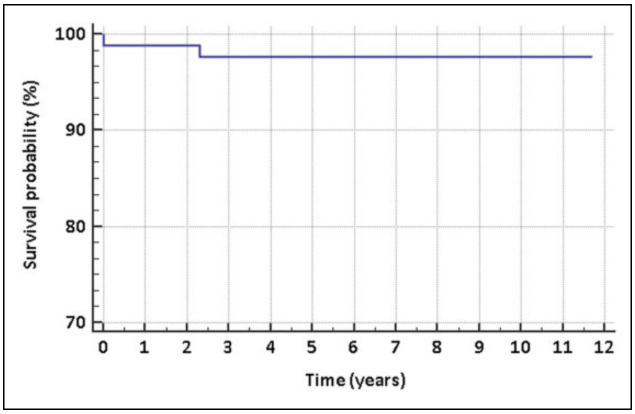

Figure 3. Graph to show Kaplan–Meier survivorship of the Proxima short stem.

the end point. The all cause stem revision rate at the end of the study was 2.4% (2 of 84). A 7-year Kaplan–Meier survival rate of 97.6% was determined for Proxima short stems (Figure 3).

Discussion

Uncemented short stems are very tempting proposition as they load the proximal femur more physiologically,[11] thus potentially avoiding thigh pain and proximal stress shielding. These implants also preserve proximal femoral bone stock and can be inserted in a minimally invasive fashion. However, skepticism exists regarding their use, due to several reasons, including the learning curve involved and potential complications such as stem malalignment, incorrect sizing, subsidence and intraoperative fractures. Furthermore, well-established uncemented stems offer reliable long-term results with a low complication rate.[12] Uncemented short stems need to establish that they have a comparably low complication rate to conventional uncemented stems and an equivalent survivorship if they are to gain widespread acceptance and use.

Our study demonstrated that at over 7 years follow-up, the Proxima stem performs very well, with all cause stem survivorship over 97%, which is on course to equal or better established guidelines by NICE which recommend only implants which have a maximum of 5% revision rate in the first 10 years following implantation.[13]

Available literature on short stems shows a heterogenous picture. Some stems have proven to be reliable in the short term,[14] while studies of others showed varied results.[15] Early studies of the Proxima stem have focused on surgical technique,[16] migration pattern and bony integration using radiostereometric analysis and/or dual energy X-ray absorptiometry (DXA).[17–19] There have been several clinical studies regarding this implant, but they are limited by either the length of follow-up[20] or the patient number.[21]

Thigh pain is a common complaint following uncemented hip arthroplasty using conventional stems, with up to one in eight patients affected, some of which eventually require revision.[3] A recent review of short stems found a variable rate of thigh pain with various short-stem designs, with an overall thigh pain rate of 0.4%.[6] However, among the lateral flange designs such as the Proxima, no thigh pain was reported, and similarly we had no patients complaining of this particular complication.

Early periprosthetic fractures after uncemented THR are major complications and thus a serious concern when considering new implants. The frequency of intraoperative and early periprosthetic fractures (within 30 days) differs as per surgeons experience, but also by stem design, and can range from 0.3% to 2.5%,[22] although much higher numbers have been reported, over 5% for primary hips and 20% for revisions.[23] We experienced three periprosthetic fractures, giving us a 3.5% fracture rate. It has to be stressed that all fractures happened, among our first 20 cases, thus our learning curve constituted to their occurrence. Some technical points also need to be mentioned here, such as the level of femoral neck resection which should be more proximal and less oblique (flatter), to preserve proximal bone stock and to provide a wider entrance to the femoral canal. Ender et al.[24] reported a higher revision rate with the CUT™ (ESKA Implants, Lübeck, Germany) stem if a more diagonal (traditional) resection was performed. The around the corner technique required for the Proxima stem facilitates the use of minimally invasive approaches, but at the same time precludes the use of intramedullary guides and can also result in a varus position when the tip of the stem can touch the lateral cortex contributing to a potential fracture. During the learning phase, the use of fluoroscopy is advisable.

Malalignment (varus or valgus malalignment of $\geq 5°$) of short femoral stems is not unusual and the reported incidence is over 20%.[6] With lateral flare design, such as the Proxima, malalignment seems to be less frequent, just over 14%. In our study, this was even lower at 12% (10 of 86). While varus or valgus alignment might contribute to early failure in conventional uncemented and cemented femoral stems (which at least partially are fixed in the diaphysis), the importance of this radiological finding remains to be seen with uncemented short stems. Malposition leads to a change in femoral offset, thus influencing the abductor lever arm. A stem positioned in varus also carries the risk of increasing the torque at the bone implant interface, which might increase the incidence of loosening. Long-term follow-up studies are needed to assess the effect of stem malposition on functional outcomes and survivorship.

Conventional uncemented stem designs are often associated with proximal femoral stress shielding and component migration. Outcome relates to these factors.[25] In our series, we did not observe any macroscopic bone mineral density change, although no formal bone mineral density measurement was undertaken routinely, thus our assessment is subjective. Neither vertical (subsidence) nor horizontal (change in varus or valgus malalignment) component migration was experienced apart from one stem, which was undersized and eventually subsided.

Functional outcome is paramount for both the patient and the surgeon. Our overall increase of 50 points in the HHS over the reported period is in line with previous reports.[16] In addition, all of our patients were satisfied and would undergo the operation again.

Our study has several weaknesses, most notably the lack of a control group. Our patient group was young (average age of 50 years), with some high-risk patient groups excluded (systemic inflammatory conditions and abnormal proximal femoral anatomy). However, it is still one of the largest series of this particular stem design, with a reasonably long medium-term follow-up. Our results are comparable with the established so-called conventional stem designs. Our complications were concentrated to the first 20 cases, that is, the learning curve.

Conclusion

We can state that midterm results of the Proxima short stem are comparable to traditional uncemented stems. In our experience, once the short but steep learning curve is passed, the implantation of the Proxima stem is safe and reproducible.

Further long-term prospective comparative studies are required to establish the role of short femoral stems in the treatment of end-stage OA of the young and active patient.

Declaration of conflicting interests

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II.

A Szegedi Tudományegyetem Szent-Györgyi Albert Klinikai Központ Ortopédiai Klinika közleménye

Kiterjedt acetabularis csontdefektusok (Paprosky 3B medence diszkontinuitással) kezelése impaktált csont allograft és ilioischialis cage használatával

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ÖSSZEFOGLALÁS

A revíziós csípősebészet egyik legnagyobb kihívása a medence folytonosságának megszakadásával járó vápadefektusok kezelése. Az esetek túlnyomó részében a törés egy krónikus stressztörés, ami az elvékonyodott vápafenéken alakul ki, és általában egy haránt lefutású, az acetabulumot gyakorlatilag megfelező elváltozást jelent. A rutin röntgenfelvételeket ala és obturator felvételekkel, valamint CT-vel kiegészítve a diagnózis és a műtéti terv elkészíthető. Több műtéti megoldás létezik, és jelenleg nincs konszenzus az ideális megoldásról. Az alkalmazott megoldások közül a leggyakoribb négy, az úgynevezett cup-cage konstrukció, a magas porozitású vápabeültetés hátsó oszloplemezeléssel, az úgynevezett medence disztrakció és cement nélküli vápabeültetés, és a két vagy három füllel rendelkező (egyedi gyártással vagy anélkül készült) vápakosarak használata. Ezen technikák közös célja a vápa hosszú távú megbízható rögzítése mellett a diszkontinuitás gyógyulása (csontos vagy fibrosus módon). A szerzők 5 saját medence diszkontinuitás miatt impaktált csontgraft beültetéssel és vápakosár használatával kezelt eset kétéves klinikai és radiológiai utánkövetését mutatják be.

Kulcsszavak: ***Acetabulum; Csípőprotézis; Csontdefektus; Csontgraft; Reoperáció;***

G. Friebert, Cs. Gombár, K. Sisák: Treatment of extensive acetabular bone defects (Paprosky 3B with pelvic discontinuity) with the use of impaction bone grafting and ilioischial cage

The treatment of large acetabular defects with pelvic discontinuity remains one of the biggest challenges in revision hip surgery. In the majority of cases the discontinuity is a chronic transverse stress fracture of the acetabular floor, heavily compromised by osteolysis. Judet views and a CT scan compliment routine radiographs to establish the diagnosis and prepare the surgical plan. There are several surgical management options available, although there remains to be no consensus about the ideal one. The four most frequently utilised techniques, are the cup-cage construct, the use of high porosity cups with posterior column plating, the pelvic distraction with uncemented cup implantation and the use of two- or three-flanged (custom made or off the shelf) cages. The common aim of all these methods is to provide stable fixation for the acetabular component and to ideally achieve bony or fibrosus union of the compromised acetabular floor. The authors present their own 5 cases of pelvic discontinuity where impaction bone grafting and an antiprotrusion cage were used. A two year clinical radiological follow-up was performed.

Keywords: ***Acetabulum – Surgery; Allografts; Arthroplasty, replacement, hip; Bone diseases –Surgery; Bone transplantation – Methods; Hip Prosthesis; Reoperation;***

BEVEZETÉS

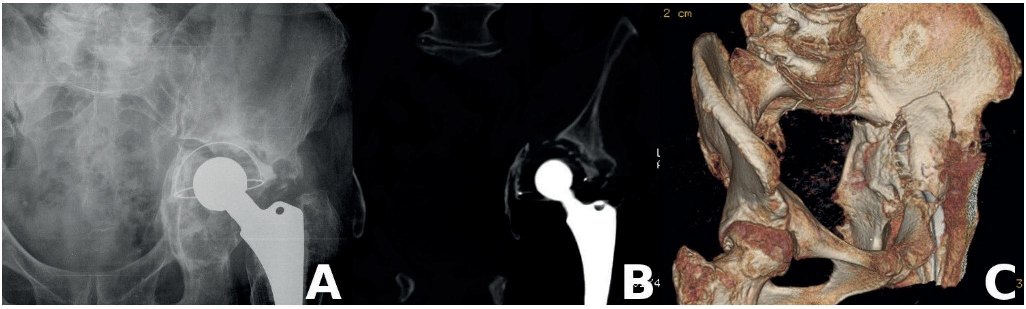
Az évről-évre végzett csípőprotézis revíziók száma az elmúlt két évtized során emelkedett (6). Az újgenerációs primer eszközök, kopófelszínek, illetve a nagy porozitású bioaktív felszínek kifejlesztésével az implantátumok kihordási ideje egyre hosszabbodik, de a mindennapi magyarországi ortopédiai gyakorlatban még mindig gyakran találkozunk elsősorban a vápakomponensek „idő előtti” elhasználódásával, kopásával, lazulásával. A kilazult, illetve kopott komponensek körül a terhelési erők eloszlása megváltozik, kopástermékek halmozódnak fel, helyi gyulladásos folyamatok aktiválódnak, ez progresszív csontfelszívódáshoz, végül nagyméretű hiányok kialakulásához vezethet (10). A rendszeresen végzett kontrollvizsgálatokon a korai felismerés és beavatkozás szükségszerű, a csontállomány mennyiségének és minőségének megmentése, illetve a jó rekonstrukciós eredmény elérése szempontjából (9, 23). A fájdalom sok esetben késői tünet, így a ritka vagy rendszertelen kontroll miatt, gyakran már nagy vápadefektusokkal jelentkeznek az elhanyagolt betegek (10). A fent leírt krónikus folyamat végül akár minor trauma vagy inadekvát behatás következtében is stresszfraktúrához, csontos folytonosság megszakadásához vezethet. A teljes csípő endoprotézis (TEP) vápa komponens lazulás a revíziók leggyakoribb indikációja. A nagy csonthiánnyal, medence folytonosságának megszakadásával járó esetek előfordulása ritka (incidencia ~ 0,9%) (7), épp ezért alapos kivizsgálást, gondos műtéti tervezést igényelnek és a legösszetettebb technikai kihívást jelentik (4, 20).

A műtéti tervezés alapját a röntgendiagnosztika adja. A súlyos periprotetikus vápadefektusok pontos feltérképezéséhez a rutin kétirányú (anteroposterior (AP) és oldal-) felvételek elégtelenek. Ezeket Judet szerint készült ferde (obturator és iliaca oblique) irányokkal szükséges kiegészíteni. Ezek alapján közel pontos klasszifikáció adható a vápakomponens körüli csontdefektusról. A legelterjedtebben alkalmazott besorolás a *Paprosky* és munkatársai által kidolgozott rendszer, amely egy validált, reprodukálható és a megfelelő műtéti technika megválasztására is alkalmazható rendszer (18, 19, 29). A hagyományos radiológiai elemzés csupán 40–70%-os szenzitivitással rendelkezik a periprotetikus vápadefektusok esetében. Még több aspektusból készült felvételeken is lehetnek a fém komponensek által kitakart területek. A preoperatívan készült computer tomográfiás (CT) felvételekkel pontosabb kép és háromdimenziós (3D) rekonstrukció nyerhető az acetabulum defektusairól, szenzitivitása 74–98% (10) (*1. ábra*).

A Paprosky 3B periprotetikus defektusok esetében a vápakomponens medio-cranialis irányban vándorol. Ezzel együtt nem csak kavitális defektus, hanem a csontos medence szegmentális hiánya is kialakul. Ez végül az acetabulum, így a teljes medencefél haránt irányú szétválásával szövődhet (*2. ábra*). A medence diszkontinuitással járó Paprosky 3B defektusok megoldására „gold standard”, minden esetben jó eredménnyel alkalmazható módszer nincs. A kidolgozott protézisrendszerek sikeres alkalmazhatóságát befolyásolja a megmaradt csontállomány mennyisége, minősége, biológiai kapacitása és gyógyhajlama. Ezek meghatározása nem mindig egyszerű feladat. Igen súlyos esetekben a nagy szférikus „Jumbo” vápákkal és a cup-cage rendszerekkel primer stabilitás nem érhető el a szegmentális defektusok miatt, mivel gyakran nincs olyan félgömb részlet, ami legalább 50%-ban megtámasztja a revíziós vápakomponenst (22). Kiterjedt csonthiányok esetén jól alkalmazható disztrakciós technika trabecular metal (TM) augmentekkel kiegészítve, amennyiben a megmaradt csontállomány több irányban is alkalmas csavaros rögzítésre. Bizonyos esetekben a csontos vápa csupán egy papírvékony kortikális csontkarima, a csontintegrációs potenciál elégtelen és a csavaros fixáció sem lehetséges. Legtöbb esetben a hátsó vápaszél még igen nagy hiányok esetén is képes támasztó funkció betöltésére. Ezt kihasználva egyedi, a defektust átívelő, hátsó oszlopra támaszkodó és az iliumba, az ischiumba, illetve az os pubisba csavarokkal rögzíthető, szférikus antiprotrusiós vápakosarak (antiprotrusion cage – APC) alkalmazhatók. Legyártásuk 3D CT rekonstrukció alapján időigényes, költséges folyamat. Beültetésükhöz nagy feltárás szükséges, hogy az ép, csavaros rögzítésre alkalmas csontfelszínek elérhetők legyenek. Erre a posterolateralis feltárás alkalmas, amellyel a hátsó vápaszél, az ilium és az ischium is jól megközelíthető. A környező kavitális csonthiányok feltölthetők

TM augmentekkel, vagy csontgrafttal. Végül a stabilan beültetett vápakosárba kerül becementezésre a tényleges polietilén vápa (1). Az egyedi vápakosarak elvét képviselik, de könnyebben elérhető megoldást adnak a sorozatgyártott úgynevezett bi- vagy tri-flange vápakosarak. Rögzítésük a vápadefektuson túl, az ép iliumban és ischiumban történik. Felszínüket legtöbb esetben bioaktív anyag (hidroxy-apatit vagy porózus titán) fedi, mely jobb cage-graft fixációt eredményez. A csontgraft használatának előnye, hogy a medence csontos folytonosságát állítja helyre. Jó átépülést követően a későbbi revíziók tervezésekor a komponensválasztást megkönnyítheti.

Munkánk célja az évtizedek során kifejlesztett számos csípőprotézis vápa revíziós technika közül egy összetett módszer bemutatása, a klinikánkon operált, saját esetek elemzésén keresztül. A Protrusio Cage és impaktált csontgraft beültetésével a súlyos, aszeptikus lazulásos (Paprosky 3B), a medence csontos folytonosságának megszakadásával járó esetek, stabil, jól terhelhető rendszer létrehozásával és a csontállomány rekonstrukciójával kezelhetők. Emellett kiemeljük a rendszeres és módszeresen végzett utánkövetés fontosságát az implantátumok késői mechanikai szövődményeinek időben történő felismerésében és kezelésében.



1. ábra
Műtét előtti diagnosztikus képek:
***A**: AP röntgenfelvételen már jól látható a vápa medio-cranialis vándorlása és a medence folytonosságának megszakadása;*
***B**: CT képen a vápafenék betört, a vápa a medencébe protrudált;*
***C**: 3D CT rekonstrukción is jól látható a folytonosság megszakadása, a tört darabok elhelyezkedése.*

2. ábra
A periprotetikus medencedefektusokat osztályozó Paprosky-klasszifikáció. A 3B ábrán látható a lehetséges medence-diszkontinuitás típusos elhelyezkedése (3).

ANYAG ÉS MÓDSZER

Betegszelekció

Retrospektív vizsgálatunkba a klinikánkon 2016–2017 között medence diszkontinuitás miatt APC (DePuy Protrusio Cage – DePuy Orthopaedics, Inc, Warsaw, IN) és csontgraft beültetésével operált betegeinket vontuk be. A diszkontinuitás oka a vápakomponens aszeptikus lazulása, vagy adekvát traumára már lazult komponens körül létrejött, medencefolytonosság megszakadásával járó vápafenéktörés volt.

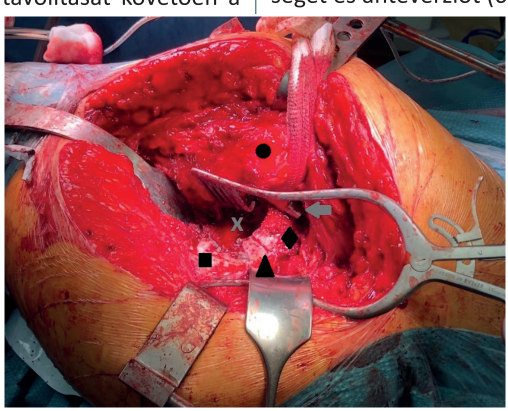
Preoperatív diagnosztika

A periprotetikus medence diszkontinuitás sikeres ellátásának legfontosabb alappillére az alapos preoperatív diagnosztika és tervezés. Preoperatív röntgen- és CT felvételeken elvégeztük a vápadefektusok Paprosky-szerinti klasszifikálását, a vápakosár beültetés indikációjaként, amit a műtéti lelet is megerősített (2. ábra). A 3D CT segítségével meghatározható volt a választandó APC hozzávetőleges nagysága, szükséges allograft mennyisége, és a csavaros rögzítésre alkalmas csontterületek elhelyezkedése (10).

Műtéti technika és eszközök

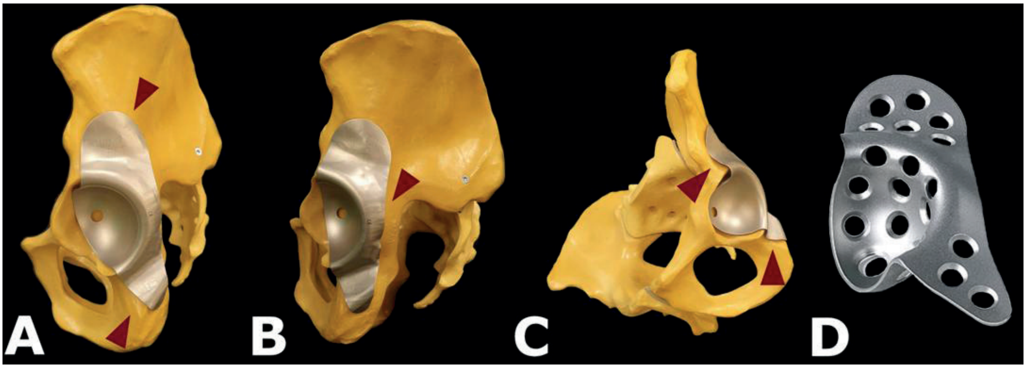
A váparevíziót minden esetben oldalfekvő pozícióban, hátsó feltárásból végeztük a korábbi feltárás vagy feltárások típusától függetlenül. A kilazult vápa eltávolítását követően a benőtt sarjszövetet mind a csontfelszínekről, mind a krónikus törtvégekről alaposan eltávolítjuk. A műtét során meghatározott vápakosárhelyzetnek megfelelően a csontfelszíneket felmarjuk úgy, hogy a lehető legnagyobb vitális csontfelszínt kapjuk a beültetéshez, így érhető el a legjobb biológiai beépülési potenciál. A vápakosár próbájának, a végleges APC beültetéséhez és minél nagyobb implantátum, csontkontaktushoz, az acetabulum hátsó oszlopát kipreparáljuk, az ischiumot, valamint az ilium proximalis részét feltárva (1, 2, 7, 20) (*3. ábra*).

A csonthiányos területeket liofilezett, homológ „spongiosa chips”-szel feltöltjük, a graftot amennyire a meggyengült, gyakran pergamenszerű csontállomány engedi, impaktáljuk. Így a defektus méretét valamelyest csökkentjük és szegmentális hiány mellett észlelhető kavitális defektusokat kitöltjük, megadva a lehetőséget a csontos integrációra a terhelési viszonyok rendezését követően. A megfelelő méretű vápakosár próbát először a hátsó vápaperemhez illesztjük, a füleit, a csontos anatómiának megfelelően modelláljuk. Ezt követően a végleges, a próbának megfelelő méretű APC-t szintén modelláljuk és először a füleit az iliumhoz és az ischiumhoz rögzítjük, melyet transacetabuláris csavarokkal egészítünk ki (*4. ábra*). Ezzel a technikával csökkenthetők a fülek tövénél ható deformáló erők, így a komponenstörés kockázata (28). Megfelelő primer stabilitás elérését követően polietilén vápát cementezünk be különösen figyelve a méretezésre és figyelembe véve a megfelelő meredekséget és anteverziót (6) (*5. ábra*).

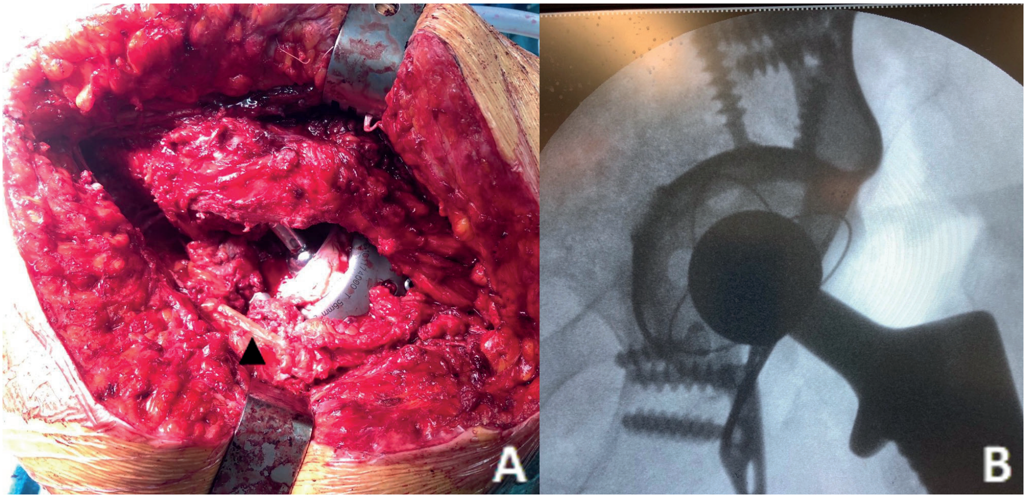


3. ábra

*Hátsó feltárás, a femurt (●) a protézisnyaknál (←) fogva ventral felé elemelve jól látható az előkészített vápa (**x**), annak hátsó pereme, a folytonosság megszakadása (▸), illetve a csavaros rögzítéshez feltárt és előkészített ilium (♦) és ischium (■).*



4. ábra
A vápakosár komponenssel megegyező méretű, modellálható alumínium próba eszköz „száraz modellje" látható. ***A*** *és* ***B****: Az eszköz a vápadefektust áthidalja, az iliumon, az ischiumon és a hátsó oszlopon támaszkodik (▸);* ***C****: Jól látható, hogy az eszköz teljesen kitölti a vápát, szárnyai modellálást követően az iliumra és az ischiumra tökéletesen illeszkednek (▸);* ***D****: Jól látható, hogy a próba formájában csak a csavaros fixálásra kialakított lyukak hiányában tér el a végleges komponenstől.*



5. ábra
A*: Hátsó feltárásból végzett revízió, a femurt ventral felé elemelve jól látható a végleges vápakosár és a becementezett polietilén vápa. N. ischiadicus (▸).*
B*: A végleges protézis röntgenképe. A műtét során minden komponens és csavar elhelyezkedését képerősítővel ellenőrizzük.*

Posztoperatív rehabilitáció

A műtétet követően az alábbi rehabilitációs protokollt alkalmaztuk, figyelembe véve a csontgraft és az osteosynthesis tehermentesítését. Az első 48 órában megkezdtük az operált ízület gyógytornász vezette passzív tornáztatását. Majd aktív torna indult és a 8. posztoperatív hétig segédeszköz használatával az operált végtag terhelését csak talpérintéssel engedélyeztük (15–20 kg-os részterhelésnek felel meg). Az első radiológiai kontrollt követően, a terhelés hetente 10–15 kg-os növelésével fokozatosan terheltettük a csípőt.

A 15. posztoperatív héttől engedtük a végtag teljes testsúllyal terhelését és a segédeszközök fokozatos, igény szerinti elhagyását.

Adatgyűjtés

A demográfiai adatok (nem, kor, testsúly, testmagasság, BMI, revíziók száma, a korábbi vápakomponens túlélési ideje, műtéti indikáció) mellett, az operatív adatokat (műtét hossza, anesztézia típusa, beültetett komponensek mérete, csavarok száma és elhelyezkedése, műtéti vérvesztés) és a posztoperatív eseményeket (perioperatív vérvesztés mértéke, transzfúziós igény és mennyisége, osztályos tartózkodás hossza) is feljegyeztük. E mellett külön hangsúlyt fektettünk a korai és késői szövődmények adminisztrálására.

Követési stratégia

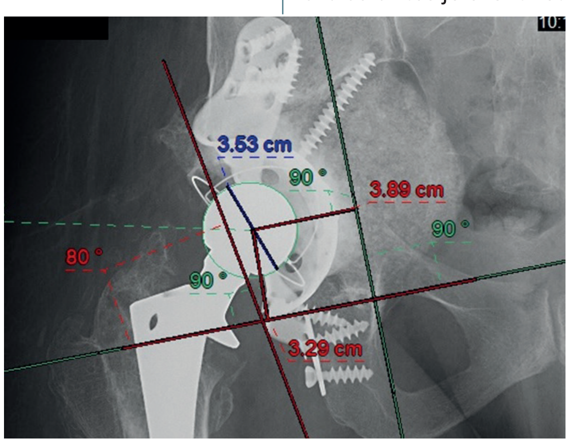
Betegeinket minimum két éven át követtük. A kontrollvizsgálatokat a műtét utáni 6. héten, a 3., illetve 6. hónapokban, egy évvel a műtétet követően, majd évente végeztük.

Klinikai állapot felmérése

Minden vizit alkalmával megtörtént a rutin fizikális vizsgálat, amit az Oxford Hip Score (OHS) és Visual Analog Scale (VAS) skálák önértékelő tesztjeivel egészítettünk ki, illetve feljegyeztük a segédeszköz szükségletet.

Radiológiai követés

Radiológiai kontroll minden alkalommal készült, kétirányú csípő- és AP medencefelvételek formájában. Méréseinket a symphysisre centrált AP medence felvételeken végeztük. A mért értékeket az ismert átmérőjű protézis fej komponens valós/kép arányával korrigáltuk. A medence csontdefektus minden esetben súlyosan érintette a Köhler–vonalat (Sutherland–módszer) (12), így e helyett az obturator vonalhoz viszonyítva határoztuk meg a vápakosár vertikális, horizontális elhelyezkedését és a vápakosár dőlési szögét (27) (6. ábra). A kontrollok során kapott eredményeket összehasonlítottuk az egyes időpontokban az eszköz stabilitását vizsgálva. Maximum 5 mm-es, illetve 5°-os elmozdulási hibahatárt alkalmaztunk a felvételeken előforduló nagyítási és expozíciós különbségek miatt. Stabilitási vizsgálatok során feljegyeztük a csavarok lazulását/elmozdulását is, illetve vizsgáltuk a csavarok körüli csontfelszívódást, minimum 2 mm-es radiolucens sávok megjelenését. A beültetett csontgraft átépülését, illetve felszívódását a graft–cage határon DeLee–Charnley I–III zónákban és a graft–host határokon vizsgáltuk. A beépülés biztos jeleként a graftban trabekulumok, a felszívódás biztos jelének minimum 2 mm-es radiolucens sávok megjelenését vettük (11). Ochs és munkatársai munkája alapján 5 mm, illetve 5° fölötti komponens vagy csavar elmozdulást, csavartörést, progresszív graftfelszívódást a lazulás biztos jeleként vettük (17).



6. ábra

*Műtét utáni AP röntgenfelvétel, amelyen mérési módszerünk látható: **Kék vonal**: Fejátmérő (ismert paraméter), ennek viszonyításával kiküszöbölhető a különböző időpontban készült röntgenfelvételek közötti nagyítási különbség. **Zöld vonal**: Obturator vonal és a ráhúzott merőleges, ehhez viszonyítjuk a forgásközéppont helyzetét. **Piros vonal**: A forgásközéppont vertikális és horizontális elhelyezkedése, illetve a vápakosár meredeksége.*

Kizárási kritériumok

A vizsgálatba nem vontuk be azokat a betegeket, akiknél a preoperatív radiológiai leletek vagy a műtéti lelet kizárták a vápakomponens körüli súlyos Paprosky 3B fokú aszeptikus lazulást és medence folytonosságának megszakadását, illetve más eszközökkel és eltérő módszerekkel végzett revíziókat.

EREDMÉNYEK

Vizsgálatunkba eddig 5 esetet válogattunk be, amelyek mindegyike nő, átlagéletkoruk a műtét időpontjában 68 év (53–76 év), Body Mass Index (BMI) átlag: 27,5 kg/m² (min.: 23,7 kg/m², max.: 29,4 kg/m²) volt. Minden esetben röntgenvizsgálattal Paprosky 3B típusú acetabularis defektust diagnosztizáltunk medence diszkontinuitással, amelyet 3D CT rekonstrukcióval igazoltunk, műtéti lelettel megerősítettünk. Az APC vápakosárral történő revíziót két esetben első, két esetben második és egy esetben harmadik revíziós műtétként végeztük. Négy esetben a vápakomponens aszeptikus lazulása, míg egy esetben a lazult komponenst érő alacsony energiájú trauma következtében kialakult törés okozta a medence folytonosságának megszakadását. Aszeptikus lazulásos esetekben az előzőleg primeren vagy már egy korábbi revízió során beültetett vápa komponensek átlagos túlélése 114 hónap volt (5–196 hónap). A műtétek átlagos hossza 172 perc volt (160–180 perc). Szárrevízió egy esetben sem történt. A defektusok feltöltését homológ „spongiosa chips” impaktálásával végeztük. A csontdefektusok méretének megfelelően 2–7 felezett, liofilezett combfej graftot használtunk fel. A vápakosár rögzítése 3 esetben 7, egy-egy esetben 6 és 8 darab csavarral történt. A műtéti tervezés során, a készült CT felvételek segítségével az egyéni csontviszonyoktól függően terveztük meg a csavarok helyzetét. Egy vagy kettő csavar transacetabularisan került elhelyezésre. A hosszú, közel háromórás műtétek során az átlagos vérvesztés 480 ml (300–700 ml) volt. Az osztályos tartózkodás alatt rendszeres laborkontrollt végeztünk. Két esetben került sor transzfúzióra, a többi esetben a vérkép paraméterek a kezdeti esést követően stabilak maradtak, illetve a betegek objektív és szubjektív klinikai állapota (major hypoxiás tünetek hiánya) nem indokolta a vértranszfúzió adását. Az egyik transzfúziós esetben (4. beteg) a transzfúziót 2 egység vörösvérsejt (vvs.) koncentrátummal a késői posztoperatív napokon végeztük, folyamatos haemoglobin (hgb.) esés miatt, illetve itt tapasztaltuk a műtétet követő leghosszabb hospitalizációs időszakot is (23 nap). A másik esetben (5. beteg) már a műtőben 2 egység vvs. koncentrátum adása történt, amit az 5. posztoperatív napon folyamatos hgb. esés miatt ismételtünk. Ebben az esetben a műtétet követően osztályon eltöltött napok száma 11 volt. Ezt a beteget (5. beteg), ahol már a műtét során transzfúzióra került sor kizártuk a perioperatív vérvesztéssel kapcsolatos elemzéseinkből. Az 1–4. beteg hgb. esése átlagosan 44 g/l (33-51 g/l). Mind a négy esetben jelentős mértékű, több mint 20 g/l hgb. csökkenést észleltünk. A teljes perioperatív vérvesztés mértékét (haematocrit (htc.) drop) a Nadler-formula segítségével számítottunk (8). Az 1-4. beteg átlag vérvesztése 1,7 liter (1,3–2,2 l), kiugró értéket nem tapasztaltunk (σ=0,413). A posztoperatív hospitalizáció átlaga 13 nap (8–23 nap) (*I. táblázat*).

A rendszeres kontrollvizsgálatokat a műtétet követően 3, 6 hónappal, 1 és 2 évvel végeztük. A minimum utánkövetési idő 24 hónap. Radiológiai követéssel a graft–host határokon kielégítő átépülést, illetve trabekularizálódást észleltünk. Minden esetben kielégítő vápakosár-graft és vápakosár–host kontaktust észleltünk (*7. ábra*). Graft felszívódás nem történt. Csavarlazulást két esetben találtunk az os ischiiben, az eszköz stabilitását nem befolyásolta (*8. ábra*). A vápakosarak migrációját egy oldali, csípőre fókuszált AP felvételeken vizsgáltuk. Hibahatárt meghaladó horizontális (5 mm), vertikális elmozdulást (5 mm), rotációt (5°) egy esetben sem észleltünk (17).

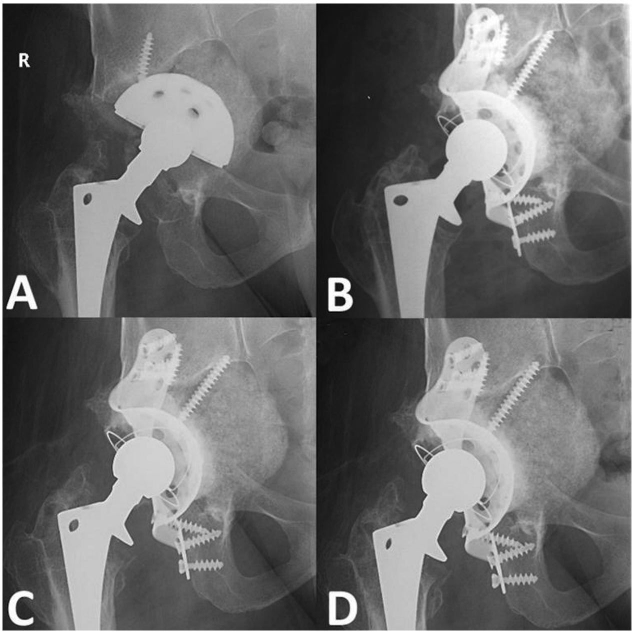
A klinikai állapot felmérésére kitöltött OHS kérdőíveket kiértékelve, a műtét előtti átlag pontszám 10 (3–16), az utolsó kontroll átlaga: 29 (24–32). A VAS skálán jelzett pontértékek a műtét előtt átlagosan 8 pont (5–10), míg az utolsó kontroll alkalmával átlagosan 3 pont (0–7). Mind a VAS, mind az OHS tesztek eredményei minden betegnél pozitív irányú tendenciát mutattak (*9. ábra*).

Az utolsó kontrollvizsgálatra két beteg

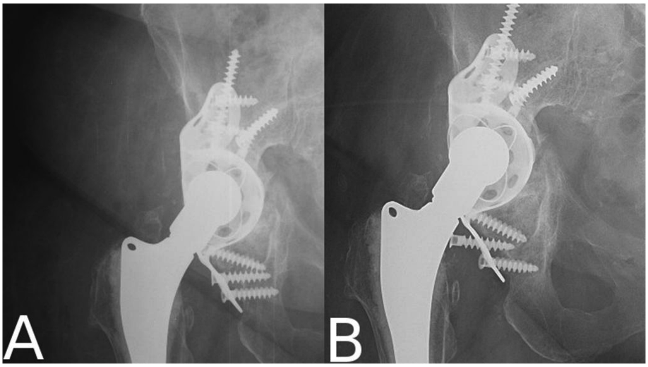
járóbottal, három beteg pedig segédeszköz nélkül érkezett. A korábban említett vérzéses szövődményeken kívül még egy esetben tapasztaltunk a műtéti területen szövődményt. Itt elhúzódó sebgyógyulás és seromás váladékozás jelentkezett, emiatt az ismételt osztályos felvételre további megfigyelés és rendszeres kötéscsere igénye miatt volt szükség. A seromából nyert minta mikrobiológiai vizsgálata negatív eredményt adott. Az alkalmazott terápia hatására a tünetek szűntek, sebe rendben gyógyult. A követési szakban egy esetben sem volt szükség re-operációra.

I. táblázat: A vizsgált betegek demográfiai és perioperatív adatai

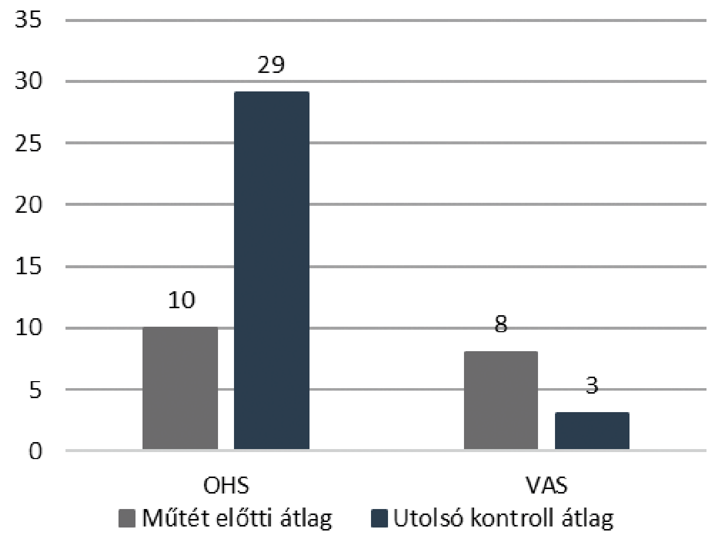
Nem	5 nő beteg
Indikáció	Paprosky 3B + medence diszkontinuitás
Aszeptikus Lazulás	4
Periprotetikus Törés	1
Revízió száma	
1.	2
2.	2
3.	1
Átlag életkor:	68 év (53-76)
Átlag BMI:	27,5 kg/m2 (23,7-29,4)
Előző komponens:	
Primer cementes vápa	2
Revíziós cement nélküli vápa	2
Single flange cage	1
Előző komponens túlélése:	114 hónap (5-196)
Átlag műtéti vérzés:	480 ml (300-700)
Transzfúzió:	2 esetben
Átlag Hgb esés (4):	44 g/l (33-51)
Átlag Htc esés (4) (Nadler):	1,7 l (1,3-2,2)
Átlag hospitalizáció:	13 nap (8-23)



7. ábra
***A**: Revízió előtti felvételen a korábban beültetett revíziós vápa malpozíciója, a rögzítőcsavar törése látható;*
***B**: Közvetlen műtét utáni kontroll röntgenfelvétel;*
***C**: Féléves kontroll röntgen;*
***D**: Kétéves kontroll röntgen;*



8. ábra
***A**: Műtét utáni első röntgenkontroll.*
***B**: Féléves kontroll röntgenfelvétel, az ischiumban jól látható csavarlazulás, a protézis helyzete változatlan, stabil eszköz látható.*



9. ábra

OHS és VAS tesztek átlagai a műtét előtt és az utolsó kontroll alkalmával

MEGBESZÉLÉS

Súlyos, a medence folytonosság megszakadásával is járó teljes csípőprotézis vápakomponens körüli, Paprosky 3B csonthiányok műtéti megoldása az alapos képi diagnosztikán és preoperatív tervezésen alapszik. Ennek fontos részei a többirányú, jó minőségű röntgenfelvételek és a CT vizsgálat, illetve a belőle készült 3D rekonstrukciós képek. Fontos, hogy „gold standard" eljárás hiányában a legmegfelelőbb revíziós eszközök kiválasztása ezek, illetve a rendelkezésre álló technikai és szakmai/gyakorlati feltételek alapján történjen. Mivel a súlyosabb defektusok összetett, akár több technika kombinált alkalmazását is igénylik, a műtétet megelőzően az alapos tervezés elengedhetetlen a stabil, jól terhelhető rendszer kialakítása érdekében.

Rövid távú, kis elemszámmal bíró vizsgálatunk alátámasztja, hogy az igen súlyos medence diszkontinuitással járó Paprosky 3B periprotetikus csontdefektusok ilioischialis cage és impaktált spongiosa allograft együttes használatával kezelhetők. Stabil, jól terhelhető rendszer hozható létre.

Az impaktált spongiosa graft minden esetben átépülést mutatott, felszívódást nem észleltünk. *Kawanabe* és munkatársai tanulmánya biomechanikai vizsgálatokkal támasztotta alá, hogy a különböző váparekonstrukciós eszközök sínező, és a pótlásban keletkező stresszerőket csökkentő funkciója a graftok összeesését megakadályozza, az átépülést elősegíti (13, 26).

Wedemeyer és munkatársai strukturális és impaktált allograft átépülését vizsgálták munkájuk során. 36 revíziót végeztek Paprosky 2C–3A–3B típusú vápadefektussal diagnosztizált betegen. 84,2 hónapos utánkövetési idő alatt csupán két esetben volt szükség a graft felszívódása és klinikai panaszok miatt re-revízióra (27).

Az utánkövetés során tapasztalt ischialis csavarlazulások ugyan az eszközök stabilitását nem befolyásolták, de a környező lágyrészképleteket (n. ischiadicus) hosszú távon irritálva panaszokat okozhatnak. Ennek elkerülése más típusú eszközök, mint a Burch–Schneider Cage (BSC) használatával lehetséges. A BSC ischiumban rögzülő szárnya modulálható, rögzítése a csontba vágott horonyban történik, cserébe a primer stabilitásuk kevésbé kiszámítható, mert a gyakran lítikus ischiumba kerül a háromszög formájú distalis vég, ahol csak korlátozott megtámasztást ad.

Regis és munkatársai kutatásuk során 56 Paprosky 3A, illetve 3B defektus miatt vápacserén átesett beteg átlag 11,7 éves utánkövetését végezték. A revízió során BSC–homograft beültetés történt. 49 esetben jó graft átépülést tapasztaltak, az összesített túlélési ráta pedig 87,5% (21).

Berry és munkatársai 42 súlyos acetabularis csonthiánnyal kezelt eset 11 éves utánkövetéses vizsgálata során 76%-os túlélést írtak le BSC és csontgraft használatával (5).

Hsu és munkatársai munkájukban 31 súlyos Paprosky 3A és 3B típusú csontdefektussal diagnosztizált beteg utánkövetését végezték. Átlag 5,5 év után ugyancsak 76%-os BSC-homograft kompozit túlélést írtak le (11).

A BSC graft–/host–csont felőli felszínén bioaktív, hidroxiapatit (HA) felszínkialakítás az eszköz csontos integrációját segíti. Míg az általunk alkalmazott Depuy Protrusio Cage „gyenge" tulajdonsága, hogy ilyen felszínkialakítást nem kapott. Ennek ellenére grafttal, illetve a host–csonttal érintkező felszíneken csontfelszívódást vagy támasztó felületvesztést nem észleltünk.

A biobanki graftokkal a medence csontos folytonossága helyreállítható, így a defektus mérete csökkenthető, az esetleges későbbi revíziók egyszerűbb technikákkal is elvégezhetők. Hátránya, hogy fertőzések, betegségek átvihetők, a revaszkularizáció és az átépülés zavart szenvedhet, a donorcsont felszívódhat. A TM augmentek használatával mindez elkerülhető (6).

López-Torres és munkatársai TM rendszer és BSC–graft kompozit csoportok összehasonlítását végezték. 84 eset 7,5 éves vizsgálata során nem találtak szignifikáns különbséget az infekciós és re-revíziós rátában, illetve a csont átépülés tekintetében. Ellenben a klinikai vizsgálatok szerint a TM csoportban kevesebb beteg igényelt segédeszközt, szubjektív önértékelő tesztekben magasabb pontszámot értek el, illetve magasabb elégedettségi rátát jegyeztek (14).

Migaud és munkatársai 2019-ben készült TM és BSC–graft revíziós rendszereket összehasonlító összefoglalójában kiemeli, hogy az évtizedek óta alkalmazott BSC-graft technika Paprosky 3A defektusok esetén, 18 év után 85%-os túlélési rátával rendelkezik. Csontfelszívódást a jó eredményeket adó eszközök környezetében is észleltek 10 év után. A TM rendszerek vizsgálatai 90% fölötti túlélést mutatnak, de a 10 éves követési időt még nem haladják meg. Infekciós ráta a TM rendszernél 4,9%, míg az APC-k esetén 3,3%. Szeptikus szövődmény esetén a TM komponensek eltávolítása nehézkes lehet, és nemkívánatos csontvesztéssel járhat. A Mayo Klinika ajánlása súlyos, diszkontinuitással járó vápadefektusok kezelésére az „a la carte rekonstrukció" moduláris TM komponensekkel („pelvic distraction"). A TM rendszerek viszont jóval drágábbak. TM komponensek használatát főleg APC–graft revíziót követően csont átépülési zavar, graftfelszívódás esetén javasolja a szerző (15).

Szczepanski és munkatársai 2019-ben publikált meta-analízise a medencediszkontinuitás kezelésében a fentebb már leírt 4 kezelési technikát vizsgálja a mechanikai szövődmények szemszögéből rövid, közép és hosszútávon. Összesített túlélés tekintetében az egyedi vápakosarak (5%) és a cup–cage (7%) alacsonyabb szövődményrátát adtak, mint a TM rendszerek (12%) és a legrosszabb eredményt adó APC-k (24%). Eredményeiket limitálja, hogy az APC-k rendelkeznek a leghosszabb, a legjobban dokumentált és legtöbb beteget vizsgáló utánkövetésekkel (24).

Rossman és munkatársai a törtvégek egyesítésére strukturális és impaktált graftot alkalmaztak, melyet a GAP II cage (Stryker) használatával fixáltak a medencéhez. Ötéves betegkövetésük során 87,8%-os vápakosár revízió nélküli túlélést írtak le (22).

KÖVETKEZTETÉS

A medence folytonosság megszakadásával járó súlyos periprotetikus, acetabularis csonthiányok megoldása alapos preoperatív diagnosztikát és tervezést igényelnek. Megoldásuk az egyik legnagyobb kihívást jelenti az ortopéd sebészek számára. Az antiprotrúziós vápakosár és impaktált allogén csontgraft használatával stabil, jól terhelhető rendszer hozható létre, a medence csontos folytonossága helyreállítható. Még a legsúlyosabb csonthiányos defektusok esetén is alkalmazható, amikor a TM augmentátumok és cup–cage konstrukciók stabil beültetéséhez nem áll rendelkezésre megfelelő csontállomány. Az ízületi mozgás és a végtaghossz megőrzésére irányuló kényszerű megoldásként használható technika.

Mindennapi gyakorlatot és sebészi döntést befolyásoló eredményekhez, illetve statisztikai elemzésekre alkalmas adatokhoz nagyságrendekkel több beteg bevonása és hosszabb utánkövetési idővel végzett vizsgálat szükséges. Revízió végzése ott optimális, ahol a technikai lehetőségek tárháza mind protetikai, mind a csontpótlás oldaláról elegendően széles, és az adott esethez a rendelkezésre álló lehetőségek közül a legjobbat lehet választani (25).

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RESEARCH ARTICLE

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Differences between proximal bone remodeling in femoral revisions for aseptic loosening and periprosthetic fractures using the Wagner SL stem

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Abstract

Background: Monoblock taper fluted stems have been reliably used to treat proximal femoral periprosthetic fractures (PFF) and femoral aseptic loosening (AL). Although proximal femoral remodeling has been observed around the Wagner Self-Locking (SL) stem, the exact characteristics of this process are yet to be established. Our aim was to compare the remodeling that takes place after femoral revisions for PFF and AL.

Methods: Consecutive patients between January 2015 and December 2017 undergoing femoral revision using the Wagner SL stem for PFF or AL without an extended trochanteric osteotomy (ETO) or bone grafting were selected from our database. Radiological follow-up was performed using plain antero-posterior hip radiographs taken postoperatively and at 3, 6, 12 months and at 24 months. The Global Radiological Score (GRxS) was utilized by four blinded observers. Intra and interobserver variability was calculated. Secondary outcome measures included the Oxford Hip Score and the Visual Analog Scale for pain.

Results: We identified 20 patients from our database, 10 PFF and 10 AL cases. The severity of AL was Paprosky 2 in 2 cases, Paprosky 3A in 2 cases and Paprosky 3B in 6. PFF were classified as Vancouver B2 in 7 cases and Vancouver B3 in 3 cases. Patients undergoing femoral revision for PFF regained 89% (GRxS: 17.7/20) of their bone stock by 6 months, whilst patients with AL, required almost 2 years to achieve similar reconstitution of proximal femoral bony architecture 86% (GRxS: 17.1/20). Inter-observer reproducibility for numerical GRxS values showed a "good" correlation with 0.68, whilst the intra-observer agreement was "very good" with 0.89. Except immediate after the revision, we found a significant difference between the GRxS results of the two groups at each timepoint with pair-wise comparisons. Functional results were similar in the two groups. We were not able to show a correlation between GRxS and functional results.

Conclusions: Proximal femoral bone stock reconstitutes much quicker around PFF, than in the cases of AL, where revision is performed without an ETO. The accuracy of GRxS measurements on plain radiographs showed good reproducibility, making it suitable for everyday use in a revision arthroplasty practice.

Keywords: Hip prosthesis, Revision arthroplasty, Bone-prosthesis Interface, Bone remodeling, Periprosthetic fractures, Prosthesis loosening

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Background

Severe bone loss in the proximal femoral metaphysis remains one of the biggest challenges in reconstructive hip surgery. The majority of patients develop proximal bone defects due to aseptic loosening (AL). The most common periprosthetic femur fractures (PFF) (Vancouver B2 and B3) present a similar reconstructive dilemma, where the proximal femur can no longer be used for anchoring the new implant. Removal of the previous implant can also contribute to further bone loss during revision surgery. Autologous bone grafting has limitations in terms of bone available. Using allografts (both morselized and structural) is not without risk, and long-term outcome is unknown with regards to structural grafts.

Taper fluted nonmodular diaphyseally fixed uncemented stems have been proven to be clinically effective in these patient groups [1, 2]. According to the advocates of this stem design, after initial mechanical fixation during surgery, relatively quick biological fixation is achieved by the mechanical stability, the low modulus of elasticity and the grid blasted titanium surface, which promotes bony ongrowth. There is no rigid modular coupling, which might slow down proximal bone restoration. Despite bypassing compromised bone stock proximally, there is no stress shielding in this region, on the contrary, there is predictably proximal new bone formation [3, 4]. This phenomenon does occur with or without a proximal extended trochanteric osteotomy (ETO) or fracture. The exact timeframe and characteristics of this process is unknown.

Assessing fracture healing on radiographs is a subjective process. Evaluating bone restoration is perhaps even more so. Historically both quantitative [5] and qualitative measurement options [1] exist for describing bone restoration in the femur. None of these are easily applicable for both PFF and AL scenarios. Several attempts have been made to objectively describe bone remodeling, although most of the attempts use arbitrary scales. Isacson et al. [6] used a scale from 0 to 3 (0 = no new bone; 1 = some indication of new formation; 2 = cancellous bone surrounding the stem; and 3 = large areas of cortical bone adjacent to the stem surface). Alternatively the presence of residual osteolytic areas can registered according to the work of Böhm and Bischel [7] as increasing defects, constant defects or osseous restoration. Recently more robust and reproducible scoring systems have been introduced to describe bone remodeling. The Global Radiological Score (GRxS) [8] summarizes two previously validated scores, the secondary bone stock (SBS) [9] and osseointegration–secondary stability (O-SS) [10] scores.

The aim of this study was to determine and compare the characteristics and timeframe of bone remodeling around the Wagner Self-Locking (Wagner SL, Zimmer, Warsaw, IN) monoblock stem in revisions for femoral AL and PFF. Our working hypothesis was that there is a distinct difference between the speed of bone stock recovery in the two groups, with AL cases showing a slower recovery process. We also aimed to investigate whether there is a correlation between clinical outcomes and bone regeneration, hypothetising that quicker bone remodeling results in better function.

Methods

Consecutive patients undergoing revision total hip replacement (THR) between January 2015 and December 2017 utilizing the Wagner SL stem at the Department of Orthopaedics, University of Szeged, were chosen from our prospectively collected revision hip database to be included in the study. According to the indication for femoral revision, the patients were subdivided into AL-group and a PFF-group. Revision procedures for AL were classified according to the Paprosky classification [11]. Patients undergoing revision for PFF were classified according to the Vancouver classification system [12]. The femoral bone loss in PFF patients was also classified using the Paprosky classification usually reserved for AL, as the periprosthetic femur fractures were deemed to represent a deficient proximal femur, just like one encounters in AL. Patients undergoing femoral revisions for other indications (instability, infection, etc.) were excluded. Within the AL-group, only patients where an endofemoral approach was utilized were included. Patients, who had an ETO [13, 14] or where a transfemoral approach was used for acetabular access, component removal or varus remodeling were also excluded.

All operations were performed by the senior author, with the patient in the lateral decubitus position, utilizing a posterolateral approach. Procedures were performed under general anaesthesia. The technique was endofemoral in all AL cases (Fig. 1), whilst fractures were treated with either provisional fixation (with clamps and/or wires and an endofemoral technique) or with distal preparation first and proximal reconstruction after revision stem implantation (Fig. 2). A prophylactic wire was used in all PFF cases [15]. Cables and/or cerclage wires were used for fixation of fracture fragments. Trochanteric plates were not required in these PFF cases. After the removal of the components and any cement or intramedullary granulomatous tissue, cannulated power reaming was utilized when required, whilst the final femoral preparation was done manually, prior to trialing and the implantation of the Wagner SL stem. An image intensifier was used in all cases. Supplementary bone graft was never used. Routine thromboprophylaxis was administered using Thrombo-Embolus Deterrent Stockings (TEDS) and low-molecular-weight heparin (LMWH) during hospitalization and 30 days

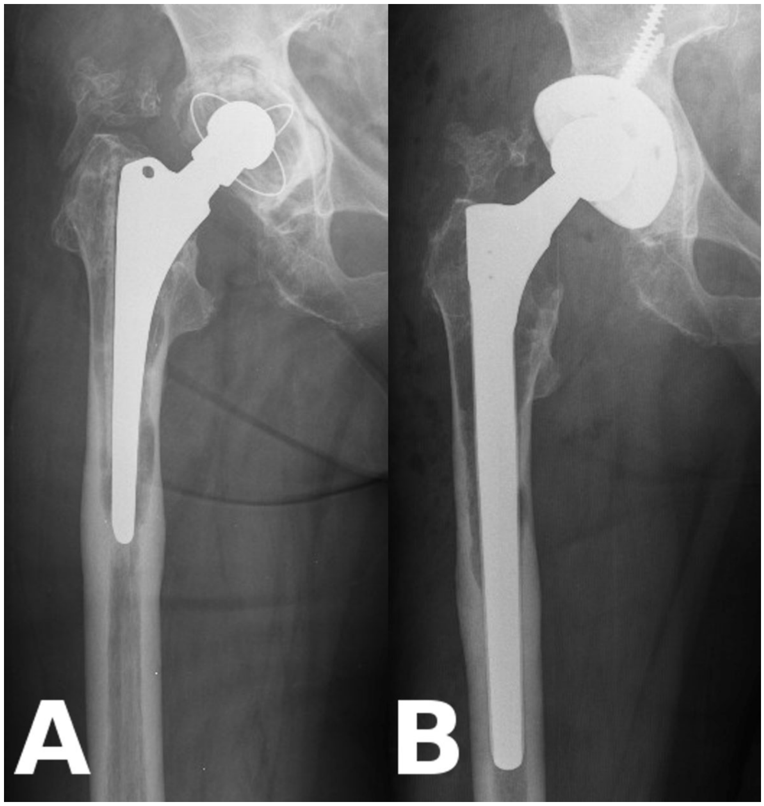

Fig. 1 Example for aseptic loosening of the stem. **a**: Preoperatively massive, Paprosky 3B type resorption of proximal femoral bone stock around a cemented stem. **b**: Wagner SL stem fixed in the healthy diaphysis below the lytic region without an ETO (Patient 11)

thereafter. Antibiotic prophylaxis included intravenous 1.5 g of cefuroxime administered immediately preoperatively and continued for the first 24 h with two additional doses of 750 mg. Passive range of movement exercises were started 24 h after the operation, with touch-toe weight-bearing for 6 weeks. Partial weight-bearing was started 6 weeks postoperatively with 30 kg and increased by 15 kg per week.

Patients were clinically and radiologically followed up for a minimum of 24 months, with follow-ups at 3, 6, 12, 24 months and yearly thereafter.

Radiological follow-up

Standard antero-posterior (AP) pelvis, AP and lateral radiographs of the operated hip and femur were performed for all patients on the first postoperative day and at 3, 6, 12 months and at 24 months. All postoperative and subsequent follow-up radiographs were performed at the Department of Radiology, University of Szeged following an identical protocol for all patients. Patients were positioned supine, with their feet together. The roentgen tube was positioned at the level of the symphysis, 1 m above and perpendicular to the table. Measurements were performed twice by four doctors: a Consultant Radiologist, a Radiology Regsitrar, a Consultant Orthopaedic Surgeon and by the first author (Orthopaedic Registrar), neither of whom were involved in the operations. All four observers were blinded to the identity of the patients and the date of follow-up radiographs. Intra and interobserver variability was also calculated.

Measuring bone restoration

Primary outcome measure was the change of the proximal femoral bone stock assessed by using the GRxS [8] with a view to compare the two different indications (AL vs. PFF). The GRxS is the sum of the SBS [9] and the O-SS [10] scores.

Both the SBS score and the O-SS score utilize AP radiographs of the affected hip and use the well-established Gruen zones [16], namely zone 1,2,3,5 and 6 (Fig. 3).

The SBS score gives each zone a numerical designation, whilst considering cortical thickness, bone density and cortical bone defects. The SBS scoring system is shown in Table 1.

The sum of the measurements of the 5 zones are used to create a cumulative value from − 10 to 20. The secondary bone stock is designated very good (20–18), good (16–14), average (12–10) or poor (< 10).

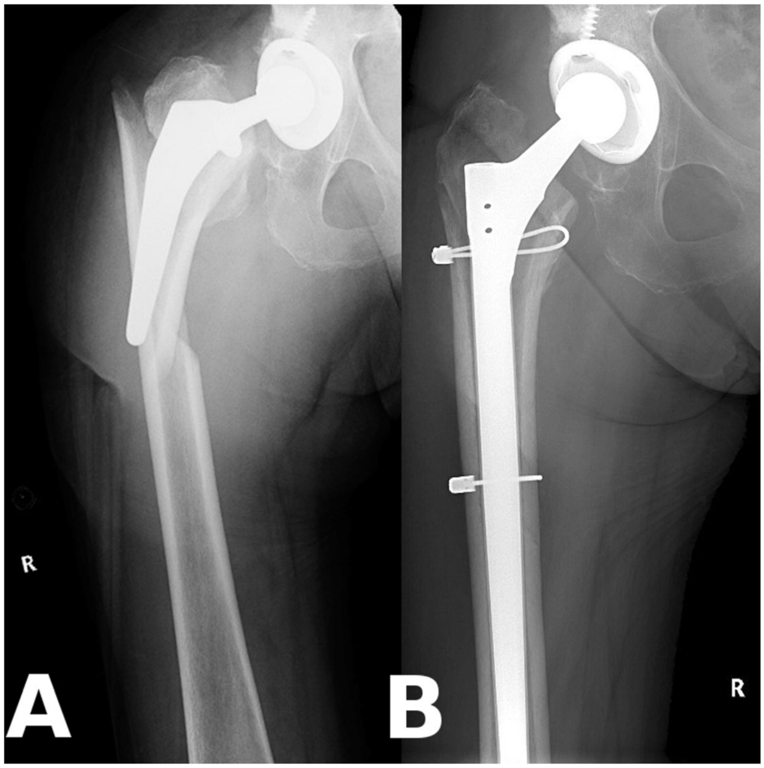

Fig. 2 Example for periprosthetic femur fracture. **a**: Vancouver B2 type periprosthetic fracture with component loosening around a cementless stem; **b**: Anatomical reduction with two cables around a Wagner SL stem (Patient 10)

The O-SS score examines the proximal (zone 1,2 and 6) and distal femur (zone 3 and 5) separately. The O-SS evaluation system of radiolucent lines is presented in Table 2.

The osteointegration and secondary stability is designated very good (20–18), good (14), average (11) or poor (5–8) (weighting is used by adding 1 point for good proximal bone but some distal radiolucent lines (+ 1) and deducting 3 points for significant proximal radiolucent line scores regardless of distal integration (− 3). To calculate GRxS, one simply gives each very good a 10, good an 8, average a 5 and poor a 2, for both the SBS and O-SS and then adds them together. GRxS is very good (20), good (18–16-15), average (13–12) or poor (≤10) [8].

The evaluation process is illustrated with radiographs Figs. 4 and 5.

The immediate postoperative radiographs were compared with those performed at 3, 6, 12 and 24 months to examine bone restoration. Inverted radiographs can aid assessing bone defects and bone quality (Figs. 6 and 7).

The Wagner SL stem is a straight stem without a bevel, thus longer stems can abut to the anterior cortex, due to the normal anterior femoral bow. Bone loss due to the eccentric position of the tip of the stem in the femoral canal has been described and can be evaluated on the lateral view according to Zalzal et al. [17]. The central position of the stem was checked with radiograph intraoperatively as well from lateral view. We utilized only the AP radiographs for measuring bony remodeling, the tip of the stem was not separately assessed on lateral views.

Radiological measurements were performed using the GEPACS software (General Electric Company Healthcare, Chicago, Illinois, USA).

Secondary outcome measures

Basic demographic data (age, gender, body mass index - BMI) and time to revision were collected. Perioperative parameters recorded included: duration of surgery, type of anesthesia, intraoperative blood loss, transfusion requirement and length of stay.

Clinical examination included grading the pain using the Visual Analogue Scale (VAS), and using the Oxford Hip Score (OHS) as our preferred patient reported outcome measure.

Statistical analysis

We performed the statistical comparison of demographic data between the AL and PFF groups with Student's two sample t-test for continuous variables (age, time to revision, length of surgery, blood loss, BMI,

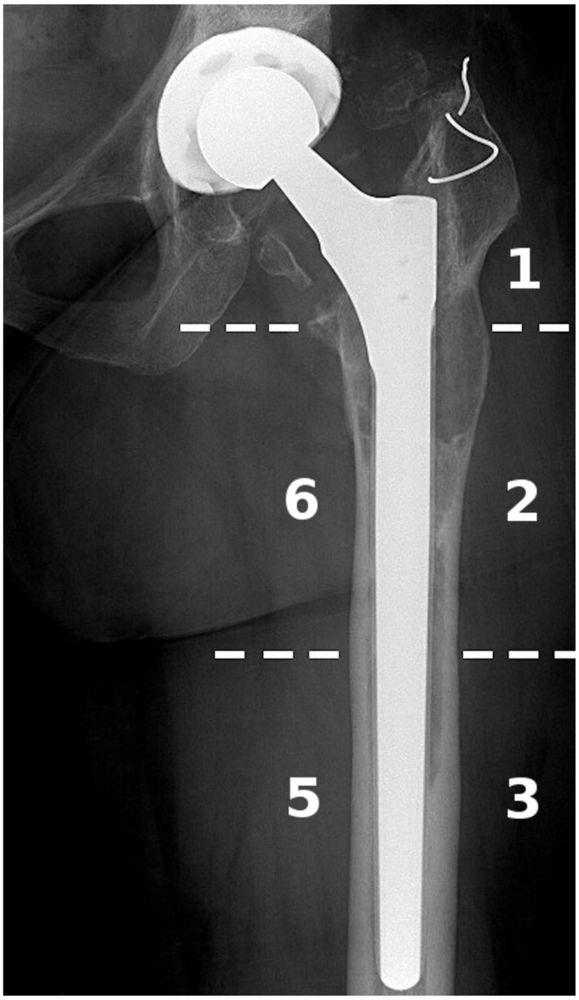

Fig. 3 Example for evaluation of Gruen zones on AP radiograph (Patient 18)

length of stay) and Fisher's exact test for discrete variables (gender, cup revision rate).

We used the Wilcoxon test to compare OHS and VAS results (non-parametric data), two sample or signed design as required.

We analysed the intra-, and interobserver agreement between the numerical GRxS results with intraclass correlation coefficient (ICC) test. For the categorical GRxS results we performed Cohen's-Kappa for intraobserver and Fleiss-Kappa for interobserver reliability.

Table 1 Evaluation of SBS scoring of the bone stock by Gruen zones

Score	Bone stock evaluation
+ 4	no damage or complete regeneration (density and thickness)
+ 2	moderate damage: decreased thickness or density or defects < 10 mms
0	severe damage: decreased thickness and density or defects > 10 mms
-2	major damage in density and thickness or cortical lysis

Table 2 Evaluation of O-SS scoring around the stem by femoral parts

Score	Bony bed evaluation
10	no radiolucent line
7	radiolucent line < 50%
4	radiolucent line > 50%

For the statistical analysis of the GRxS results, we used both the numerical results and the categorical evaluation "very good", "good", "average" and "poor". The patients were grouped accordingly.

We compared the GRxS measurements between the different timepoints with the Friedman test, KendallW was calculated and for the post-hoc analysis we used the paired Wilcoxon signed-rank test.

For assessing the correlation between GRxS with OHS and VAS values we made Spearman's rank correlation test.

The significance level was determined at 5% ($\alpha = 0{,}05$).

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

Our observational study has obtained the approval of the Clinical Research Coordination Office of the University of Szeged, with the registration number: 3/2019-SZTE. Written consent was attained from all patients involved.

Results

From our prospective hip revision database, 39 patients were identified who underwent stem revision using the Wagner SL stem, during the above mentioned period. Twenty patients matched our inclusion criteria for diagnosis and surgical technique, and had a minimum of 24 month follow up.

They were divided into two groups according to the reason for revision: 10 patients had a PFF and 10 patients had stem revision for AL. The severity of aseptic loosening was classified in the AL group as Paprosky 2 in 2 cases, Paprosky 3A in another 2 cases and Paprosky 3B in the other 6. In the PFF group the fracture was classified as a Vancouver B2 in 7 cases and Vancouver B3 in 3 cases. The Paprosky classification of PFF cases showed 7 cases of Paprosky 3A and 3 cases of 3B femoral defects. Six out of the seven VB2 cases were classified as P3A, whilst only one of the three VB3 cases was P3A, the rest were P3B. The comparative classification of PFF patients can be *found in* Tables 3 and 4.

The revision was a first revision in 15 cases, second revision in 3 cases and a third revision in 2 cases. The side

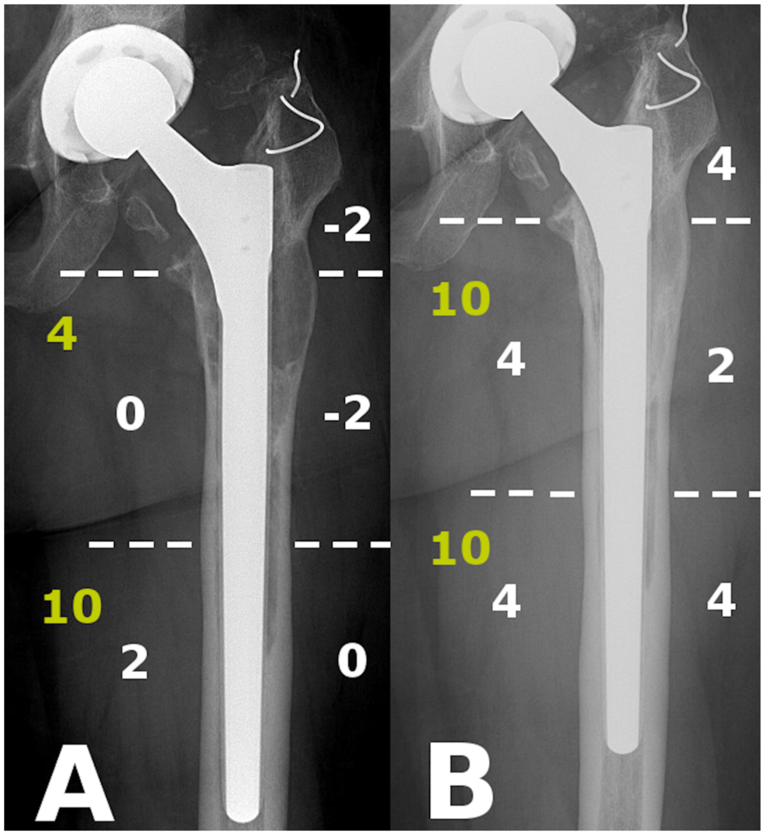

Fig. 4 Example for SBS (white) and O-SS (yellow) measurements in AL group. **a**: IBS -2, O-SS 14 immediate after the revision, GRxS: 4; **b**: SBS 18, O-SS 20 at latest follow-up, GRxS: 18 (Patient 18)

distribution was even with 50% (10/20) left and 50% (10/20) right. 65% (13/20) of the patients required a blood transfusion, nine of them intraoperatively.

Detailed patient demographics and peri-operative data can be found in Table 5.

OHS/vas

Clinical follow-up included, in terms of patient reported outcome measure, the OHS, and for pain specifically the VAS. Preoperative values were compared with the ones at the latest follow-up.

In the AL group OHS values improved significantly from an average preoperative value of 13 points (3–25), to a latest follow-up value of 30 (15–41) (Wilcoxon rank sum test with continuity correction; $p = 0.005857$). As periprosthetic fracture are mostly acute events, measuring the OHS preoperatively is inappropriate, due to pain and restricted mobility (or applied skeletal traction). Comparing postoperative values, PFF patients scored higher 35 (14–48), although the difference was not significant (Wilcoxon rank sum test with continuity correction; $p = 0.2892$).

VAS values were analyzed in a similar way. In the AL group preoperative values averaged 7.3 (4–10), whilst at the latest follow-up the average was 2.6 (0–7) (Wilcoxon signed rank test with continuity correction; $p = 0.005603$). PFF patients scored 1.9 (0–7) at the latest follow-up. AL vs PFF comparison did not show a significant difference (Wilcoxon rank sum test with continuity correction; $p = 0.7017$).

GRxS

In terms of inter-observer reproducibility, for the four independent examiners who performed the measurements, the results showed “good” reproducibility, with ICC 0.68 ($p < 0.001$; 95% CI 0.57–0.77). For categorical variables the Fleiss-Kappa showed a “good” correlation with 0.548 (p < 0.001).

The intra-observer agreement for numerical GRxS values was considered “very good” ICC 0.89 (p < 0.001; 95% CI 0.84–0.93), whilst for categorical variables the weighted Cohen-Kappa was also “very good” with Kappa 0.84 (p < 0.001).

At the immediate postoperative follow-up in the AL group 9 patients had a poor (6.7 points), one an average (13 points) GRxS evaluation, whilst for patients in the PFF group 6 had a poor value (8.5 points) and 2 each had an average (13 points), and good (18 points)

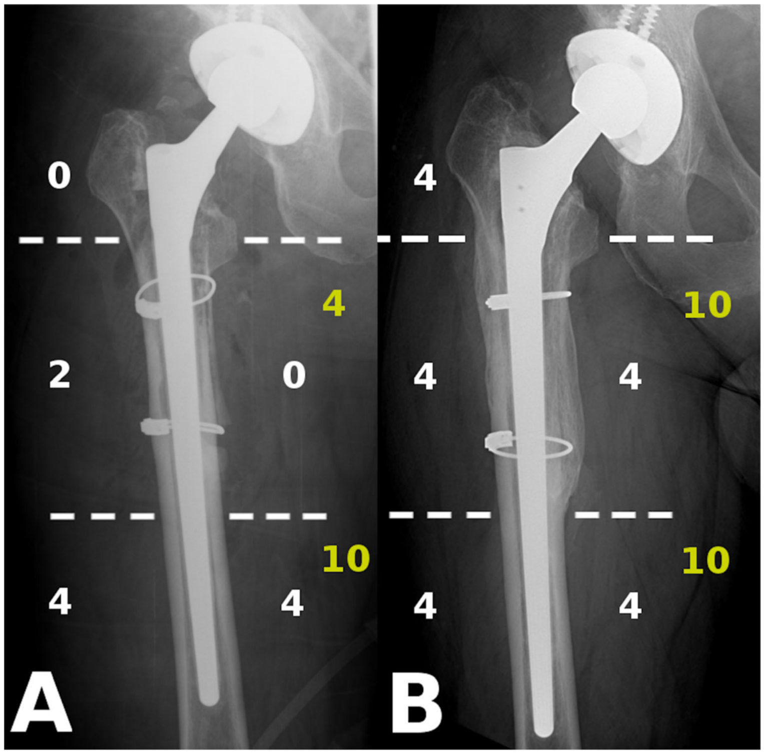

Fig. 5 Example for SBS (white) and O-SS (yellow) measurements in PFF group. **a**: IBS 10, O-SS 14 at first immediate after the operation, GRxS: 13; **b**: SBS 20, O-SS 20 at latest follow-up, GRxS: 20 (Patient 07)

categorization. None of the patients had a very good designation at this point. At the latest follow-up (minimum of 2 years) the GRxS scores for the AL group showed average category in one (13 points), good in 7 (17.6 points) and very good in 2 cases (numerical 20). For the PFF patients 2 patients had a good rating (numerical 18), whilst the remaining 8 had a very good rating (20 points). The differences between the groups in different timepoints are illustrated in Fig. 8.

The change of GRxS group classifications between first and last measurements is illustrated in Fig. 9. The bony changes are demonstrated with radiographs between the follow-up sessions on Figs. 6 and 7.

We analyzed 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 immediate after the operation, we found a significant difference between the two groups at each timepoint.

The comparison between the groups is illustrated in Fig. 8.

As illustrated, patients undergoing femoral revision for PFF using the Wagner SL stem, can expect to regain 89% (17.7/20) of their bone stock by 6 months, whilst patient having a revision for AL, require almost 2 years to achieve nearly similar reconstitution of proximal femoral bony architecture 86% (17.1/20).

Finally we compared the correlation of GRxS with OHS and VAS values. We did not find a significant relationship between these parameters with Spearman's rank correlation test (rho = – 0.2 and – 0.1; $p > 0.05$).

Complications

There was one early dislocation, which was successfully treated with a closed reduction. There was one intraoperative greater trochanter fracture, which went on to unite in 6 months.

None of the femoral components required a revision within the follow-up period. The overall survivorship therefore was 100% for the stems, with femoral revision being the endpoint.

Discussion

The treatment of femoral AL and PFF has undergone a paradigm change over the last 30 years. Although impaction bone grafting and the implantation of a long cemented stem remains a viable option, with a good track record in some centers [18], the mainstay of treatment has been the use of uncemented revision stems. Cylindrical, nonmodular cobalt-chromium uncemented

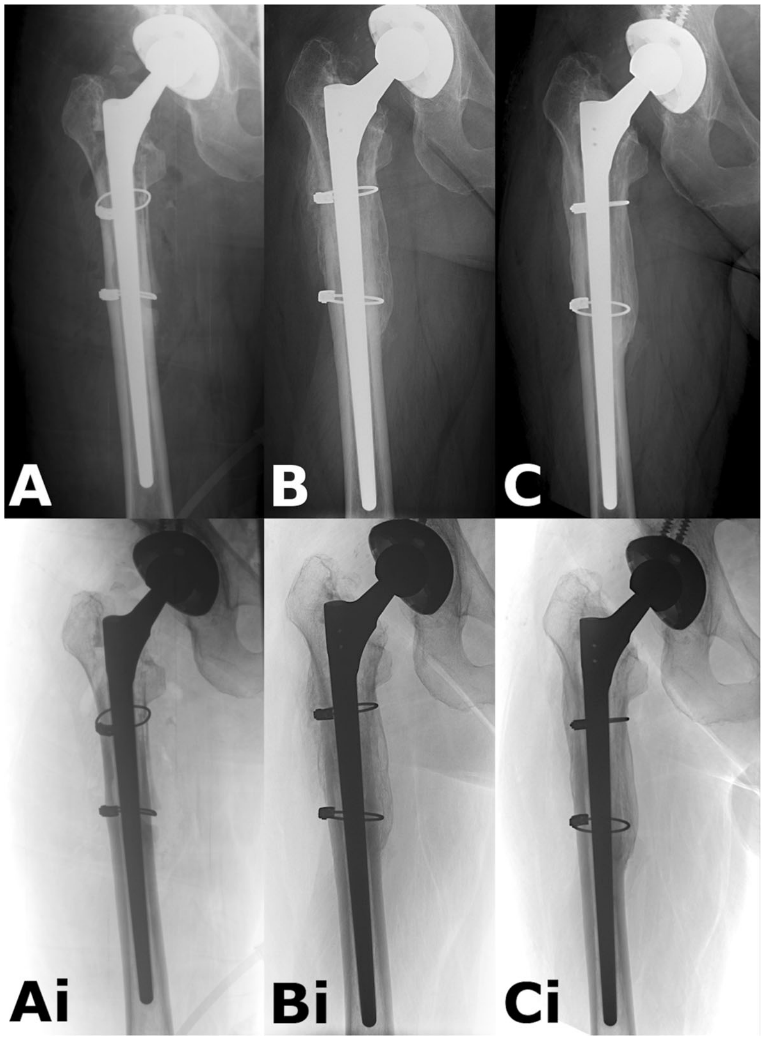

Fig. 6 Example of a PFF case. **a**: Immediate postop radiograph after revision. The poor quality of the proximal bone stock is unequivocal. **b**: obvious new bone formation seen at 6 month follow-up. There is some subsidence. **c**: Radiograph 2 years after the operation. Complete reconstitution of bone stock. Ai-Bi-Ci: Shows the same pictures in inverted view (Patient 07)

stems [19] have given way to tapered fluted titanium stems both in a nonmodular [20–22] and modular configuration [23]. Both provide reliable long-term functional results, with nonmodular implants having the disadvantage of potential early subsidence and the lack of proximal modularity (thus instability), but the advantage of being more elastic, osteointegrating quicker whilst avoiding the risk of coupling failure.

Osseointegration of uncemented implants is required for long-term stability and appropriate joint function. In our study we have demonstrated that proximal femoral bone restoration takes place reliably, both after revision for PFF and for AL, using a monoblock taper fluted revision stem. However, there is a distinct difference in the timeframe of this process in the two patient groups, with PFF patients taking only 6 months to regain about 90% of the bone stock, whilst AL patients require more than 2 years to achieve nearly the same.

Our findings are comparable with other studies. Some papers reported similar timeframe (4–6 months) of fracture healing in PFF cases and also in cases where an ETO was performed [1, 22, 24].

Sandiford et al. [2] reported in patients with P2 and P3 type defects encouraging proximal femur bony regeneration after 2 years.

Measuring radiological bone quantity and assessing bone quality on plain radiographs is a subjective process. Determining the radiological features of cementless arthroplasty components has been a topic of ongoing research for decades.

Canovas et al's [8] designed a complex and detailed scoring system. The radiological evaluation of remodeling has thus became more accurate.

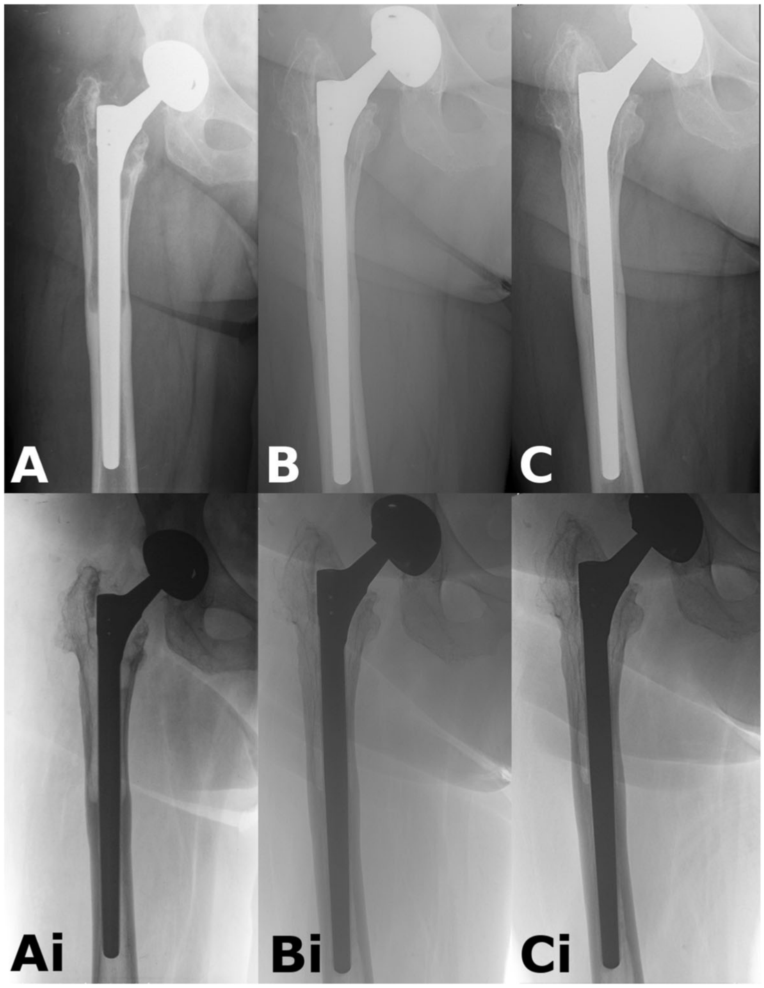

Fig. 7 *Example for AL case.* **a**: Postoperative radiograph after revision. Obvious proximal femoral lysis. **b**: After 12 months there is mild subsidence, and continuous bony remodeling. **c**: Almost complete reconstitution of bone stock at 2 years. Ai-Bi-Ci: Shows the same pictures in inverted view (Patient 17)

Canovas et al. [9] in their first study of the topic created a new scoring system from a different perspective that used the former (Engh et al. [25]) radiological signs to evaluate the bony remodeling after stem revision. The initial bone stock (IBS) and SBS scores can determine the bone stock around modular revision stems [9].

Roche et al. [10] in their study have found that the measurement of radiolucent lines using the O-SS score can be a reliable method evaluating the osseointegration and the secunder stability of extensively porous coated (scratch fit cylindrical) uncemented stems. They have found a significant difference between their method and Engh's method, and have found no correlation between stem stability and secondary subsidence.

Canovas et al. [8] finally merged these two scoring systems to form the GRxS, which was the scoring system that we utilized in our study. In Canovas's medium term study, they evaluated a modular taper fluted porous coated stem (Revitan, Zimmer, Warsaw, IN) which was used for revisions in aseptic loosening cases. There was no bone graft used during the procedures, but in two thirds of the cases an ETO was performed. They found a

Table 3 Paprosky classification of AL and PFF groups

	AL	PFF
P2	2	0
P3A	2	7
P3B	6	3

Table 4 Comparison of the Paprosky and Vancouver classifications of PFF group

	VB2	VB3
P3A	6	1
P3B	1	2

Table 5 Peri-operative data and demographics of AL cases and PFF patients

	Sum. Mean	AL	PFF	*p*-value	95% CI
Age (years)	66 (41–78)	65 (41–78)	66 (51–78)	0.8736	9.815032; 8.415032
Gender (Female)	55% (11/20)	35% (7/20)	20% (4/20)	0.3698	0.03005364; 2.46429183
BMI (kg/m^2)	31.3 (17.8–44.3)	34.1 (27.2–44.3)	28.5 (17.8–40.6)	0.06305	0.3417606; 11.6617606
Time to revision (months)	144 (3–316)	173 (75–316)	115 (3–264)	0.098	−11.76233; 127.16233
Surgery length (minutes)	175 (100–260)	163 (100–245)	187 (120–260)	0.1917	59.89746; 12.89746
Cup revision (Y/N)	13 / 7	9 / 1	4 / 6	0.05728	0.9487882; 684.4235629
Bloodloss (mls)	800 (0–1800)	600 (0–1500)	1000 (300–1800)	0.06291	− 822.03633; 24.03633
Length of stay (days)	12 (6–23)	9 (6–13)	15 (10–23)	0.00053	−8.997446; −3.002554

Sum. Mean Summarized means; *95% CI* Confidence Interval 95%; ranges in the parentheses

significant relationship between the GRxS score and the functional outcomes.

In our study we did not find a statistical relationship between GRxS and OHS or VAS parameters.

Gutierrez et al. [1] examined the bone regeneration after stem revision using the Wagner SL stem. They reported 92.3% stem survival with the most common failure mechanism being subsidence and instability. They observed more pronounced bone remodeling and cortical thickening when there were no major proximal femoral defects. The bone formation was most pronounced at the site of PFF fractures or ETO, which in a sense is similar to our finding that bone remodeling is significantly faster if there is a fracture present.

In AL proximal femoral stress shielding and bone atrophy following total hip replacement, with time will leave very little viable cancellous bone proximally, with thinned and often eroded cortices. Callus formation after fractures on the contrary seems to accelerate bone remodeling. Whilst endofemoral bony apposition and remodeling takes place around a taper fluted stem regardless of preoperative diagnosis, pronounced periosteal bone formation is seen in fracture cases, especially if the required reduction and retention (osteosynthesis)

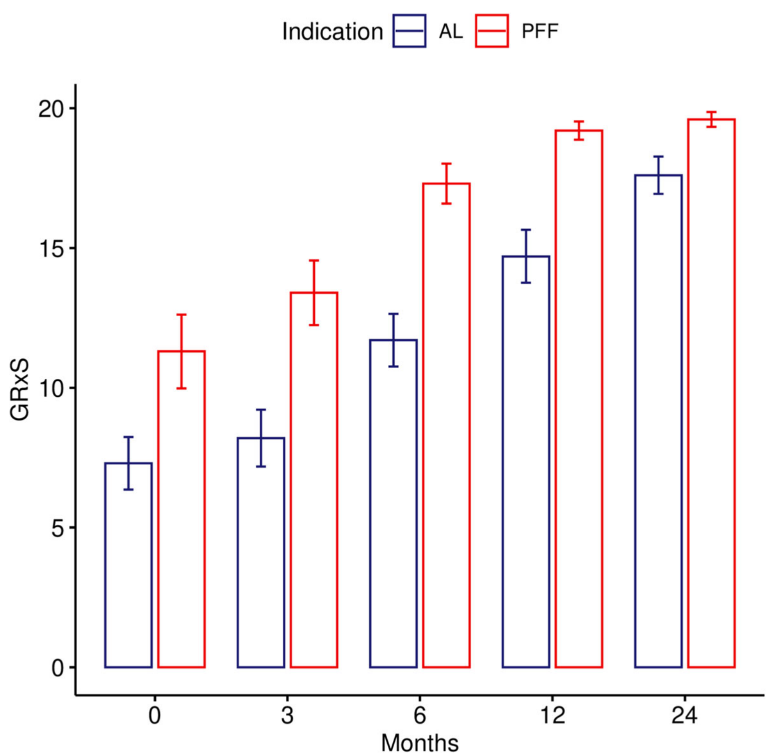

Fig. 8 The GRxS means of AL and PFF groups at the follow-up timepoints. There is a significant difference between the results of the groups at each timepoint (except immediate after the operation) with paired Wilcoxon signed-rank test (0 = immediate after the operation (*p*-value = 0.08198), after 3 months (*p*-value = 0.03412), 6 months (*p*-value = 0.008492), 12 months (*p*-value = 0.0213), and 24 months (*p*-value = 0.01788))

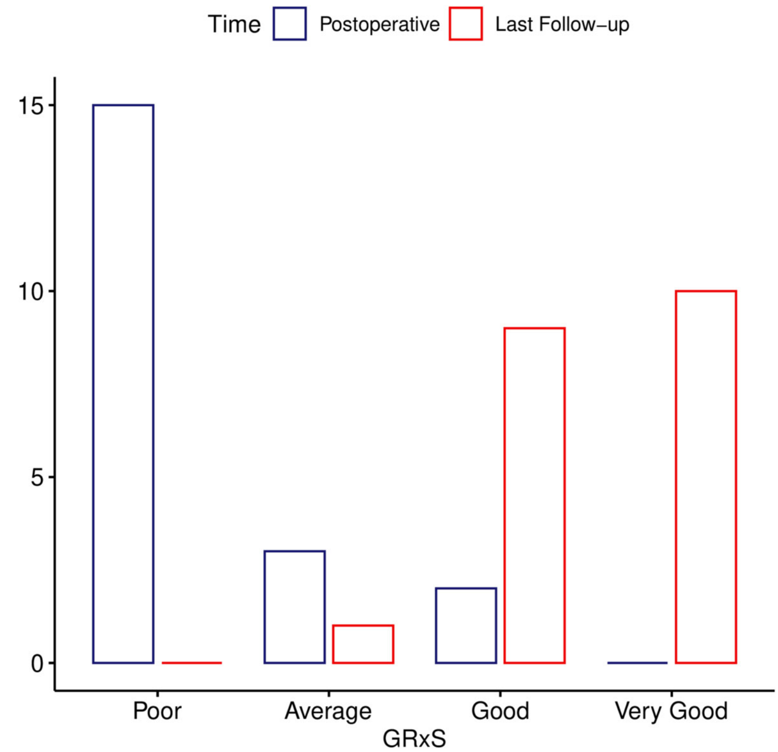

Fig. 9 Change of GRxS group classification between immediate postoperative and last follow-up measurements

technique respects the blood supply of bone fragments. Proximal femoral callus increases the contact area between implant and host bone, thus facilitating load transfer through a larger surface. Fracture pattern and bone quality will influence the required fixation method [26]. Close to anatomical reduction of fracture fragments accelerates the bone remodeling process.

To evaluate the bone remodeling we used a four blinded observer model with two independent measurements each. The GRxS values showed "good" inter-observer reproducibility and "very good" intra-observer agreement for categorical and numerical variables. We analyzed the GRxS measurements between the different timepoints and we found a greatly significant difference between the results at each 5 timepoints. Pair-wise comparisons showed a significant difference between AL and PFF groups at each timepoint, except at the first follow-up. To our knowledge, this paper is the first to compare PFF and AL bone remodeling in such detail using the Wagner SL stem.

The known limitations of our study are the relatively small patient numbers, and the length of follow-up, although other papers examining the same stem have similar numbers, e.g. Zang et al. reviewed 40 hips operated during a much longer, 12-year period [27]. The small patient numbers effected our statistical analysis. The established strengths include, a universal treatment protocol (surgical approach, one surgeon series, postoperative rehabilitation protocol) and the rigorous radiological assessment of the proximal femoral bone stock performed by four independent, blinded observers. The detailed chronological comparison of periprosthetic femoral fractures and aseptic loosening cases is also unique to our study.

Measuring bone stock on plain radiographs is feasible and reproducible. CT scans might provide more detailed information about three dimensional bony remodeling and implant-host bone contact [28]. Further long term assessment is required for detailing the bone remodeling according to preoperative defect category (Paprosky or Vancouver) to help better understand risk factors for delayed osteointegration. Comparison of monoblock and modular stems in regards of bone remodeling would also clarify the indications for the different stem types.

Conclusions

From our hip revision database we examined femoral revisions using the Wagner SL stem without an ETO or bone grafting. Our main finding is that proximal femoral bone stock reconstitutes much quicker around periprosthetic fractures, than in the cases of aseptic loosening, where revision is performed without an ETO. The accuracy of our measurements on plain radiographs is accurate enough for everyday orthopaedic arthroplasty practice with the use of a GRxS scoring system.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12891-021-04062-6.

Additional file 1.

Abbreviations

AP: Antero-posterior; AL: Aseptic loosening group; Av: Average; BMI: Body Mass Index; 95% CI: Confidence Interval 95%; ETO: Extended trochanteric osteotomy; GRxS: Global Radiological Score; G: Good; IBS: Initial bone stock; ICC: Intraclass correlation coefficient; LOS: Length of stay; LMWH: Low-molecular-weight heparin; mms: Millimeters; O-SS: Osseointegration–secondary stability; OHS: Oxford Hip Score; PFF: Periprosthetic femoral fracture group; Pr: Poor; SBS: Secondary bone stock; SL: Self-Locking; Sum. Mean: Summarized mean; TEDS: Thrombo-Embolus Deterrent Stockings; THR: Total hip replacement; vs: Versus; VG: Very Good; VAS: Visual analogue scale

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Authors' contributions

GF is the correspondent author and the main author of the manuscript. GF, GC performed the measurements as orthopaedic surgeons. GF also performed a repeat of his measurements for the intra-observer comparison. ÁB and IP performed the radiological measurements as radiologists. GF and ÁB performed all the statistical analyses in cooperation. GF, GC and AB performed the clinical follow-up including contact with the patients (personally, e-mail, telephone), they prepared and edited the Figs. GC and AB prepared the radiographs and performed the subsidence measurements. KS is the senior author and the main conductor of our study. He performed all the revision procedures. All authors have read and approved the final manuscript.

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Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

The authors state that all methods of our observational study on human participants were carried out in accordance with the Declaration of Helsinki, relevant guidelines and regulations of BMC journal policy.

Our observational study has obtained the approval of the Clinical Research Coordination Office of the University of Szeged, with the registration number: 3/2019-SZTE.

Written consent was attained from all patients involved. Informed consent was obtained from all patients (all patients were above the age of 18).

Consent for publication

Written, informed consent for publication of identifying information/images in an online open-access publication was obtained from all patients (all patients were above the age of 18).

Competing interests

The authors declare that they have no competing interests.

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