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Accuracy of navigated cam resection in femoroacetabular impingement: a randomised controlled trial

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Complete List of Authors:	Van Houcke, Jan; Universitair Ziekenhuis Gent, Khanduja, Vikas; Addenbrooke's - Cambridge University Hospital, Department of Trauma & Orthopaedic Surgery Nakano, Naoki; Addenbrooke's Hospital, Department of Trauma & Orthopaedic Surgery Krekel, Peter; Clinical Graphics Pattyn, Christophe; Ghent University Hospital, Department of Orthopaedic Surgery and Traumatology Audenaert, Emmanuel; Ghent University, Orthopaedic Surgery; Addenbrooke's - Cambridge University Hospital, Department of Trauma & Orthopaedic Surgery; Universiteit Antwerpen Faculteit Toegepaste Economische Wetenschappen, Op3Mech
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Abstract:	Background The main cause for revision hip arthroscopy surgery is incomplete bony resection of femoroacetabular impingement (FAI). This study aimed to compare the cam resection accuracy via the conventional hip arthroscopy technique compared with the navigation technique. Methods Two prospectively randomized groups were recruited: navigated (n=15) and conventional (n=14). A pre-operative CT and post-operative MRI scan were obtained in all cases to compare alpha angle, range of motion simulation and determine a pre-operative 3D surgical resection plan. Results Post-operatively, the mean maximal alpha angle improved significantly in the navigated group compared with the conventional group (55°vs.66°;p=0.023), especially in the 12 o’ clock position (45°vs.60°;p=0.041). However, positioning time and radiation exposure

	were significantly longer in the navigated group. Conclusion Navigated surgery is effective for patients with cam type FAI in helping restore normal anatomy, however, not without drawbacks. Larger studies will be required to validate our results.

Title

Accuracy of navigated cam resection in femoroacetabular impingement: a randomised controlled trial

Authors

Van Houcke Jan[1], Khanduja Vikas[2], Nakano Naoki[2], Krekel Peter[3], Pattyn Christophe[1], Audenaert Emmanuel[1, 2, 4]

Author Initials

Van Houcke, J.[1]
Khanduja, V.[2]
Nakano, N.[2]
Krekel, P.[3]
Pattyn, C.[1]
Audenaert, E.[1, 2]

Institution

[1] Department of Orthopaedic Surgery and Traumatology, Ghent University Hospital, De Pintelaan 185, 9000 Ghent, Belgium.

[2] Department of Trauma and Orthopaedics, Addenbrooke's Hospital, Cambridge University Hospitals NHS Foundation Trust, Hills Road, Cambridge, CB2 0QQ, UK

[3] Clinical Graphics, Molengraaffsingel 10, 2629JD Delft, The Netherlands.

[4] Department of Electromechanics, Op3Mech research group, University of Antwerp, Salesianenlaan 90, 2660 Hoboken, Belgium

Corresponding Author

Prof Dr Emmanuel Audenaert: emmanuel.audenaert@ugent.be

Abstract

Background

The main cause for revision hip arthroscopy surgery is incomplete bony resection of femoroacetabular impingement (FAI). This study aimed to compare the cam resection accuracy via the conventional hip arthroscopy technique compared with the navigation technique.

Methods

Two prospectively randomized groups were recruited: navigated (n=15) and conventional (n=14). A pre-operative CT and post-operative MRI scan were obtained in all cases to compare alpha angle, range of motion simulation and determine a pre-operative 3D surgical resection plan.

Results

Post-operatively, the mean maximal alpha angle improved significantly in the navigated group compared with the conventional group (55°vs.66°;p=0.023), especially in the 12 o' clock position (45°vs.60°;p=0.041). However, positioning time and radiation exposure were significantly longer in the navigated group.

Conclusion

Navigated surgery is effective for patients with cam type FAI in helping restore normal anatomy, however, not without drawbacks. Larger studies will be required to validate our results.

Introduction

Hip arthroscopy has gradually evolved to become a standard technique for the surgical treatment of patients with femoroacetabular impingement (FAI) (1,2). Its minimal invasive nature comes at the cost of reduced visibility and manoeuvrability as compared with open surgical procedures. As a result, recent studies have demonstrated that up to 25% of arthroscopic cam resections appear to be incomplete on post-operative 3D imaging (3). Moreover, a total of 5 to 10% of all hip arthroscopies require revision arthroscopy, and of these the vast majority (80-90%) are revised because of residual bony impingement (4-6).

Recently, several studies have explored the potential of computer-assistance in performing an osteochondroplasty for cam type of FAI using either imageless or image-based protocols (2,7-9). Virtual surgical planning and computer-aided surgery can potentially increase the accuracy and thereby enhance patient reported outcomes. They can also aid in the training of junior surgeons. However, to date, there are no studies which have objectively looked at the potential improvement in surgical accuracy or patient reported outcomes of these techniques.

The aim of our study, therefore, was to evaluate the accuracy of resection of computer-assisted resection of the cam type of FAI versus standard fluoroscopically guided resection in a prospective, randomised study design. The primary outcome measure was the post-operative maximal anterolateral alpha angle. Secondary outcome variables consisted of a detailed clockwise alpha angle, simulated bony range of motion, operative radiation exposure and surgical time. Our hypothesis was that computer-assisted resection would result in the normalisation of the alpha angle.

Patients and Methods

The study was designed as a prospective randomised controlled trial. Recruitment was carried out between 1st January 2015 and 30th March 2016 and comprised of males between the ages of 18 and 40 years with cam type of FAI. The local ethics committee approved the study and all the participants signed an informed consent. Brunner et al. have previously reported on mean maximal alpha angles after fluoroscopic guided cam resection of 56° in a cohort of 25 patients (10). A mean maximal alpha angle of 48° was considered to be normal based on a sample of 53 normal proximal femurs (11). The primary aim of navigated cam resection surgery is normalisation of the maximal anterolateral alpha angle. Therefore our sample size calculation was performed using the following parameters: effect size = 8°, standard deviation (sigma = 7°), type II error rate (beta = 0.2) and type I error rate (alpha = 0.05). A minimum sample size of 13 cases per group was calculated as needed to statistically support the primary study hypothesis. A sample of 30 patients with cam FAI - 15 in each arm were therefore recruited. Inclusion criteria were defined as male gender, positive C-Sign, positive impingement test on clinical examination, predominantly cam type of FAI on standard imaging and a 45° Dunn view (alpha angle > 60°, 20° < CE < 35°) and an absence of previous hip surgery. Male gender was preferred because of the higher prevalence of isolated cam lesions compared with the females (12). Secondly we wanted to strive for gender homogeneity between the 2 groups following randomisation. Exclusion criteria involved the presence of clear signs of degenerative change (Tönnis grade > 1) or any history of inflammatory joint disease.

The senior author recruited patients that met the criteria until all the 30 patients were included. Each patient was consecutively randomised using a tailored block based randomisation algorithm, as is preferred in small sample randomisation studies (13). A block size of 6 cases during randomisation ensured an equal allocation to the case and control groups at the end of the recruitment period. Eventually, one patient in the fluoroscopic guided (conventional) group was excluded during the actual surgical procedure given the unexpected severe and extended articular cartilage delamination at the time of surgery, which the senior surgeon considered beyond the indication of hip preservation surgery.

All patients underwent pre-operative CT scanning (Somatom Definition Flash, Siemens, Erlangen, Germany) of the hip including additional slices through the knee to account for femoral version. A low radiation dose CT protocol (120KV, 160 mAs effective mass, automatic exposure control system was turned off in order to prevent dose increase for increased image quality, 0.6mm slice thickness, slice resolution of 0.69 x 0.69 mm) was applied. The ipsilateral pelvic bone, proximal and distal femur were segmented in Mimics (Version 17.0, Materialise NV, Heverlee, Belgium) which were then further analysed morphologically and dynamically with the Articulis software package (Clinical Graphics, Delft, The Netherlands). The software algorithm systematically simulates different physiological motions, for example, flexion, abduction, internal rotations with 90° flexion and has been previously validated (14-16). It has been demonstrated to be a reliable tool for evaluating bony end range of motion with a median error of only 1.9° compared with electromagnetic measurements of range of motion in a cadaver study (14). Using Articulis, the diagnosis of cam-type FAI was confirmed and measurements of the maximal alpha angle (from 11 till 3 ‘o clock), radial plane clockwise alpha angle (11, 12, 1, 2 and 3 o’clock position), centre-edge angle, central acetabular version angle, caput-collum-diaphyseal (neck-shaft) angle, femoral version angle and detailed range of motion analysis were made. Flexion refers to elevation parallel to the sagittal plane along the Z-axis of the pelvis. Abduction refers to an elevation in the coronal plane along the X-axis of the pelvis and internal rotations refer to axial rotation along the femur shaft of Y-axis of the femur. Secondly, the dynamic collision software determined a surgical cam resection plan aimed at normalising the bony range of motion (14) (Fig. 1).

All patients were operated on in a supine position. In the conventional surgery group, fluoroscopic guided cam resection was performed with the C-arm tilted 45 degrees to increase the visibility of the superolateral portion of the hip as well as to avoid physical obstruction of the C-arm and the arthroscopic tools during the actual procedure. The surgeon studied the pre-operative planning of the cam resection before starting the arthroscopic procedure. During the actual procedure, fluoroscopy was used until a satisfactory resection was obtained according to the senior surgeon. In the navigated group, the procedure starts with the fixation of an optical tracker by means of 2 Schanz screws at the level of the distal femur. Next, calibration of the optical distal femoral tracker, the navigation pointer and the 3D fluoroscope were performed. In order to transfer the virtual resection plan to the operating theatre, the volumetric geometry of the pre-operatively determined cam resection was highlighted in the patients' pre-operative CT scan images and exported in DICOM format for use by the navigation system (17). The pre-operative plan was imported in the Orthomap 3D navigation software on the NAV3i Navigation Platform (Stryker, Mahwah, NJ, USA). The platform provides segmentation tools that allow the user to accentuate anatomical structures of interest, such as tumours, bone surfaces and vessels. In our case, the previously defined cam-like lesions were accentuated. Next, an intra-operative fluoroscopic scan using the Ziehm Vision 3D fluoroscope (Ziehm, Nürnberg, Germany) was performed. The pre-operative plan was matched to the current patient position by means of an intra-operatively acquired fluoroscopic scan. The C-arm unit was therefore rolled in obliquely between the patient's legs in a 45-degree angle. The height and translation of the C-arm were manipulated in order to get the proximal femur in the isocentre of the C-arm and a radiation-free manual test run was performed to ensure that the unit did not collide with other objects during the automated scan. The C-arm was aimed at capturing only the specific anatomy of the proximal femur, including the greater and lesser trochanter all the way up to the level of the femoral neck. Visualisation of the acetabulum was avoided because it would have compromised the image matching procedure based on the femoral anatomy. The image-based registration protocol as described was previously validated and has demonstrated its accuracy with a mean spatial error of 0.8 mm in matching the proximal femur (2). Identical to the conventional surgery group, the femoral neck was approached via arthroscopic access to the central compartment first followed by a transition to the peripheral compartment. In the navigated group, fluoroscopic assistance was limited to the placement of the first and blind portal. Following this, the cam resection was exclusively assisted by visual feedback of the navigation system. Previous testing has shown that the hollow nature of shavers and burrs used in face of the soft tissue envelope resulted in deviations of the prediction accuracy of the tip due to deformation of the instrument. Therefore during the navigated procedure, resection accuracy is controlled through regular feedback by means of the rigid navigation pointer. Surgical setup is demonstrated in Fig. 2. Surgical time and radiation exposure during the procedures were also recorded for further comparative analysis.

Post-operatively all patients had a MRI scan at 3 months (Magnetom Trio-Tim System, Siemens, Erlangen, Germany). Dedicated hip proton density weighted sequences (slice thickness 0.5mm, pixel spacing 0.9 x 0.9 mm, repetition time 1880 milliseconds, echo time 38 milliseconds) were used to allow for detailed segmentation of the post-operative proximal femur. The resection results were evaluated following overlay of the bony anatomy obtained from the pre-operative CT imaging. The post-operative surface meshes were then evaluated structurally and dynamically by means of the Articulis software package.

Statistical analysis was performed using SPSS 20.0 (SPSS Inc., Chicago, IL, USA). All continuous variables were tested for normal distribution in each group according to the Kolmogorov-Smirnov test. Where the assumption of normal distribution was met, parametric unpaired or paired Student t-tests were used. In the case of non-normality, the Mann-Whitney U test for the unpaired hypothesis testing and Wilcoxon signed-rank test for the paired testing were applied. The Fisher's exact test was used for evaluating the number of incomplete resections in both groups. For the secondary outcome measures, multiple statistical comparisons were made, thereby increasing the possibility of detecting significant differences by mere chance (type 1 error). However, in light of the limited sample size, the threshold for statistical significance was held at 0.05.

Results

Both groups had comparable demographics (Table 1). A significant improvement in the maximal alpha angle at the head-neck junction from 11 to 3 o'clock was observed in the navigated group (55° vs. 66°; p=0.023). More specifically we found that the post-operative alpha angle at the 12 o'clock position was significantly lower in the navigated group compared with the conventional group (45° vs. 60°; p=0.041). The other clockwise post-operative alpha angles did not differ significantly between both groups. An illustration of the clockwise alpha angles is given in figure 3. The simulated post-operative bony range of motion was overall higher in the navigated group compared with the conventional group, however it did not reach statistically significant thresholds.

There were 4 out of 14 incomplete resections (alpha > 60°) in conventional group compared with 2 out of 15 in navigated group. Five out of 6 incomplete resections were observed at the 12 and 1 o'clock position, one case in navigated group presented with insufficient bony resection at the 2 o'clock position.

In the navigated group a significant improvement was found in the range of internal rotation in 90° of flexion, internal rotation in 90° of flexion and 20° of adduction and the alpha angle at 12 – 1 – 2 – 3 o' clock position post-operatively. In the control group a significant improvement was found in the range of internal rotation in 90° flexion and 20° of adduction as well as alpha angle at the 1 – 2 – 3 o'clock position post-operatively.

Since intra-operative 3D fluoroscopic scanning was necessary in the navigated group for the image-based registration of the resection plan, a significant increase in radiation exposure (time and dose) was noted in this group as compared with the conventional group. Time used for positioning the patient was significantly longer in the navigated group with an average of 14 minutes more than the conventional group. On the other hand, there was no statistical difference in the surgical time between the two groups. An overview of these findings is provided in Table 2.

Discussion

This is the first prospective, randomised clinical report, which shows that the use of surgical planning and computer-navigation in arthroscopic cam-type FAI surgery improves accuracy of resection of the cam lesion. The principal finding is a significant improvement in mean maximal alpha angle in the navigated group compared with the conventional group, especially at the 12 o'clock position. The simulated post-operative bony range of motion was significantly improved in the navigated group as well. More radiation exposure and longer installation time compared with the conventional method were the main drawbacks for the navigation technique.

In the last two decades, hip arthroscopy has become more popular in addressing FAI, because of its minimally invasive approach (18-20). However, assessing the adequacy of bone resection when correcting FAI can be difficult, because the visualisation of the joint is poor and because of limited spatial awareness (21). Also, evaluation of the sphericity of the femoral head in the treatment of cam-type FAI is almost impossible. It is often difficult to execute a pre-operative plan accurately, as it requires not only a high level of arthroscopic skills (22,23) and good visualisation but also precise identification of the margins of the osseous bump and decision-making on the amount of bony resection. Even in the hands of experienced hip arthroscopists who have achieved adequate exposure, precise resection of the cam lesion is not always easy. Hip arthroscopists usually combine arthroscopic appearance with fluoroscopy to perform an intra-operative assessment of an adequate resection. The problem with this method is that both of them are 2D modalities for the assessment of a 3D morphological abnormality. Osseous abnormalities are often under-resected, and this is a major cause for revision hip arthroscopy, accounting for up to 78% to 90% of all unsuccessful arthroscopic FAI surgery (24,25).

Recently, computer-assisted navigation and modelling have emerged as a potential solution to increase the accuracy of intra-operative correction of the osseous deformity. There have been several clinical and cadaveric studies, which have reported on the merits and limitations of navigated hip arthroscopy. Brunner et al (3) uploaded pre-operative CT images of patients into a system and a C-arm adapter was used to synchronise intra-operative fluoroscopy with the 3D CT dataset. This allowed real-time feedback of the placement of the surgical instrument in relation to the femoral head-neck junction. In patients with cam-type of FAI, the navigation software did not increase the rate of operative success. It might be partially due to the fact that this prototype software did not allow pre-operative planning and thus did not highlight the zone of impingement or the amount of resected bone. Monahan et al (9) first developed an encoder linkage system to track surgical instruments during hip arthroscopy. The encoder linkages are calibrated with pre-operative, patient-specific 3D imaging data so the position of the surgical tools can be verified with patient anatomy. In other words, the system displays the real-time surgical instrument position relative to patient anatomy on a screen with a pre-operatively generated, patient-specific 3D image. Kendoff et al (26) evaluated an image-based approach in a cadaver study of six hips and found that a combined CT-fluoroscopy matching navigated procedure allowed for a reproducible registration process for navigated FAI surgery at the femoral site, and precision was high at the femoral neck and head-neck junction area with mean deviations below 1 mm. Also, using 12 paired cadaver hips with a virtual cam lesion, Audenaert et al (2) reported that the estimated accuracy of image-based registration by means of 3D fluoroscopy had a mean error of 0.8 mm, while the estimated accuracy of imageless registration in the arthroscopic setting was poor, with a mean error of 5.6 mm. Ecker et al (8) developed a computer-assisted planning and navigation software, which uses pre-operative ROM analysis on 3D models of patients' pelvic and femoral bone where virtual resection can be performed. Intra-operatively, the planned virtual resection area was shown as a highlighted color-coded distance map, which aided the surgeon's awareness of the depth of resection. Strazar et al (27) reported on the retrospective results of computer aided navigation of electromagnetically tracked arthroscopic shaver blades in 20 male patients with isolated cam type FAI. They performed a pre-operative planning based on 3D anatomical restoration of sphericity as well as on kinematical evaluation. Post-operatively, in all cases a complete resection was performed with post-operative alpha angles on Dunn and AP views of 38 degrees on average and a post-operative shape analysis on low dose CT showing only 4% of bone resection mismatch to a maximal distance of 1 mm.

The current navigational surgery protocol still resulted in 13% of incomplete resections in contrast to the original study hypothesis of normalisation of alpha angle. In our opinion, this is due to the combination of errors during image registration and manipulation of the leg during surgery. Off course this requires further investigation to understand the exact origin of the remaining error margin.

Nevertheless, a statistically significant benefit in surgical accuracy at the 12 o' clock position compared with the conventional technique was observed in this study.

The alpha angle was chosen as a parameter for evaluating the resection accuracy. Historically, this parameter was most used in literature for evaluating cam type FAI (28,29). The alpha angle has also been shown to correlate with increased chondral damage, labral injury, decreased ROM, and pre-operative symptoms (30-32). Other parameters evaluating the overall hip morphology have been described, but are not yet widely accepted and were therefore not evaluated (33). Reporting the resection accuracy by means of the amount of resected volume could potentially show adequate resected volume that is however resected at a wrong location. Therefore, the alpha angle was chosen as the primary outcome measure. Also, as the maximal loss of head–neck offset is present at different locations in different patients (34), a detailed information on the clockwise alpha angle (11 to 3 o'clock) was described and analysed in this study.

There are however, a few limitations to this study. Firstly, the study population consisted of a cohort of males exclusively and this could create a potential bias in the results. Secondly, computer-based simulation for measuring ROM is the state of the art currently but not without limitations (e.g. lack of insight into soft tissue pathology, restriction to concentric hips only and this should be borne in mind when evaluating results. Thirdly, cam resections were performed by a single surgeon in a supine approach allowing easy access to the anterolateral surface of the neck. Incomplete resection was mainly seen at the strict lateral side of the femoral neck, which means that this finding could be attributed to the surgeon and the positioning of the patient. Nevertheless the use of navigation significantly improved the resection accuracy in this area, thereby supporting the value of navigation as a supportive surgical tool and potential learning tool. Furthermore, no evaluation of functional outcome or clinical success (i.e. improvement of subjective scores) following computer-assisted surgery was assessed in this study. It is imperative to undertake comparative trials determining the efficacy of computer-assisted hip arthroscopy surgery in terms of clinical outcomes and patient satisfaction in the future.

Finally, multiple comparisons for the secondary outcome measures, pose the risk of falsely detecting significant differences and as such caution should be exercised whilst interpreting these results. Nevertheless, the primary outcome measure for which the study has been powered was shown to be significantly better in the navigated group.

Conclusion

The use of surgical planning and computer-navigation in arthroscopic cam-type FAI surgery improves accuracy of resection of the cam lesion. The simulated post-operative bony range of motion was significantly improved in the navigated group as well. More radiation exposure and longer installation time compared with the conventional method were the main drawbacks for the navigation technique.

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Conflict of Interest: Peter Krekel is an employee of Clinical Graphics. No financial benefits have been received or will be received from any commercial party related directly or indirectly to the subject of this article.

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Ethics: The current study was approved by the ethical board of the Ghent University hospital under case number 2013/1032.

Table 1

Patient's demographic data

The mean value is reported with the 95% confidence interval in parentheses.

Differences for which P was <0.05 were considered statistically significant (*).

	Conventional group	Navigated group	P-value
Side (Right : Left)	8 : 6	8 : 7	N.S.
Height (cm)	160-193 (176.5)	163-193 (177.6)	N.S.
Weight (kg)	58-93 (77.8)	61-105 (79.0)	N.S.
BMI (Kg/m²)	21.3-27.8 (24.9)	22.4-28.7 (25.0)	N.S.
Age (year)	18-35 (25.3)	18-34 (25.7)	N.S.
Neck-shaft angle (°)	123-139 (130.9)	119-142 (131.9)	N.S.
Center-edge angle (°)	23-35 (31.0)	20-35 (31.4)	N.S.
Femoral anteversion (°)	-10 - 21 (7.6)	-4 - 18 (7.1)	N.S.

Table 2

Overview of the results

The mean value is reported with the 95% confidence interval in parentheses.

Differences for which P was <0.05 were considered statistically significant (*).

shows statistically significant (P <0.05) improvement after the operation.

	Conventional group	Navigated group	P-value
Pre-op maximal α-angle (°)	74 (67-81)	76 (73-78)	N.S.
Pre-op 11 o'clock α-angle (°)	43 (41-46)	43 (41-45)	N.S.
Pre-op 12 o'clock α-angle (°)	63 (51-74)	58 (51-64)	N.S.
Pre-op 1 o'clock α-angle (°)	71 (63-79)	72 (67-76)	N.S.
Pre-op 2 o'clock α-angle (°)	66 (62-70)	69 (66-72)	N.S.
Pre-op 3 o'clock α-angle (°)	57 (53-62)	56 (52-60)	N.S.
Post-op maximal α-angle (°)	66 (57-75)	55 (51-59)	0.023

Post-op 11 o'clock α-angle (°)	43 (40-46)	43 (41-44)	N.S.
Post-op 12 o'clock α-angle (°)	60 (49-72)	45 (43-47)#	0.041*
Post-op 1 o'clock α-angle (°)	55 (50-59)#	53 (50-56)#	N.S.
Post-op 2 o'clock α-angle (°)	50 (46-54)#	49 (44-54)#	N.S.
Post-op 3 o'clock α-angle (°)	50 (45-55)#	49 (44-53)#	N.S.
Incomplete resection: α angle > 60°	4/14 (29%)	2/15 (13%)	N.S.
Pre-op flexion (°)	112 (105-119)	114 (111-117)	N.S.
Post-op flexion (°)	112 (105-119)	117 (114-119)	N.S.
Pre-op internal rotation with 90° of flexion (°)	23 (17-29)	24 (20-28)	N.S.
Post-op internal rotation with 90° of flexion (°)	24 (18-30)	27 (23-30)#	N.S.
Pre-op internal rotation with 90° of flexion and 20° of adduction (°)	17 (11-23)	16 (12-21)	N.S.
Post-op internal rotation with 90°	19 (13-25)#	23 (19-26)#	N.S.

of flexion and 20° of adduction (°)			
Fluoroscopy dose area product value (cGycm2)	489 (409-568)	731 (566-897)	0.01*
Fluoroscopy time (min)	0.66 (0.5-0.9)	1.04 (0.7-1.4)	0.037*
Installation time (min)	15.5 (11.4-19.6)	29.4 (24.7-34.1)	<0.001*
Surgical time (min)	88.4 (71.3-105.5)	85.5 (72.1-98.9)	N.S.

Figure 1

Analysis of simulated bony range of motion in Articulis and suggested pre-operative resection plan on the femoral neck in order to normalise the range of motion defects.

Figure 2

The navigated surgery protocol requires fixation of a distal femoral marker with 2 Schanz screws to the distal femur. The femoral marker (A) and fluoroscopy (B) are calibrated using the rigid pointer. An intra-operative fluoroscopy scan limited to the proximal femur is performed (C) in order to allow for image based matching of the pre-operative plan. Finally live resection control in relation to the pre-operative plan can be performed using the rigid pointer and fluoroscopy is no longer required.

Figure 3

Box and whisker plots of the pre- and post-operative clockwise alpha angles in the conventional and navigated group. The box represents the interquartile range and the whiskers delimit the range.

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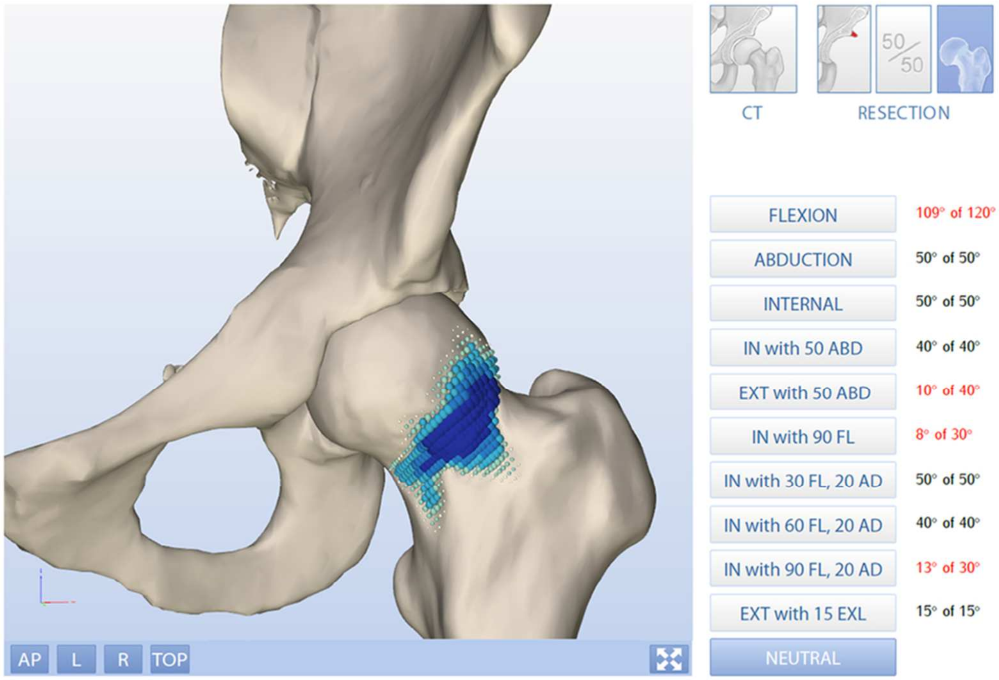

Figure1
Analysis of simulated bony ran
81x55mm (300 x 300 DPI)

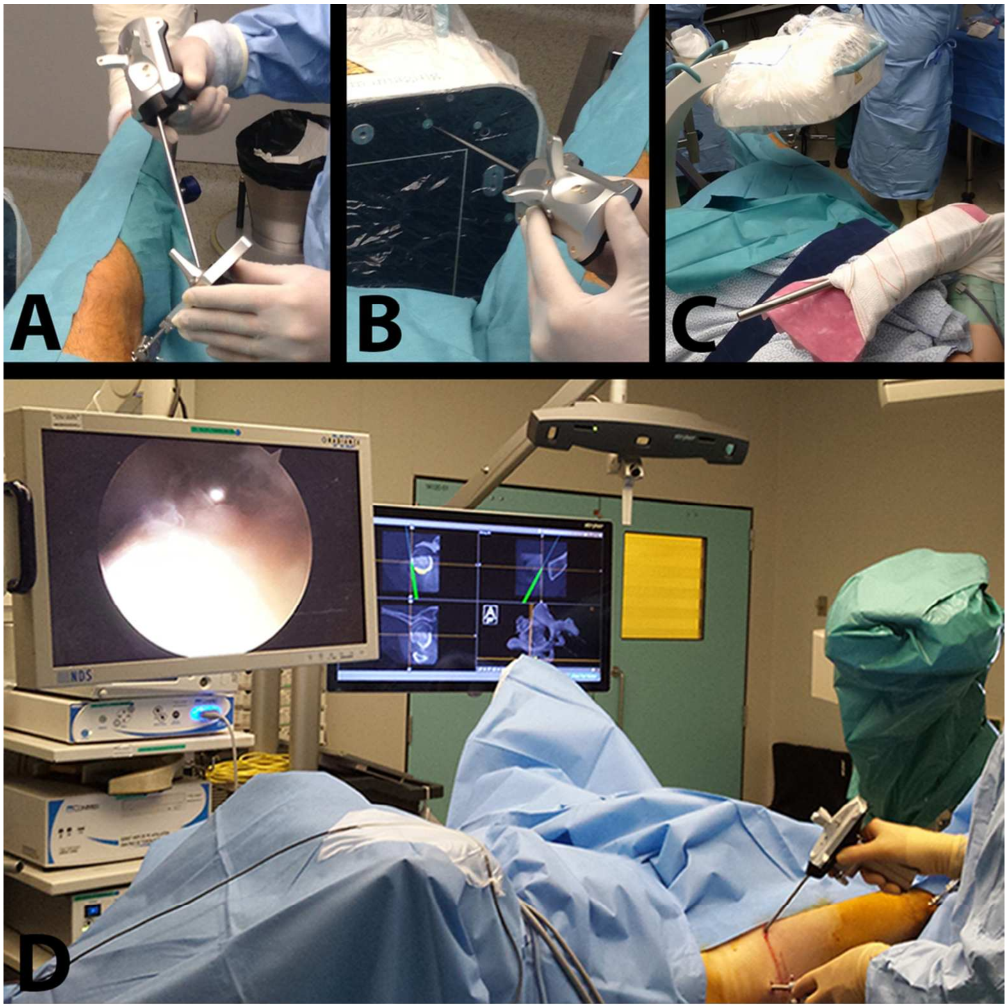

Figure 2
The navigated surgery protocol
99x99mm (300 x 300 DPI)

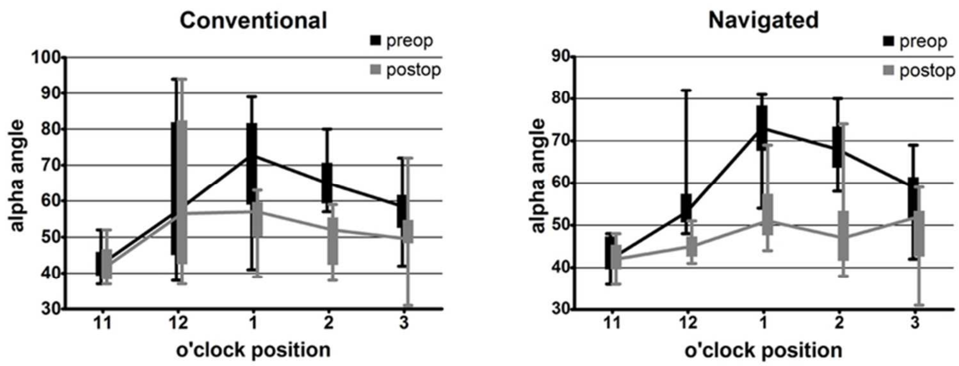

Figure 3
Box and whisker plot illustrat
74x27mm (300 x 300 DPI)