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Potential accuracy of computer-assisted pelvic tumor resections

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DECLARATION

Parts of the findings presented in this thesis have been previously published as original article in the Journal “THE INTERNATIONAL JOURNAL OF MEDICAL ROBOTICS AND COMPUTER ASSISTED SURGERY” (Postl 2017). The author of this thesis also is the first author of the paper mentioned above, which has been enclosed in the appendix of this thesis.

TABLE OF CONTENTS

LIST OF FIGURES AND TABLES

ABSTRACT

Introduction: Tumors of the pelvis are often already large when they are detected. The anatomy of the pelvis is very complex and many important structures such as nerves and blood vessels are located in this area. For this reason, tumor resections of the pelvis are considered very demanding. The aim of this thesis was to investigate the accuracy of pelvic tumor resections in human whole-body cadavers under realistic operation room conditions.

Material and Methods: After a preoperative computer tomography, the resection planes were planned in the navigation system. Kirschner-wires were inserted via computer-assistance and served as guidance for osteotomies with an oscillating saw. The accuracy of computer-assisted osteotomies was compared to the accuracy of freehand osteotomies using 3D printed pelvises with identical geometries.

Results: A mean deviation of 1.9 ± 1 mm was found for the supraacetabular computer-assisted resections. This was significantly more accurate than the mean deviation of 9.2 ± 3.2 mm in the freehand control group. Evaluation of infraacetabular resections showed a mean deviation of 3.2 ± 1.9 for the computer-assisted procedures. This was significantly more accurate than the freehand resections in this area, which showed a mean deviation of 7.9 ± 4.2 mm.

Overall a mean deviation of 2.5 ± 1.6 mm was found for all computer-assisted resections. This was also significantly more accurate compared to all freehand resections, which showed an average deviation of 8.6 ± 3.6 mm.

Conclusion: The present study was able to show under realistic operation room conditions that the above described navigation system can be successfully used for

tumor resections at the pelvis and that computer-assisted resections are significantly more accurate than freehand resections.

LIST OF ABBREVIATIONS

°	degrees
±	is used between the arithmetic mean and the standard deviation of values
3D	three- dimensional
AP-view	anterior-posterior view
CAD	computer-aided design
CAM	computer-aided manufacturing
CNB	core needle biopsy
CT	computed tomography
cm	centimeter
C-arm	mobile fluoroscopy device
DICOM	Digital Imaging and Communications in Medicine, a file format
DVD	digital video disc oder digital versatile disc
e.g.	for example
FNA	fine needle aspiration
kg	kilogram
K-wire	Kirschner-wire
L1	lumbar vertebra 1

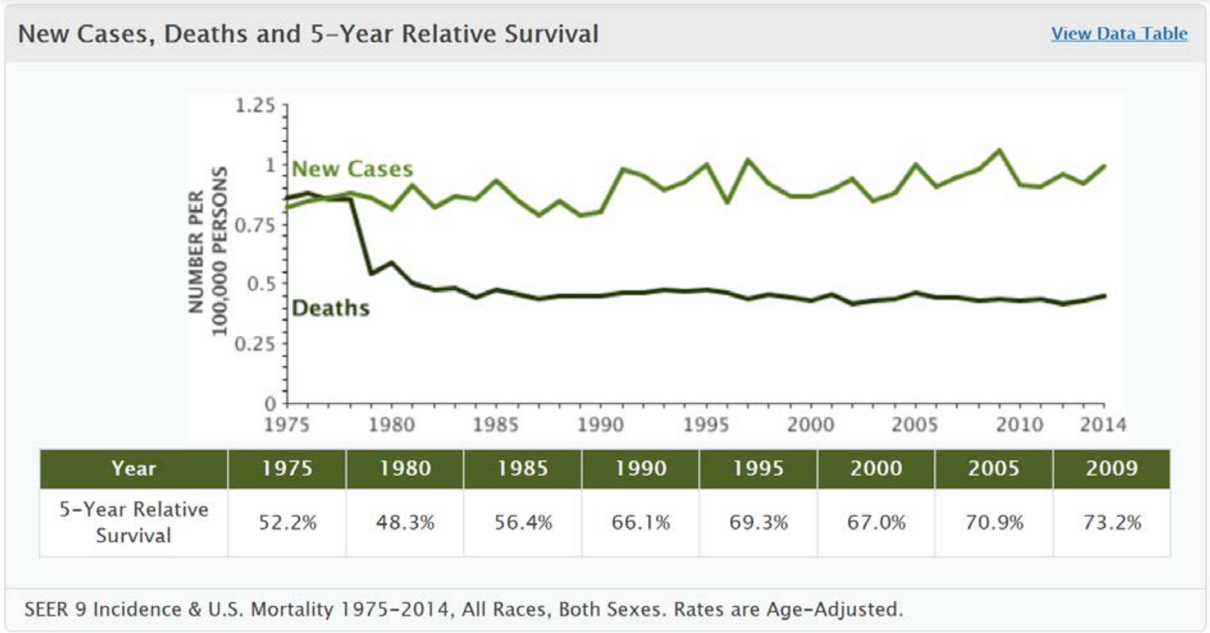
L2	lumbar vertebra 2
L3	lumbar vertebra 3
L4	lumbar vertebra 4
L5	lumbar vertebra 5
mm	millimeter
MRI	magnetic resonance imaging
n	sample size
PET	positron emission tomography
PET/CT	positron emission tomography/computed tomography
PET/MRI	positron emission tomography/magnetic resonance imaging
S1	sacral 1
S2	sacral 2
STL	Standard Tessellation Language, a file format
TUM	Technical University Munich
X-ray	Röntgen radiation

1. INTRODUCTION

Until the 1970s most malignant tumors of the pelvis had to be treated with amputation of the respective lower limb and the five year survival rate was low (Rechl 1995).

In the 1970s and the 1980s the introduction of MRI (magnetic resonance imaging) diagnostics (Aisen 1986, Zimmer 1985), staging (Enneking 1980) and chemotherapy regimens were important for the development of limb salvage procedures (Rechl 1995). Grimer and Briggs state that ‘there has been marked improvement in the management of both bone and soft- tissue sarcomas over the past three decades as a result of better imaging, effective chemotherapy for osteosarcoma and Ewing’s sarcoma and the increasing use of limb salvage surgery’ (Grimer and Briggs 2010).

The implementation of neoadjuvant chemotherapy regimens significantly improved the five-year survival rate of patients suffering from malignant bone tumors (Mirabello 2009). According to Mirabello et al. the five-year survival rate of patients suffering from osteosarcoma could be increased from approximately 20% before the 1980s to nearly 70% afterwards (Mirabello 2009). SEER (The Surveillance, Epidemiology, and End Results Program of the National Cancer Institute) in the United States confirms a substantial improve regarding the mortality and five year survival of bone and joint cancer in the last quarter of 20th century (SEER 2017). The data from SEER in the United States about the five- year survival rate of malignant bone and joint tumors as well as incidence and mortality over the last couple of decades (SEER 2017) is provided in figure 1.



Year	1975	1980	1985	1990	1995	2000	2005	2009
5-Year Relative Survival	52.2%	48.3%	56.4%	66.1%	69.3%	67.0%	70.9%	73.2%

SEER 9 Incidence & U.S. Mortality 1975-2014, All Races, Both Sexes. Rates are Age-Adjusted.

Figure 1 - Bone and joint cancer facts

The figure shows the number of new cases of bone and joint cancer per 100 000 persons per year and the number of deaths per 100 000 persons per year due to bone and joint cancer. In addition, the five- year relative survival is listed for several years. The figure originates from the following source: SEER Cancer Stat Facts: Bone and Joint Cancer. National Cancer Institute. Bethesda, MD, http://seer.cancer.gov/statfacts/html/bones.html

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An important study on 560 patients with osteosarcoma of the limb found no significant difference between amputation and limb salvage procedures regarding the incidence of local recurrence and the disease free survival (Bacci 2002). Recently a larger meta-analysis even showed significant advantages of limb salvage procedures in five- year survival (He 2017). The increased survival rates, the higher number of curative patient cases and limb salvage surgery as alternative to amputation generated a need for suitable reconstruction techniques (Gradinger 1993). In this regard it could be shown that custom made prostheses were superior in terms of functionality for extensive resections (Windhager 1996).

Malignant tumors of the pelvis are often already large in size at the time of their detection (Rudert 2012) (Yuen 2005) (Postl 2017). The anatomy of the pelvis is very complex and many important structures such as nerves and blood vessels are located in this area (Ernest U. Conrad 1998) (Postl 2017) (Yuen 2005). For this reason, tumor resections of the pelvis are considered very demanding (Holzapfel 2014).

Three main types of procedures have been identified by Enneking and Dunham: supraacetabular, periacetabular and infraacetabular procedures (Enneking and Dunham 1978). A more detailed description of different procedures is provided in the ‘surgical therapy of pelvic tumors’ section below.

Several authors point out that certain periacetabular resections require the reestablishment of force transmission from the lower extremity to the axial skeleton (Holzapfel 2014, Rudert 2012) (Postl 2017). For this purpose, the understanding of the anatomy and biomechanics of the pelvis is very important, and the following will provide an overview of these basics.

1.1 Anatomy and biomechanics of the pelvis

1.1.1 Bony elements

The left pelvic bone, the right pelvic bone, the sacrum and the coccyx form the pelvis (Drake 2009). Sacrum and coccyx belong to the vertebral column (Platzer 2005). The pelvic bone can be divided into three elements: the ileum, ischium and pubis (Drake 2009). At birth, these elements do not form a single bone as in adults, but are connected by cartilage in the area of the acetabulum (Drake 2009).

The acetabulum is located on the lateral side of the pelvic bone and is an articular socket with a fossa which is part of the hip joint (Drake 2009). Important bony elements and landmarks of the pelvis are shown in figure 2.

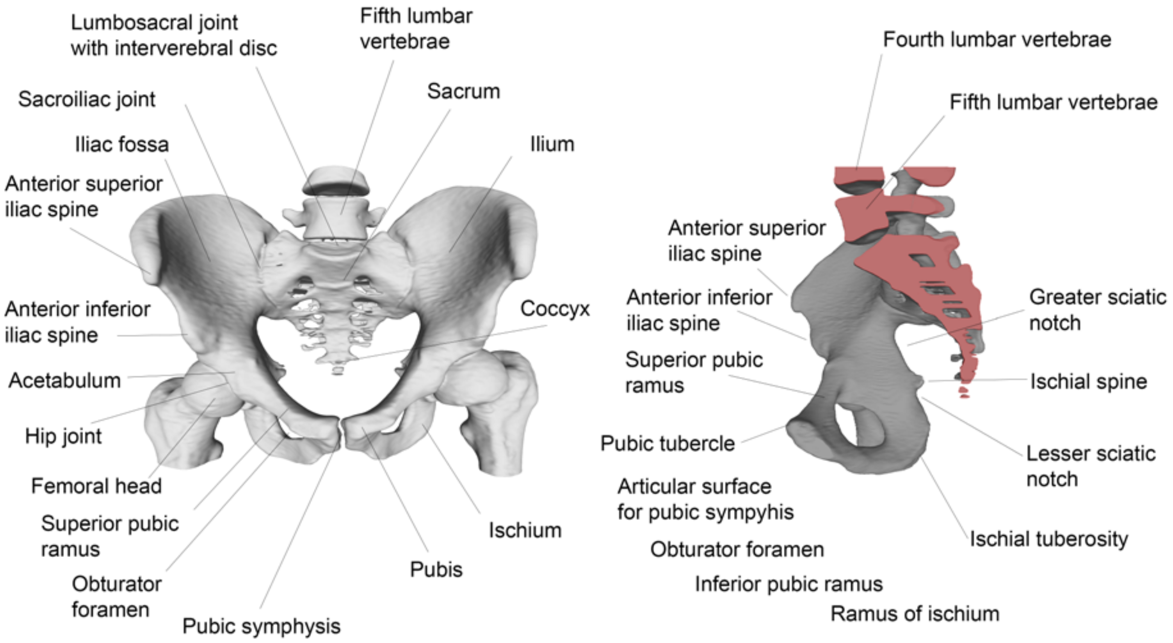

Figure 2 - Anatomy of the pelvis

On the left side of the figure a human pelvis in AP (anterior-posterior) -view is depicted. On the right side a longitudinal section of the human pelvis in lateral view is provided. The intersection is shown in red.

The figure shows important components and landmarks of the pelvis. The image is based on a 3D reconstruction of CT data from this study.

1.1.2 Joints

Hip Joint: The head of the femur is mostly covered by cartilage (Aumüller 2007a). Parts of the acetabular fossa is covered with hyaline cartilage and this area forms the lunate surface (Aumüller 2007a, Drake 2009). The head of the femur articulates with the lunate surface of the acetabular fossa (Aumüller 2007a). The hip joint is a ball and socket joint with three degrees of freedom (Aumüller 2007a).

Pubic symphysis: The pubic symphysis links the left and the right pelvic bone at the front via fibrocartilage (Drake 2009).

Sacroiliac joints: These two joints link the vertebra column to the pelvis (both pelvic bones) and are located on both sides of the sacrum (Putz and Pabst 2007). The articular surfaces of the sacrum and the pelvic bones are covered with fibrocartilage (Platzer 2005). They have irregular contours to interlock (Drake 2009).

Lumbosacral joints: Three joints can be identified between the fifth lumbar vertebrae and the sacrum (Drake 2009). The two zygapophysial joints are located posterior on both sides of the spine and consist of the respective two adjacent superior (fifth lumbar vertebrae) and inferior (sacrum) articular processes (Drake 2009). The third joint is anteriorly between the body of the fifth lumbar vertebrae and the body of the sacrum and contains an intervertebral disc (Drake 2009).

1.1.3 Important ligaments of hip and pelvis

Hip: There are three strong ligaments that stabilize the hip joint and therefore they are biomechanically important (Aumüller 2007a). The iliofemoral ligament is anterior, the pubofemoral ligament is anteroinferior and the ischiofemoral ligament is posterior to the hip joint (Drake 2009). These ligaments are spirally wound around the hip joint so that they become tensioned when the hip is extended (Drake 2009). The ligament of the femoral head runs intraarticularly and is not biomechanically important (Aumüller 2007a). It contains blood vessels that play a role in the blood supply of the femoral head (Aumüller 2007a).

Pubic symphysis: The pubic symphysis joint is surrounded by the superior pubic ligament and the inferior pubic ligament, which are above and below the fibrocartilage (Drake 2009).

Sacroiliac joints and lumbosacral joints: The anterior sacroiliac ligament, the interosseous sacroiliac ligament and the posterior sacroiliac ligament are very strong ligaments, which stabilize the sacroiliac joint and allow very little movement (Aumüller 2007a). The sacrospinous ligament and sacrotuberous ligament run from the sacrum to the ischial spine and the ischial tuberosity (Platzer 2005). The iliolumbar ligament links the iliac crest with the transverse process of the fourth lumbar vertebra and fifth lumbar vertebra (Platzer 2005). The lumbosacral ligament runs from the transverse process of the fifth lumbar vertebra to the sacrum (Drake 2009).

Obturator membrane: The obturator membrane nearly covers the obturator foramen almost completely (Platzer 2005). There is only one opening called the obturator canal (Platzer 2005) (Drake 2009). It allows the obturator nerve and the obturator blood vessels to pass through the membrane (Platzer 2005).

1.1.4 Muscles and their innervation

According to Aumüller et al. the muscles of the hip can be divided into gluteal muscles, the pelvitrochanteric muscles, adductors and the iliopsoas muscle (Aumüller 2007a).

Gluteal muscles: The muscles gluteus maximus, gluteus medius, gluteus minimus and the tensor fasciae latae are referred to as gluteal muscles (Aumüller 2007a). The gluteus maximus arises from the iliac crest, the posterior superior iliac spine, the thoracolumbar fascia, the dorsal surface of lower sacrum, the lateral margin of coccyx, the external surface of the ileum behind the posterior gluteal line, the external surface of sacrotuberous ligament and the fascia covering gluteus medius (Drake 2009, Platzer 2005). It runs to the iliotibial tract and to the gluteal tuberosity of the femur (Platzer 2005). It is innervated by the inferior gluteal nerve (L4,L5,S1) (Drake 2009).

The gluteus medius originates from the external surface of the ileum between anterior and posterior gluteal line and inserts at the greater trochanter (Drake 2009). The gluteus minimus arises from the external surface of the ileum between inferior and anterior gluteal line and also attaches to the greater trochanter (Drake 2009). Both the gluteus medius and minimus are innervated by the superior gluteal nerve (L4,L5,S1)(Drake 2009). The musculus tensor fasciae latae originates from the anterior superior iliac spine and joins the iliotibial tract (Platzer 2005). It is innervated by the superior gluteal nerve (L4,L5) (Platzer 2005).

Pelvitrochanteric muscles: The muscles piriformis, gemellus superior, gemellus inferior, obturator internus, obturator externus and quadratus femoris are classified as pelvitrochanteric muscles (Aumüller 2007a). The piriformis muscle originates from the anterior surface of the sacrum and runs to the greater trochanter (Drake 2009). The gemellus superior muscle arises from the ischial spine and attaches at the trochanteric fossa (Aumüller 2007a). The gemellus inferior and the quadratus femoris originate at the ischial tuberosity and both insert at the trochanteric fossa (Aumüller 2007a). They are innervated by branches of the sacral plexus (L5, S1, S2) (Aumüller 2007b). While the obturator externus arises from the external surface of the obturator membrane, the obturator internus arises from the internal surface of the obturator membrane and both muscles run to the trochanteric fossa (Aumüller 2007a). The obturator internus is also innervated by branches of the sacral plexus (L5, S1,S2) and the obturator externus is innervated by the obturator nerve (L3,L4) (Aumüller 2007a).

Adductors: The muscles pectineus, adductor longus, adductor brevis, adductor magnus and gracilis are referred to as adductors (Aumüller 2007a). The pectineus originates from the pectineal line of the pubis and runs to the pectineal line of the femur (Aumüller 2007a). It is innervated by the femoral nerve (L2,L3) and the anterior branch of the obturator nerve (Platzer 2005). The adductor longus and brevis arise from the pubis (superior and inferior pubic ramus) and attach to the linea aspera of the femur (Platzer 2005). Both are innervated by the anterior branch of the obturator nerve (L2,L3,L4) (Platzer 2005). The adductor magnus originates from the ischiopubic ramus and the ischial tuberosity and runs to the linea aspera and the adductor tubercle of the medial epicondyle of the femur (Drake 2009, Platzer 2005). It is innervated by the obturator nerve (L2,L3,L4) and the tibial division of the sciatic nerve (L2,L3,L4) (Drake

2009). The gracilis arises from the inferior pubic ramus (near the symphysis) and attaches to the medial surface of the tibia (Platzer 2005). It is the only adductor that affects two joints: hip and knee and is innervated by the anterior branch of the obturator nerve (L2,L3,L4) (Platzer 2005).

Iliopsoas: The psoas major muscle originates from the bodies of thoracic vertebra XII to lumbar vertebra V, their intervertebral discs and the transverse processes of the lumbar vertebrae (Drake 2009). The iliacus muscle arises from the iliac fossa (Drake 2009). These two muscles join and are referred to as the iliopsoas muscle which attaches to the lesser trochanter of the femur (Drake 2009). The psoas major is innervated by the anterior rami of the lumbar plexus (L1,L2,L3) and the iliacus is innervated by the femoral nerve (L2,L3) (Drake 2009)

1.1.5 Biomechanics

Standing on both legs: The weight of the upper body is transmitted via the sacroiliac joints, the pelvic ring and the hip joints to the lower extremity (Rechl 1995). As shown in figure 3 the pubic symphysis is exposed to tensile forces (Putz and Müller-Gerbl 1992). The sacrospinous ligaments, the sacrotuberous ligaments, the anterior sacroiliac ligaments and the interosseous sacroiliac ligaments are stressed in tension as well (Putz and Müller-Gerbl 1992). The upper parts of the sacroiliac joints are subjected to compression forces (Putz and Müller-Gerbl 1992). The sacrum tends to rotate or tilt in the sagittal plane as depicted in figure 3 (Putz and Müller-Gerbl 1992). This movement is called nutation (Kapandji 2009).

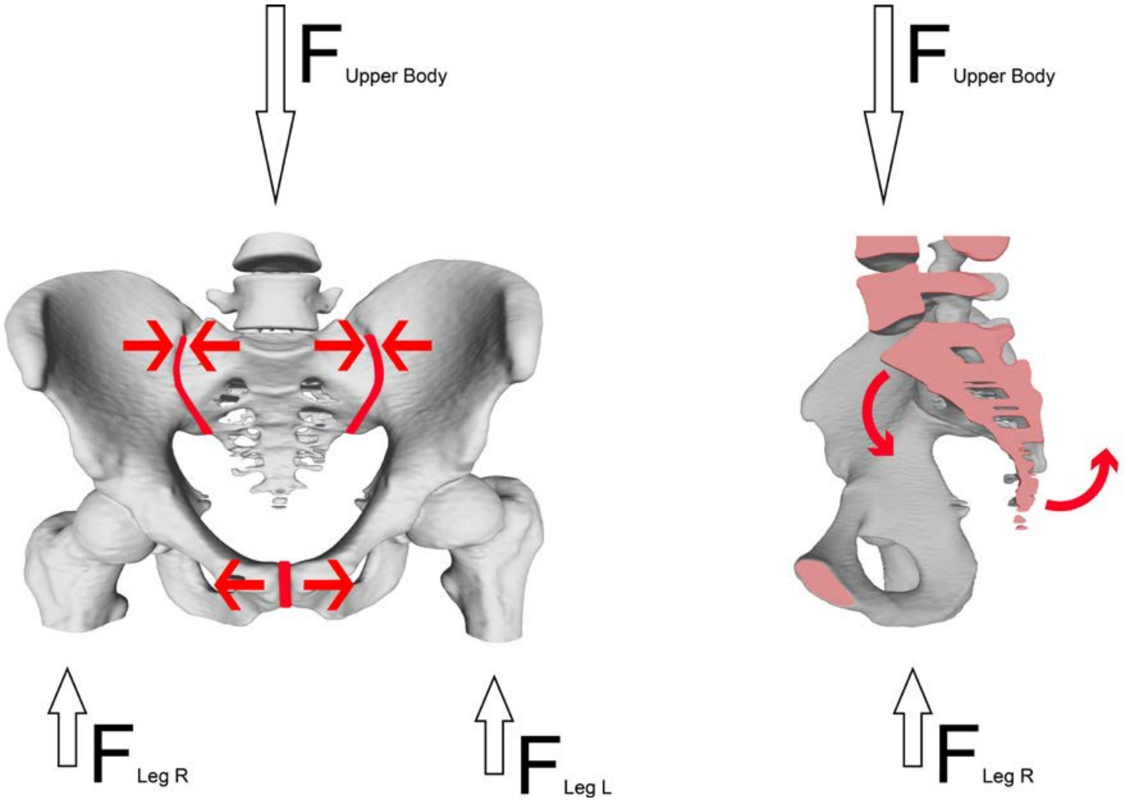

Figure 3 - Standing on both legs

Images are based on a 3D reconstruction of CT data from this study. On the left side a pelvis in AP-view is depicted. External forces are shown with white arrows. Forces on the pubic symphysis and the sacroiliac joints are depicted with red arrows. On the right side a section of the pelvis in lateral view is shown. The intersection is shown in red. External forces are shown again with white arrows. The tendency of the sacrum to rotate under the forces is shown with red arch arrows. The arrows are drawn according to Putz and Müller-Gerbl (Putz and Müller-Gerbl 1992). To simplify the images, the arrows are not proportional to the forces.

Standing on one leg: The weight of the upper body and the free leg can only be carried by the supporting leg. This results in shear forces at the pubic symphysis (figure 4). The pubic symphysis is also compressed (not shown in figure 4) and compression forces also occur at the lower parts of the sacroiliac joints (Rechl 1995). In addition, the weight of the free leg leads to a torsional moment that would lower the ipsilateral hemipelvis, but the interosseous sacroiliac ligament, the posterior sacroiliac ligament and possibly also the iliolumbar ligaments counteract (Rechl 1995) (Putz and Müller-Gerbl 1992).

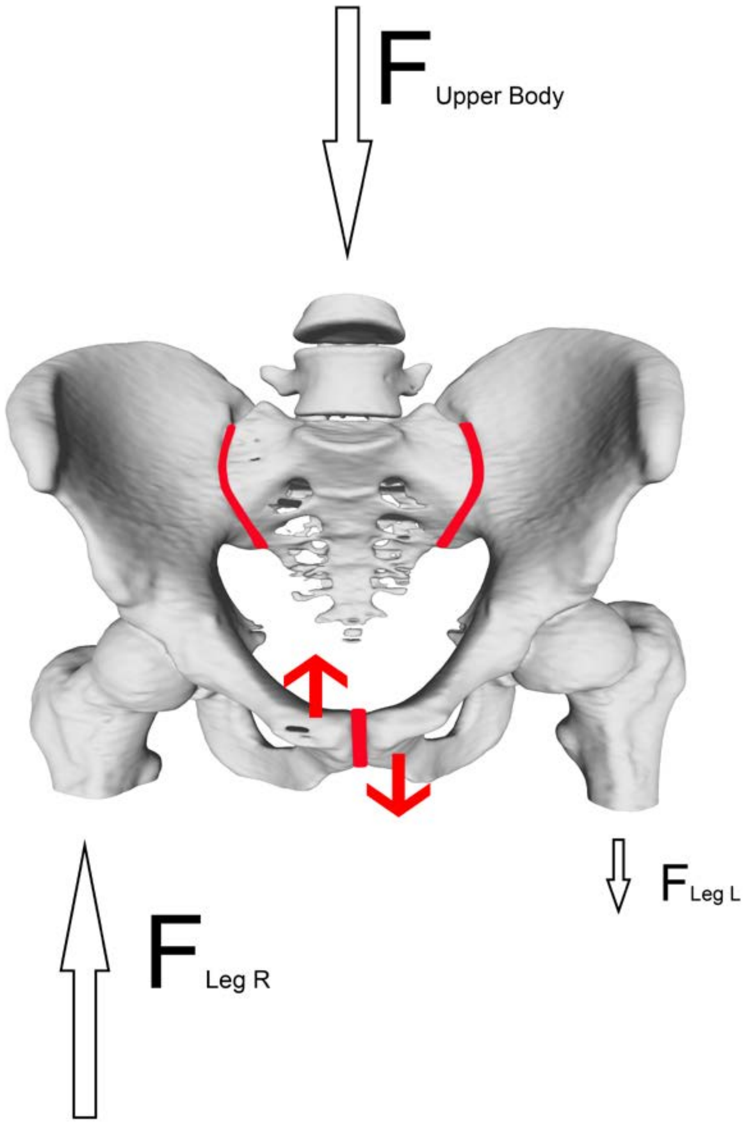

Figure 4 - Standing on one leg

Human pelvis in AP-view. The image is based on a 3D reconstruction of CT data from this study. When standing on one leg (supporting leg) the weight of the upper body and the weight of the free leg must be carried by the supporting leg. The pubic symphysis is exposed to shear forces which are indicated by red arrows. The arrows are drawn according to Kapandji (Kapandji 2009). To simplify the sketch, the arrows are not proportional to the forces. Forces on the sacroiliac joint are not shown in this sketch.

Walking and Running: Shifting the body weight between the legs, walking and running leads to intermittent compression and tension at various elements of the pelvic ring (Putz and Müller-Gerbl 1992). This has to be considered in any planning of pelvic surgery and reconstruction (Rechl 1995).

1.2 Epidemiology of bone tumors

1.2.1 Primary bone tumors

Several authors underline that most primary bone tumors are benign (Franchi 2012, Kindblom 2009). These benign lesions are often asymptomatic and remain undetected (Franchi 2012, Kindblom 2009). Therefore, it is reported that the actual incidence of benign bone tumors is probably still unclear and could be underestimated (Franchi 2012, Kindblom 2009).

In contrast, the incidence of primary bone malignancies is well documented in national registries (Kindblom 2009). For the United States and according to SEER the number of new cases of bone and joint cancer was 1.1 for males and 0.8 for females per 100 000 persons per year based on 2010 - 2014 data (Howlader N). The number of deaths was 0.5 for males and 0.3 for females per 100 000 persons per year also based on 2010 - 2014 data (Howlader N). The five year survival rate is reported to be 66% for males and 70% for females according to 2007 - 2013 data (Howlader N).

For Germany the raw incidence is reported to be 1.1 (males) and 0.9 (females) per 100 000 persons per year (Schmidt 2017). The raw mortality was found to be 0.6 for males and 0.5 for females per 100 000 persons per year and the five year survival rate was 68,9% for males and 75,9% for females (Schmidt 2017). According to the Robert Koch Institute there were approximately 360 male and 330 female incident cases of malignant bone and articular cartilage tumors in 2012 in Germany (Robert-Koch-Institute 2015).

More than a quarter of new cases of bone and joint cancer occurs in patients aged less than 20 years and the median age at diagnosis is reported to be 43 years (SEER 2017). Please see figure 5 for the distribution of new cases among age groups.

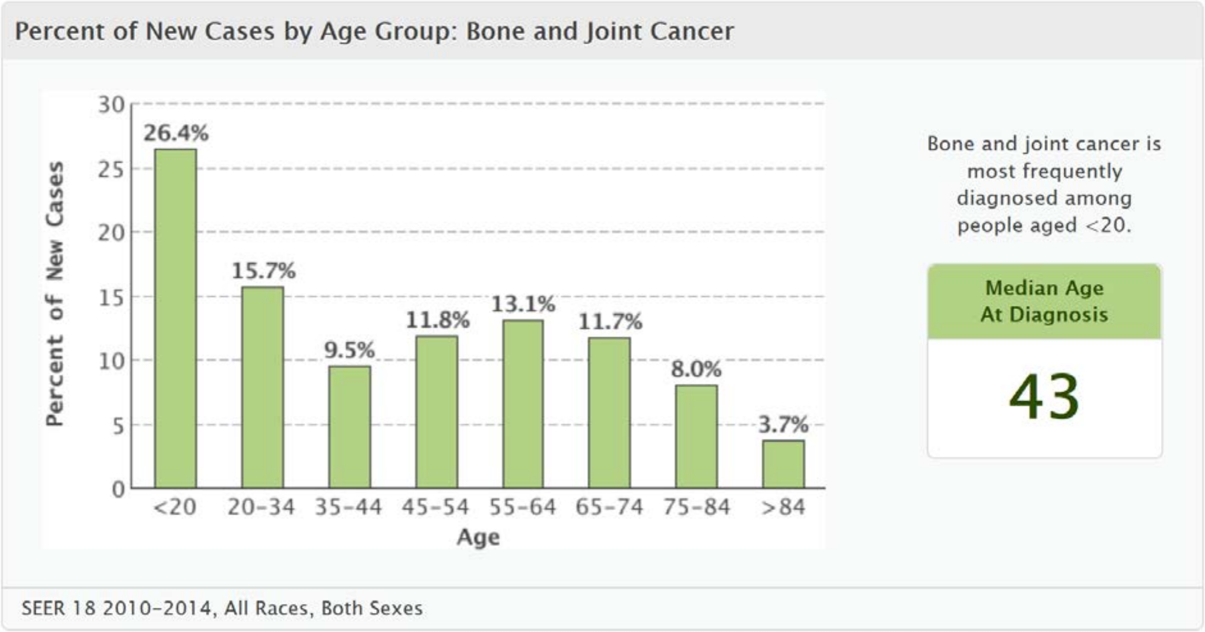

Figure 5 - Age at diagnosis of bone and joint cancer

The figure shows the number of new cases of bone and joint cancer by age group. Please consider that the first age group in this figure includes patient from birth to 19 years of age, the second age group covers a lifespan of 15 years and most of the following groups cover a lifespan of ten years. On the right-hand side, the median age at diagnosis is mentioned with 43 years of age. The figure originates from the following source: SEER Cancer Stat Facts: Bone and Joint Cancer. National Cancer Institute. Bethesda, MD, http://seer.cancer.gov/statfacts/html/bones.html

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Regarding the percentage of bone and joint cancer deaths by age group, figure 6 shows that older people are most frequently affected (SEER 2017). The median age at death was found to be 61 years for bone and joint cancer (SEER 2017).

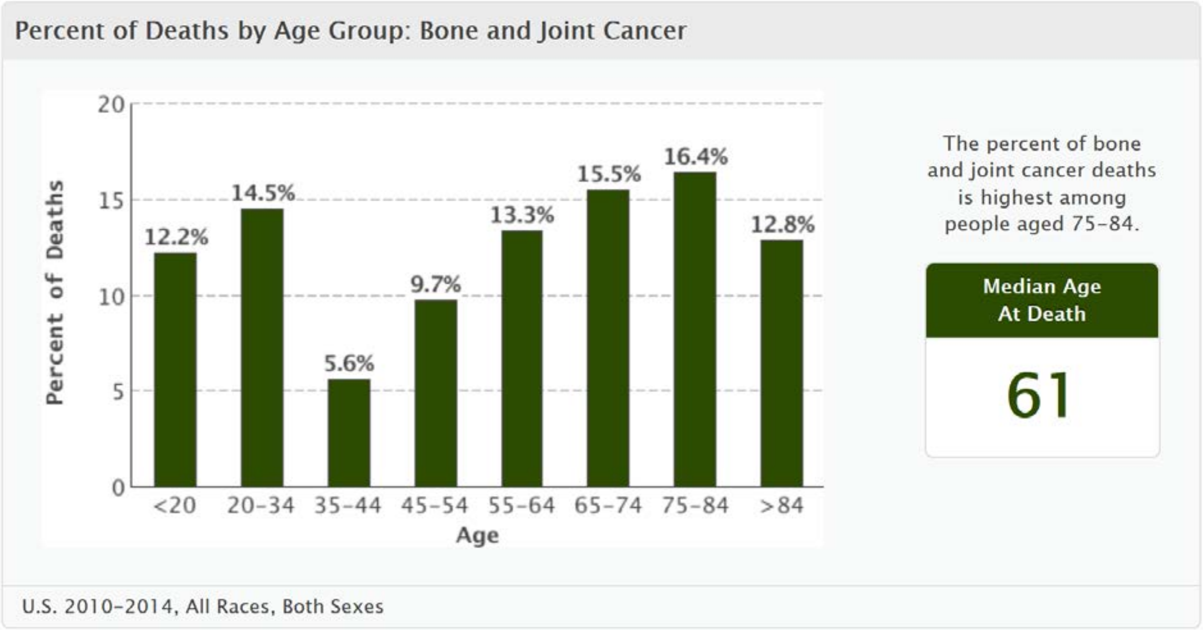

Figure 6 - Bone and Joint cancer deaths

The figure shows the number of bone and joint cancer deaths by age group. Please consider that the first age group in this figure includes patient from birth to 19 years of age, the second age group covers a lifespan of 15 years and most of the following groups cover a lifespan of ten years. On the right-hand side, the median age at death is mentioned with 61 years of age. The figure originates from the following source: SEER Cancer Stat Facts: Bone and Joint Cancer. National Cancer Institute. Bethesda, MD, http://seer.cancer.gov/statfacts/html/bones.html

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1.2.1 Secondary tumors

Bone metastases are a frequent complication of cancer (Roodman 2004). 20% of all carcinoma patients develop bone metastases (Burgkart 2009). Furthermore bone metastases are reported to occur in up to 70% of patients with advanced breast cancer, in 50% of patients with prostate cancer, in 30% of patients with lung cancer and in more than 15 % of patients with carcinomas of colon, stomach, bladder, uterus, rectum, thyroid or kidney (Burgkart 2009, Roodman 2004). Mundy estimates that ‘there are probably more than 350,000 people in the United States who die each year with bone metastases, and probably two to three times this number if patients in the European Union and Japan are also included’ (Mundy 2002).

1.3 Diagnosis of bone tumors

The diagnosis of bone tumors is often difficult due to unspecific symptoms at the beginning of the disease, the low incidence of bone tumors and the variety of bone tumor entities (Burgkart 1998) . In addition it is assumed that a general practitioner is unlikely to have a presentation of a patient with a bone malignancy during a working lifetime (Grimer 2010). Grimer states that ‘there is little doubt that diagnosing musculoskeletal tumors is far from straightforward’ (Grimer 2001). The anamnesis should include questions regarding pain (non-mechanical pain, night pain), increase of swelling/tumor, fever and weight changes, family history, tumor history and previous radiotherapy (Grimer 2010) (Burgkart 2009). This should be followed by a clinical examination (with specific attention to swelling and palpation of lymph nodes) and a blood test in patient under 40 years of age (Grimer 2010).

The age of the patient is one of the most important clinical information in the diagnosis of bone tumors, as the different tumors often show a certain age distribution. (Burgkart 2009). In children under five years of age primary malignant tumors are rarely diagnosed (Grimer 2010). Solitary bone cysts, osteoid osteomas, aneurysmal bone cysts, Ewing sarcomas and osteosarcomas are most commonly diagnosed under 20 years of age (Burgkart 2009). Giant cell tumors have an incidence peak between 20 and 30 years of age (Burgkart 2009). Chondrosarcomas show two incidence peaks at

20 and 50 years of age and the incidence of metastases increases almost exponentially, so they diagnosed more frequently with increasing age (Burgkart 2009).

Another very important information for diagnosing bone tumors is the anatomical position of the tumor within the skeleton and also within the respective bone (Baur-Melnyk 2017) (Burgkart 2009). For example, chondrosarcomas are mainly located in the pelvic bone and in the proximal femur and osteosarcomas are most frequently diagnosed around the knee joint (Burgkart 2009). Metastases and multiple myelomas are most commonly found in the spine, the ribs and the ala of the ileum (Burgkart 2009).

1.3.1 Imaging

Grimer and Briggs state that it is recommended that ‘any patient with bone pain, particularly non-mechanical pain, should be referred for radiographs’ (Grimer and Briggs 2010).

Initial imaging

Initial evaluation is typically the x-ray examination and usually two images (e.g. anteroposterior and lateral view) should be provided (Burgkart 2009, Morley and Omar 2014). In case a lesion is found, it should be described according the Lodwick classification (Baur-Melnyk 2017, Lodwick 1980). With the Lodwick classification, the predilection sites of tumors and the age of the patient allow assumptions regarding diagnosis and differential diagnoses (Baur-Melnyk 2017).

Advanced imaging

Aims of advanced imaging are finding the precise diagnosis, determining the local tumor extension, differentiating between vital and necrotic bone areas and locating skip lesions and metastases (Burgkart 2009).

For more detailed evaluations, several advanced imaging modalities such as computed tomography (CT), magnetic resonance imaging (MRI), PET/CT (positron emission tomography/computed tomography) and PET/MRI(positron emission tomography/magnetic resonance imaging) are available (Eiber 2014, Morley and Omar 2014).

Especially in complex anatomical regions (shoulder, spine, pelvis), CT imaging allows to evaluate osseous structures more detailed than x-ray imaging (Baur-Melnyk 2017). It provides advantages in analyzing cortical areas and in finding calcifications and mineralizations within a lesion (Burgkart 2009). CT can be particularly valuable for surgical planning in the pelciv area (Grimer 2010).

MRI is of great importance for detecting (the extent of) bone marrow involvement, discontinuous or skip lesions and soft tissue involvement (Morley and Omar 2014). In children and adolescents the multiplanar reconstruction allows clarification whether a tumor exceeds the epiphysis (Burgkart 2009). Contrast enhanced MRI allows the differentiation of vital and necrotic or low perfused tumor areas and is therefore important for biopsy planning (Baur-Melnyk 2017). Burgkart et al. point out that the biological activity and the local extent of the tumor should be determined before biopsy to avoid falsification of the results due to the operation (Burgkart 2009).

Recently new imaging techniques such as PET/CT and PET/MR have shown promising results in various studies.

PET/CT imaging is used for determining the treatment response in chemotherapy (Baur-Melnyk 2017).

However, with regard to the diagnostic accuracy of screening for bone metastases, it was reported that whole-body MRI is superior to PET/CT (Schmidt 2007).

Recently PET/MR with diagnostic T1-weighted TSE sequences was found to be superior to PET/CT in evaluation of malignant bone lesions (Eiber 2014).

1.3.2 Biopsy

Rechl et al. state that the biopsy serves as the final and most important step in the diagnosis of bone and soft tissue tumors (Rechl 1998a). The aim of a biopsy is to obtain a representative and vital sample of tumor tissue (Albertsmeier 2017). According to Grimer et al. it is of great importance that the biopsy is carried out in the center where definitive treatment is going to be performed (Grimer 2001). By this way appropriate staging can be completed before biopsy and the biopsy site and method can be chosen according the definitive surgical treatment (Grimer 2001). Tissue trauma should be kept to a minimum and the biopsy scar should be en bloc removable with the definitive resection (Rechl 1998a). This means that the biopsy scar should be in the area of the approach of the definitive resection and therefore the treatment options have to be already identified and evaluated at the time the biopsy is planned (Albertsmeier 2017). Biopsies can be performed as open or closed procedures (Rechl 1998a).

Closed procedures

Fine needle aspiration (FNA) and core needle biopsy (CNB) are available (Pohlig 2012). These methods are minimally invasive and have less perioperative risks than open procedures (Rechl 1998a).

The reported accuracies vary. While the dignity of soft tissue tumors could be correctly diagnosed with FNA in 90% of cases (Åkerman 1985), the type of tumor with grading was only found in 72-80% for malignancies and in 23% for benign soft tissue tumors (Rechl 1998a). A report reevaluated the method in 2010 and the accuracy in determining malignancy was reported to be only 75,4% (Kasraeian 2010). The FNA only allows the assessment of a few cells and due to the heterogeneity of musculoskeletal tumors the diagnosis is often incomplete (Rechl 1998a). According to recent guidelines, FNA should only be used in centers with specific expertise regarding this procedure (Casali and Blay 2010).

Using CNB, the amount of tissue that can be obtained is still low, but the architecture of the tumor tissue can often be identified, which eases the diagnostic evaluation (Rechl 1998a). The reported accuracies also vary for this method. A recent study comparing percutaneous, image guided CNB of soft tissue and bone tumors with open biopsy revealed a diagnostic accuracy of 92,9% for CNB and the correct histopathological diagnosis could be found in 82,4% of the cases (Pohlig 2012).

Open procedures

Excisional and incisional open biopsy procedures are available (Rechl 1998a). While excisional biopsy should only be performed in selected clinical situations (Rougraff 2009), the incisional biopsy has been referred to as gold standard (Kasraeian 2010, Pohlig 2012). The advantages of open procedures compared to closed ones are better prerequisites for obtaining sufficient representative tissue and the possibility to examine the tumor in association with the surrounding, uninfiltrated tissue (Rechl 1998a). However, a higher risk of complications such as hematoma and tumor spread have been reported for open procedures (Kasraeian 2010, Rechl 1998a). For the incision biopsy, an already above-mentioned comparative study determined a diagnosis accuracy of 98% and the correct histopathological diagnosis could be found in 93.9% of the cases (Pohlig 2012).

1.3 Preoperative planning

Modern imaging techniques such as MRT, CT und PET/CT are valuable for the preoperative assessment of tumor extension (Burgkart 2009, Dürr 2014). Based on the imaging results, the optimal approach and the surgical margins can be determined preoperatively (Burgkart 2009). Enneking has established a classification for surgical margins which distinguishes intralesional, marginal, wide and radical margins (Enneking 1980). In the case of malignant bone and soft tissue sarcomas, a wide or radical resection is generally to be aimed for (Albertsmeier 2017). A radical resection means compartment-based resection and is rarely seen as necessary today (Albertsmeier 2017) (Plötz 1998). This is due to the fact that the prognosis of patients is statistically strongly influenced by the still comparatively frequent occurrence of distant metastases, whereas local recurrences after resection and limb salvage are low after thorough planning in tumor centers (Plötz 1998). At present wide resections are usually preferred (Albertsmeier 2017). It is known that bone and soft tissue sarcomas often expand rapidly and extensively within a compartment in longitudinal direction, while transverse expansion is generally slower (Albertsmeier 2017). For this reason, greater safety distances are sought in the longitudinal direction than in the transversal direction (Plötz 1998). Generally, there is no definite recommendation beyond a margin of healthy tissue (Albertsmeier 2017, Dürr 2014). However, the aim is to achieve several millimeters in the axial direction and several centimeters in the longitudinal direction while avoiding loss of function (Albertsmeier 2017, Dürr 2014).

1.4 Surgical therapy of pelvic tumors

1.4.1 Surgical types

Enneking and Dunham have distinguished the following types of techniques: the iliac excision (type I), the iliac excision-resection (type IA), periacetabular excision (type II), periacetabular resection (type IIA), pubic excision (type III) and pubic resection (type IIIA) (Enneking and Dunham 1978).

Dunham published an updated classification in 1987 (Dunham Jr 1987). Three types of resections at the pelvic bone were differentiated: type I resections of the iliac wing, type III resections of pubis and ischium (both not including the acetabulum) and type II resections that include the acetabulum (Dunham Jr 1987). Type II resections were further subdivided, whereby in type II A resections the lower half of the acetabulum could remain, in type II B resections the upper half of the acetabulum could remain and in type II C resections the entire acetabulum had to be removed (Dunham Jr 1987).

However, the literature often presents a simplified classification (figure 7) and distinguishes between four types of resections at the pelvis: supraacetabular, periacetabular, infracetabular and sacral resections (Angelini 2015, Fujiwara 2015, Rudert 2012).

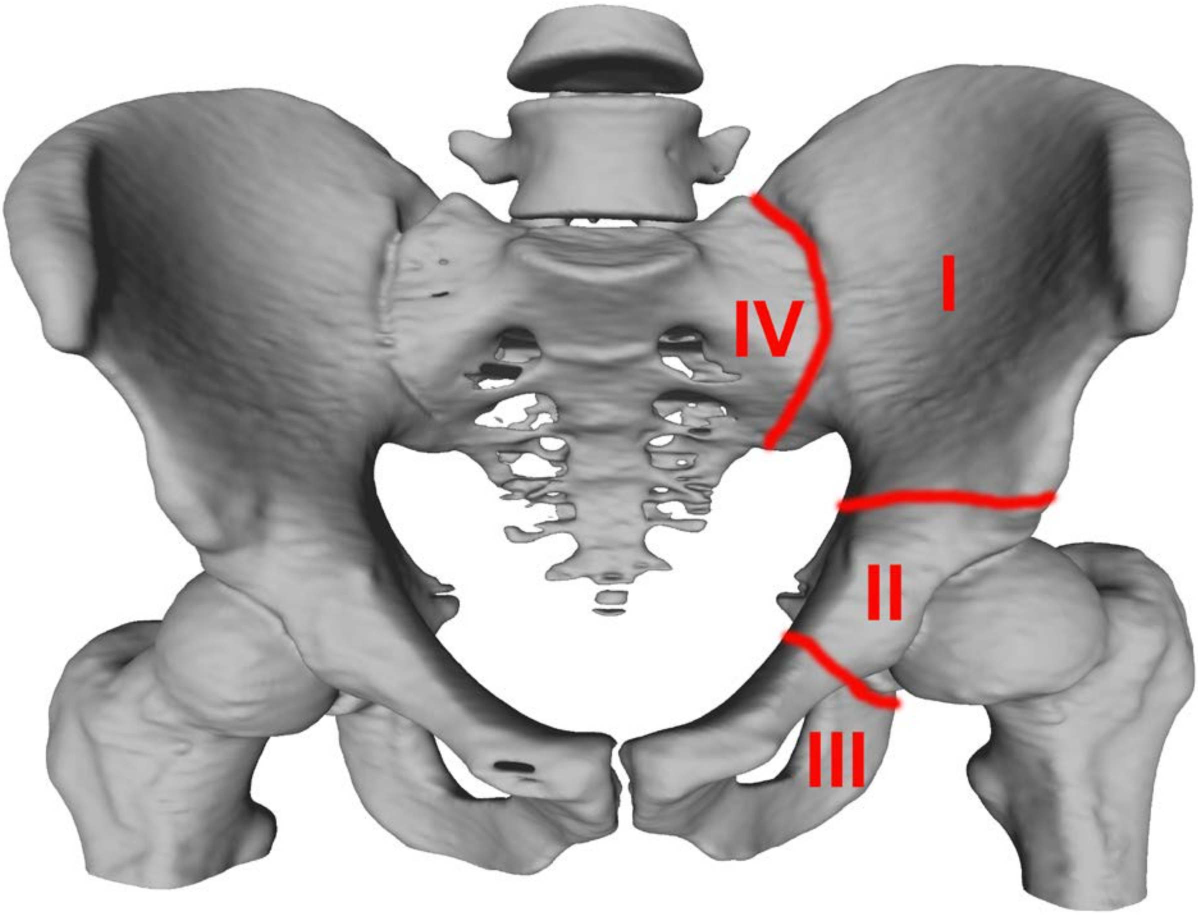

Figure 7 - Classification of resections at the pelvis

Human pelvis in AP-view. The image is based on a 3D reconstruction of CT data from this study. The area of supraacetabular resections is marked with I, the area of acetabular resections is marked with II, the area of infraacetabular resections is marked with III and the area of sacral resections is marked with IV. The classification is chosen similarly to that of many recent publications (Angelini 2015, Fujiwara 2015, Rudert 2012). The infraacetabular area includes both the pubis and ischium.

1.4.2 Concepts after resection

Several authors point out that reconstruction after pelvic tumor resections is extremely challenging (O'Connor 1997, Schwameis 2002). While supraacetabular resections with remaining vertical stability and infraacetabular resections often not have to be reconstructed, periacetabular resections require the reestablishment of force transmission from the lower extremity to the axial skeleton (Holzapfel 2014, Postl 2017, Rudert 2012). Holzapfel et al. stress that it is still not clear which reconstruction method is best (Holzapfel 2014). Various reconstruction methods are available, such as endoprosthetic reconstruction, biological reconstruction, hip transposition and arthrodesis (Schwameis 2002). Resection without reconstruction has also been reported (Schwameis 2002).

1.4.2.3 Endoprosthetic reconstruction

Advantages of reconstruction using custom-made endoprostheses include the reestablishment of force transmission, avoiding major leg length differences, maintaining a certain degree of mobility and that there is no need for bone substitutes (Rudert 2012). The endoprosthetic reconstruction has the potential to offer good functional results, however, numerous complications such as infection and implant loosening are reported (Abudu 1997, Rudert 2012). A specific disadvantage of endoprostheses as a replacement for the hip joint is wear (Abudu 1997). Another disadvantage compared to biological reconstruction procedures is that the defect situation for future interventions is not reduced (Rudert 2012). According to Burgkart, there are generally four different options for endoprosthetic treatment after tumor resection: spaceholder, standard prostheses, custom made prostheses and modular prostheses (Burgkart 2009). A conventional endoprosthesis is only suitable for small periacetabular tumors (Rechl 1998b). In the case of larger defects, special constructions are necessary to support the implant in the healthy bone (Rechl 1998b). After initial experience with custom-made megaprostheses, semi modular systems were developed (Burgkart 2009, Gradinger 1991). In semi modular solutions, only the anchoring part of the prosthesis in the ileum or sacrum is manufactured individually (Burgkart 2009, Gradinger 1991). Reconstruction with individual prostheses requires very precise resections, otherwise the implantation of the prosthesis is quite difficult (Holzapfel 2014). In this regard several computer-aided methods have been developed to improve the accuracy of resections and an overview is provided in the computer-aided surgery section below.

1.4.2.2 Biological reconstruction

Reconstruction methods using allografts often use a bony donor hemipelvis (Langlais 2001). The size of the allografts can be adjusted intraoperatively to the final resection, which is advantageous in case of geometric deviations compared to preoperative planning (Langlais 2001). Biological reconstruction also provides other advantages, such as the possibility of restoring the vertical force transmission and the leg length and regaining a certain degree of mobility. However Chan et al. point out that reconstruction using allografts requires access to a large bone bank (Chan 2016). Even if a suitable transplant is found, immune reactions and transmission of infections cannot be completely excluded (Chan 2016). Several complication have been reported including osteolysis, nonunion, fracture, wound infects and neurological damage (Davidson 2005) (Delloye 2007, Harrington 1992, Ozaki 1996). The reuse of the resected bone after autoclaving was also reported, but again there were numerous complications (Harrington 1992). Interestingly a recent rabbit study concluded that irradiation and pasteurization techniques have better outcomes in terms of bony union than autoclaving (Yasin 2015). This is in line with clinical studies - the reuse of resected bone after extracorporeal irradiation is reported to have better outcomes in terms of morbidity and functionality as the above mentioned other methods (Chan 2016, Wafa 2014). A very recent study compared pasteurized autografts with resection hip arthroplasty and the latter showed lower major and minor complications (Lee 2017). Rudert et al. state that especially for younger patients, it should always be considered whether the surgical objectives can be achieved with a biological reconstruction procedure (Rudert 2012).

1.4.2.3 Hip transposition

Hip transposition was first presented by Winkelmann in 1988 for the treatment of pelvic tumors in children (Winkelmann 1988). In the meantime, different types of transpositions have been reported and the method is also suitable for adults (Gebert 2009). In general hip transposition means relocation of the femoral head to the lateral side of the sacrum or underside of the remaining ileum without closing the pelvic ring (Gebert 2009, Rödl 2003). In order to keep the femoral head in place, either a remaining part of the acetabulum or an artificial capsule is attached to the remaining ileum or sacrum (Gebert 2009). Hip transposition is reported to have lower complications than endoprosthetic or allograft reconstruction with satisfactory functional outcome (Hillmann 2003). However a major leg discrepancy must be accepted (Hillmann 2003).

1.4.2.3 Arthrodesis and resection without reconstruction

Arthrodesis and resection without reconstruction are concepts which are still performed in certain situations (Carmody Soni 2012, Fuchs 2002, Schwameis 2002). They have much lower complications as more complex reconstruction methods (Carmody Soni 2012). In addition, surprisingly good functional results are reported for the illeofemoral arthrodesis (Fuchs 2002, Fujiwara 2015).

1.5 Computer-aided surgery for pelvis resections

As early as the late 1980s, Rechl et al. reported on the three-dimensional reconstruction of pelvises using CT data (Rechl 1988). Original-size pelvic models could be milled from this data via CAM (computer-aided manufacturing) and these were used for operation planning and simulation (Gradinger 1991). Due to the commercialization of the rapid prototyping technology, this method was increasingly used in the 1990s (Mittelmeier 1997). In the following years, customized osteotomy guides were introduced (Burgkart 2009). It was now possible not only to produce customized prostheses using CAD (computer-aided design)/CAM technology, but also to provide suitable templates which could also be made with CAD/CAM technology (Burgkart 2009). In 2014 a clinical evaluation of customized osteotomy guides for periacetabular tumors with subsequent endoprosthetic reconstruction found acceptable clinical and oncological outcomes (Holzapfel 2014).

Navigation systems had been used for some time in various areas such as the spine or the knee and promising results in terms of accuracy have been reported (Conteduca 2013, Gelalis 2012). However, in the field of pelvic tumor surgery, the use of navigation systems for pelvic tumors was not common.

Nevertheless several synthetic bone studies evaluated the accuracy of navigation systems in the pelvic area and found that the accuracy of resections was improved by the use of computer-aided planning and navigation of resections (Cartiaux 2013, Docquier 2010). Unfortunately, there were no sufficient studies in the literature to investigate the accuracy of computer-assisted resections at the pelvis in a clinical setting. Among other things, this is probably due to the fact that human cadavers are rare. In addition, the evaluation of computer-aided systems on human corpses is very complex, since the studies often have to be carried out at forensic institutes. In most cases, however, the required X-ray equipment such as computer tomographs and C-arms are not available in forensic institutes or other suitable facilities. Beyond that, navigation systems are needed and these usually have to be installed first in forensic institutes.

2. AIMS AND HYPOTHESIS

As explained above, there were no sufficient studies in the literature on the accuracy of computer-aided pelvic tumor resections in a realistic operation room setting. Therefore, this study should provide results on the accuracy of computer-assisted pelvic tumor resections in a clinical setting for the first time.

Aims of this thesis:

I. The first aim of this work was to adapt a navigation system for the use in pelvic tumor surgery. The planned osteotomies should be performed as accurate as possible.

II. Second aim of this thesis was to compare the accuracy of computer-assisted pelvic supraacetabular tumor resections with the accuracy of corresponding freehand resections (Postl 2017). In order to be able to perform most accurate resections, K-wires (Kirschner-wires) should be inserted with the aid of the navigation system, which should then serve as a guide for the oscillating saw (Postl 2017). To simulate realistic operation room conditions, human full-body cadavers should be used for the computer-assisted group (Postl 2017). In order to be able to use the same planning for the control group, customized pelvises with identical geometry should be produced by rapid prototyping (Postl 2017).

The null hypothesis was that there was no difference between the computer-assisted resections and the free hand resections (Postl 2017). The significance level was set to 0.05 (Postl 2017)

III. Furthermore, the accuracy of computer-assisted infraacetabular resections should also be evaluated and compared with free hand resections, as in the case of supraacetabular resections. The null hypothesis was again that there was no difference between computer-aided and freehand resections. The significance level here too was 0.05.

IV. The computer-assisted supraacetabular resections should be compared with the computer-assisted infraacetabular resections. Accordingly, the freehand supraacetabular resections should be compared with the infraacetabular freehand resections. No differences between the groups were assumed as null hypotheses again. Significance level was again set at 0.05.

V. The accuracy of all computer-assisted resections should be compared with the accuracy of all freehand resections. The null hypothesis was again that there was no difference between the groups and a significance level of 0.05 was applied.

3. MATERIALS AND METHODS

This study was approved by the Ethics Commission of TUM School of Medicine of Technische Universität München with the reference number 113/16S.

3.1 Specimen

3.1.1 Inclusion criteria

Included were fresh, human, full body cadavers from the department of forensic medicine of Ludwig-Maximilians-Universität München (Postl 2017). The age of the cadavers must have been greater than 18 years.

3.1.2 Exclusion criteria

Exclusion criteria were a previous use of the cadavers or a history of surgery or osseous defects including fractures, tumors or cysts at the respective hemipelvis.

3.2 Preoperative CT scans

All cadavers were transported from the department of forensic medicine to the department of radiology. A GE LightSpeed VCT XTe CT scanner (Collimation 0.6 mm, pitch 0.75 mm, 140kV, 40mAs) was used for performing scans of the pelvis including the lumbar spine and the proximal femur (Postl 2017). The CT data was provided in DICOM (digital imaging and communications in medicine) format on a DVD disc by the radiologist. Afterwards the cadavers were brought back to the department of forensic medicine.

3.3 Planning

3.3.1 Osteotomy planes

First a supraacetabular osteotomy at the ileum which was oriented from the anterior inferior iliac spine towards the greater sciatic notch was planned (Postl 2017). This was followed by planning a infraacetabular resection at the pubis which was orientated perpendicular to the superior pubic ramus with approximately 2 cm distance to the acetabulum (figure 8).

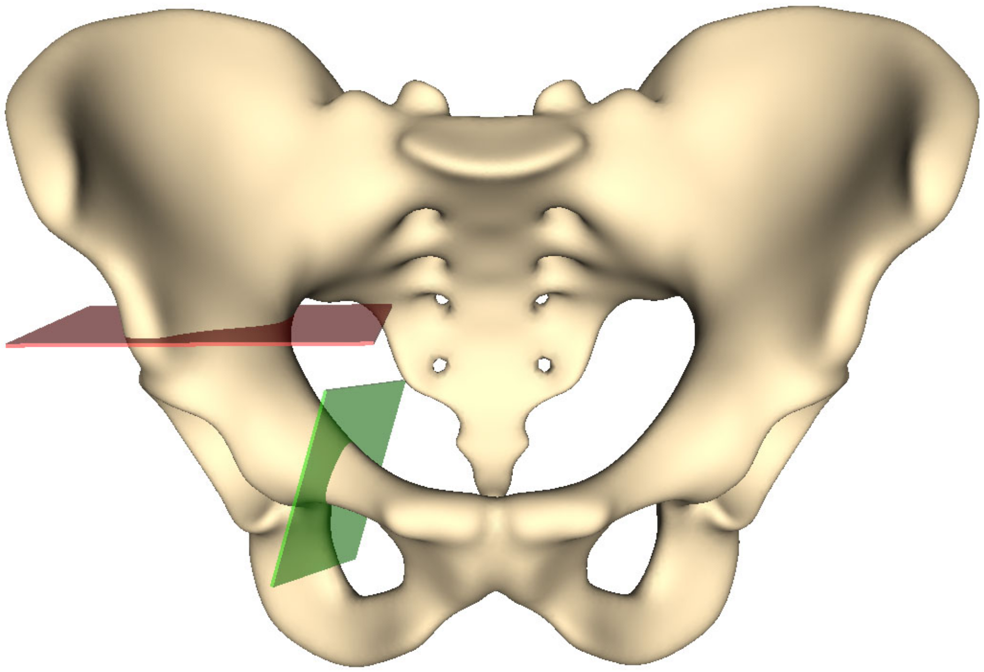

Figure 8 - Resection planes

3D sketch of the human pelvis in AP-view. The supraacetabular osteotomy plane is shown in red and the infraacetabular osteotomy plane in green.

Adapted from “Potential accuracy of navigated K-wire guided supra-acetabular osteotomies in orthopedic surgery: a CT fluoroscopy cadaver study” by Postl LK, Kirchhoff C, Toepfer A, Kirchhoff S, Schmitt-Sody M, von Eisenhart-Rothe R, Burgkart R, 2017, The international journal of medical robotics and computer assisted surgery, page number 2. Copyright 2016 by " John Wiley & Sons, Ltd". Adapted with permission.

3.3.2 K-wires as guidance

Oscillating saws are typically used for tumor resections of the pelvis. These saws can be used carefully to preserve soft tissue, but there is a lot of vibration. The sawblades can be thin and flexible. Due to the flexibility of the sawblade, the jerking movements and vibrations of the saw, it is hardly possible for the navigation system to predict the position of the sawblade with markers on the sawing tool (Postl 2017). In addition, it is very challenging to precisely start an osteotomy at a certain position of the bone surface with an oscillating saw, because the vibrations and jerking movements will lead to drifting of the saw blade on the bone surface (Postl 2017). All these reasons will result in inaccuracies in case of direct tracking of an oscillating saw (Postl 2017).

To avoid inaccuracies, two K-wires were inserted to serve as guidance for the saw blade (Postl 2017). These K-wires were planned in parallel with 2 cm distance which allowed stable guidance of the oscillating saw blade (Postl 2017). The center of the K-wires was shifted by half a diameter in the direction of the non-resected part of the pelvis (Figure 9) to avoid a systematic error (Postl 2017).

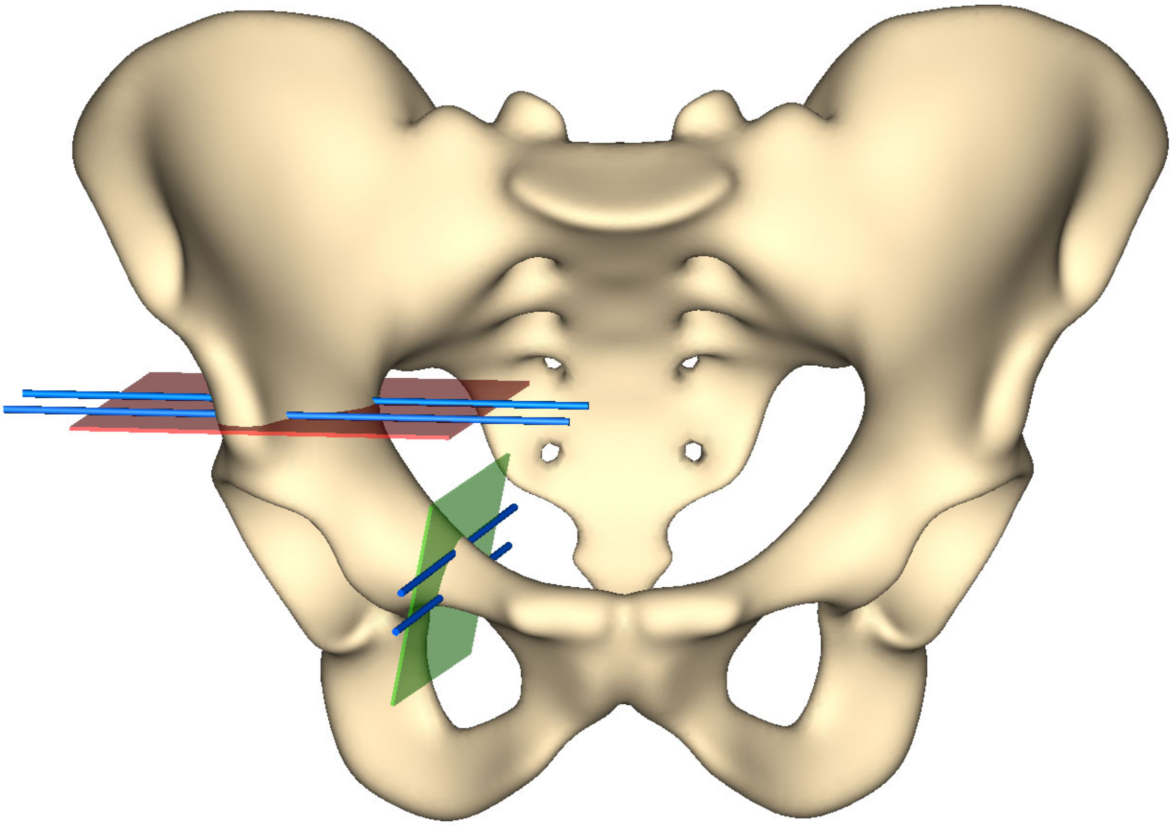

Figure 9 - K-wires axes and resection planes

3D sketch of the human pelvis in AP view. The supraacetabular osteotomy plane is shown in red and the infraacetabular osteotomy plane in green. The axes of the K-wires are depicted in blue.
Adapted from “Potential accuracy of navigated K-wire guided supra-acetabular osteotomies in orthopedic surgery: a CT fluoroscopy cadaver study” by Postl LK, Kirchhoff C, Toepfer A, Kirchhoff S, Schmitt-Sody M, von Eisenhart-Rothe R, Burgkart R, 2017, The international journal of medical robotics and computer assisted surgery, page number 2. Copyright 2016 by " John Wiley & Sons, Ltd". Adapted with permission.

3.3.3 Planning software

The planning data was transferred to a workstation and loaded into the planning software (Brainlab iPlan spine 3.0, Brainlab, Feldkirchen, Germany). The axes of the K-wires were then planned with the planning tool “Screw / Trajectory Planning” (figure 10).

Figure 10 - Planning

Screenshot while planning. The axes of the K-wires for the supraacetabular osteotomy plane are visualized in red and light blue, those for the infraacetabular osteotomy plane in green and yellow.

3.4 Operation set up

The Brainlab VectorVision navigation system (Brainlab, Feldkirchen, Germany) was used for the navigated osteotomies. To simulate operation room conditions, the cadavers were unrestrainedly placed on a radiolucent operation room table (figure 11) in supine position (Postl 2017). For the fluoroscopic registration process a C-arm (Ziehm Vision Vario C-arm, Nuremberg, Germany) was used (Postl 2017). As specified by the manufacturer of the navigation system, a registration kit (Brainlab, Feldkirchen, Germany) was mounted on the C-arm’s intensifier (Postl 2017). The registration kit is required for tracking the C-arm’s position and for calibration of potentially distorted X-ray images (Postl 2017).

Figure 11 - Operation set up

The cadaver is placed on an operating table. The green covering of the cadaver allows procedures at the right hemipelvis (right side of pelvis is marked with *). The C-arm stands on the right side of the operating table (marked with %). The registration kit is already mounted on the intensifier of the C-arm (right under %). The VectorVision navigation system is located left (marked with #).

3.5 CT-flouro registration

At this stage, the navigation system had the information about the shape of the pelvis but its exact position was still not available. Therefore, X-ray images of the pelvis were necessary to get the exact position of the pelvis after a reference base had been attached. From then on, the attached reference base with three marker spheres allowed tracking of the pelvis by two cameras. This process is called registration:

The procedure was started with a modified ilioinguinal approach (figure 12) according to Letournel (Judet 1964) (Postl 2017).

Figure 12 - Approach

The figure shows the ilioinguinal approach at the right hemipelvis.

Then the reference base was screwed down (figure 13) to the iliac crest of the respective hemipelvis (Postl 2017). This was achieved by using two parallel Schanz screws (Synthes, Solothurn, Switzerland) with 3.5mm diameter (Postl 2017).

Figure 13 - Reference base

The reference base with the three marker spheres is attached to the hemipelvis with long screws. The registration kit is shown above.

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In doing so the three marker spheres of the reference base had to be positioned in a way that allowed intervisibility between the marker spheres and the two cameras of the navigation system (figure 14) at any time during the navigation process (Postl 2017).

Figure 14 – First position of C-arm during registration

Intervisibility between the two cameras of the navigation system (navigation system marked with +) and both the reference base (right to >) had to be ensured. The registration kit is mounted on the C-arm (marked with *).

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The navigation system requires at least two X-ray images with the reference base attached to the bone to get the position of the pelvis (Postl 2017). The first X-ray image (figure 16) was taken in posterior-anterior direction with the C-arm (figure 14). According to the manufacturer the C-arm must be tilted by a minimum angle of 30° degrees for a second image (Postl 2017). In our series, the C-arm was tilted by an angle of approximately 40° (figure 15) and a second X-ray image (figure 17) was performed (Postl 2017).

Figure 15 – Second position of C-arm during registration
C-arm was tilted more than 30° for a second X-ray image.

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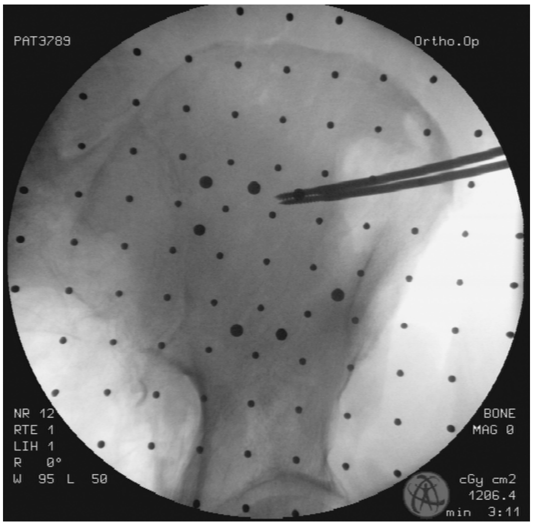


Figure 16 - First X-ray image during registration

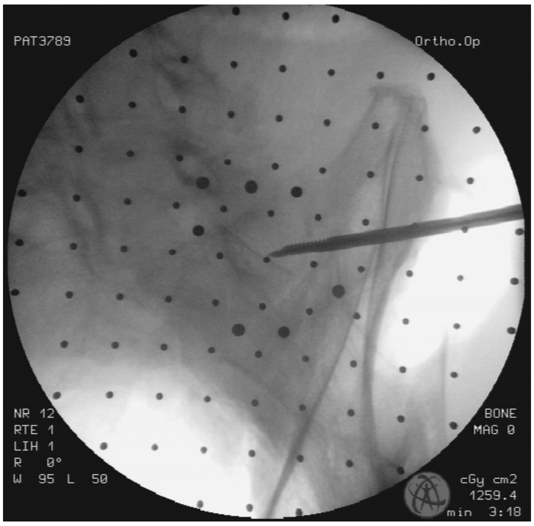
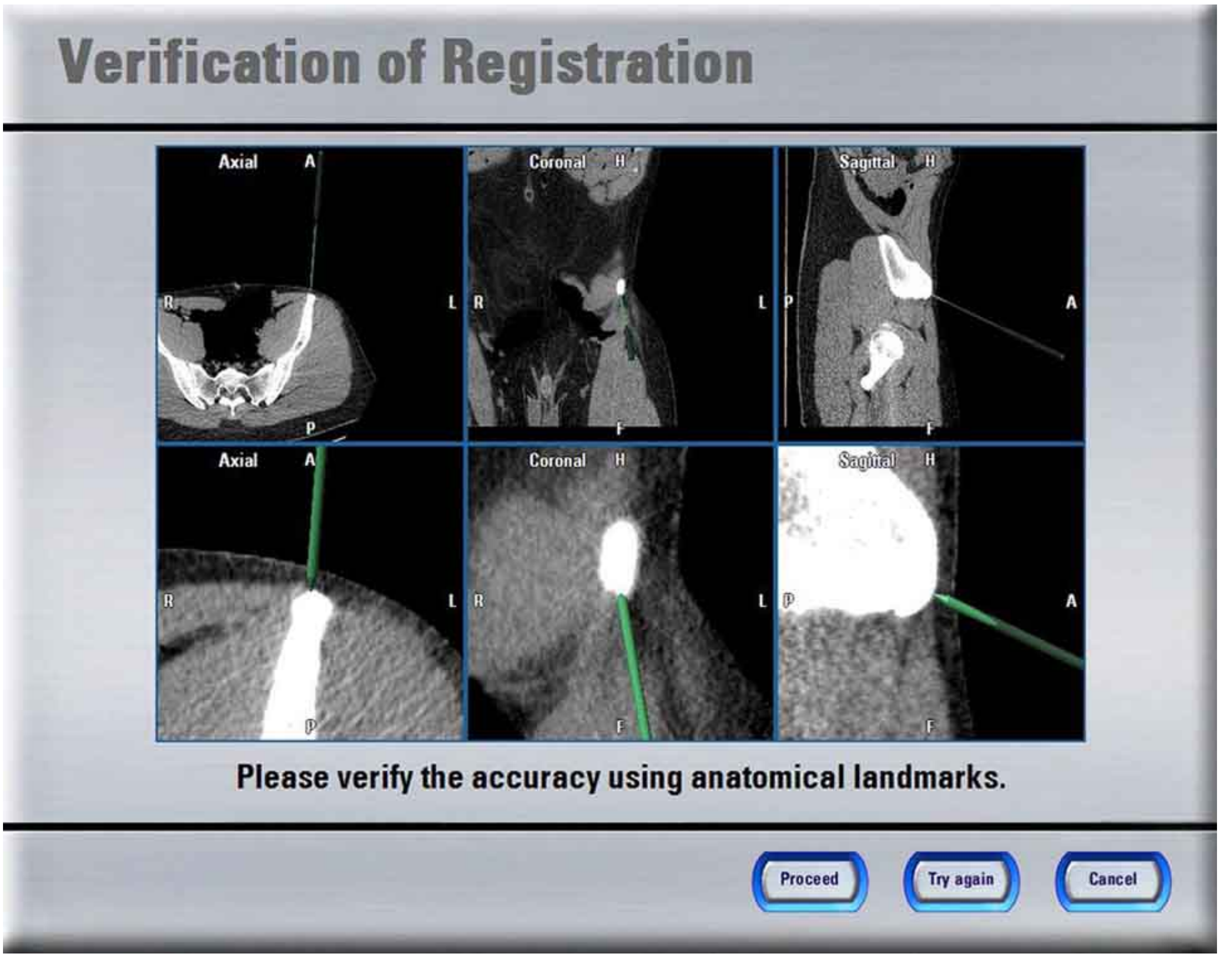


Figure 17 - Second X-ray image during registration

Afterwards, the navigation system could reference the preoperative CT data with the X-ray (fluoroscopic) data (Postl 2017). During the following procedures, the position of the pelvis was continuously calculated by the system using the image information from the two cameras of the navigation system, provided the three marker spheres of the reference base were visible.

With a pointer tool (Brainlab, Feldkirchen, Germany) the plausibility of the registration process could be checked (Postl 2017). The pointer also had three marker spheres and they had to be visible during pointing. The position of the pointer tool was also automatically calculated using the image information of the two cameras.

Several anatomical landmarks were chosen and the bone surface was touched with the pointer tool (figure 18) (Postl 2017). In case the distance between the virtual pointer tip and the virtual bone surface was more than 1.5 mm, we restarted the registration process (Postl 2017).



Verification of Registration

Please verify the accuracy using anatomical landmarks.

Figure 16 - Pointer Tool

Pointing at an anatomical landmark with the pointer tool.

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3.6 Study group (navigated osteotomies)

Using the navigated drill guide (drill guide 55839-10 with 2.0 mm reduction sleeve, Brainlab, Feldkirchen, Germany), two K-wires (Kirschner wires, diameter 2 mm, length 310 mm, Aesculap, Tuttlingen, Germany) were inserted for each osteotomy (Postl 2013). The drill guide also had tree marker spheres that had to be visible for the two cameras of the navigation system (figure 19). The position and 3D angle of the K-wires were displayed on the screen of the navigation system. The basic prerequisite for this was that the three marker spheres of the reference base and also the three marker spheres of the drill guide were visible for the two cameras of the navigation system. The drilling depth or insertion depth could not be displayed on the screen using this method.

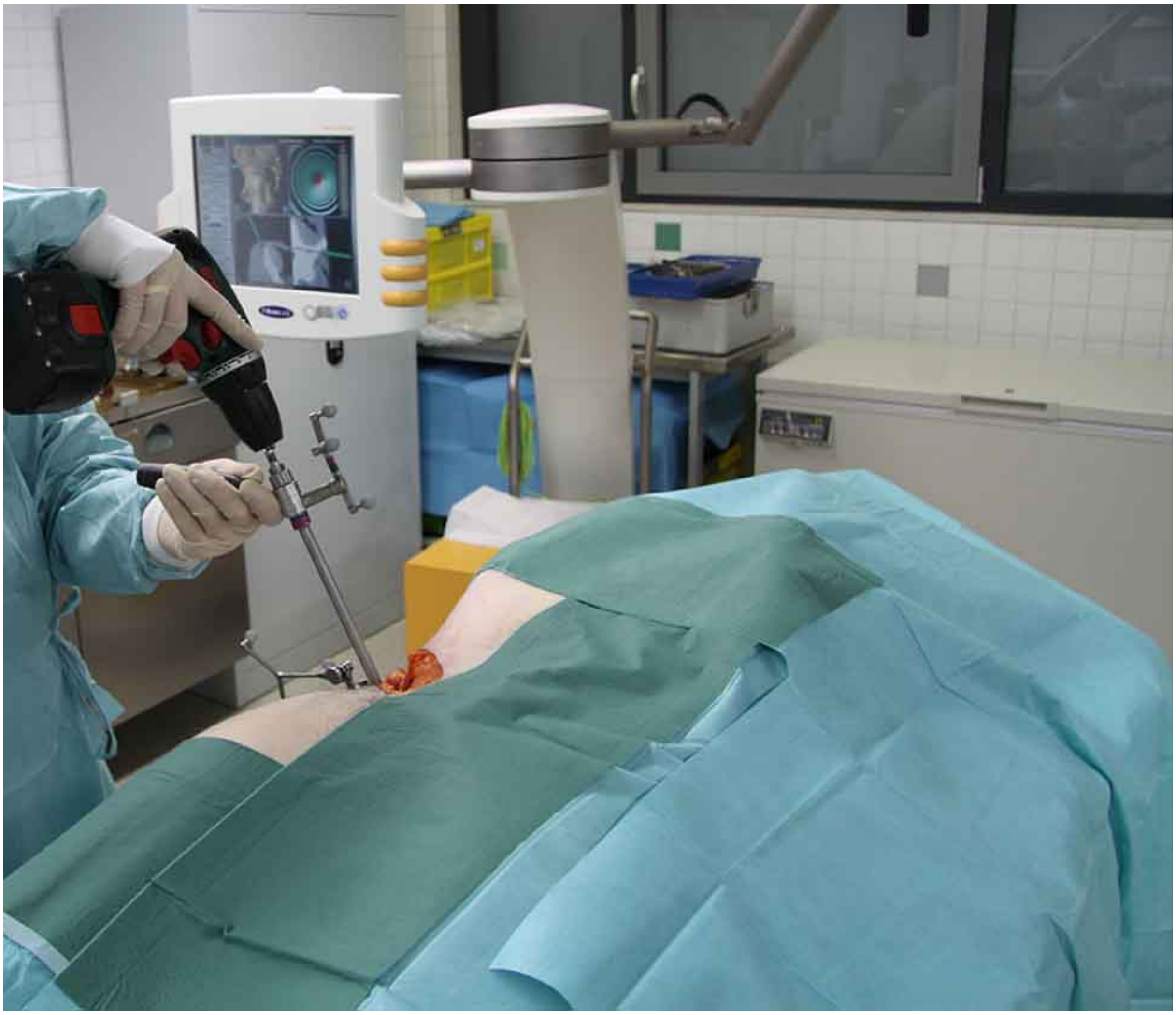

Figure 17 - Insertion of K-wires

Inserting a K-wire with the navigated drill guide. The proper position and direction of the K-wire is displayed on the screen of the navigation system.

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After the K-wires were inserted firstly the supraacetabular osteotomy and secondly the infraacetabular osteotomy were performed with an oscillating saw. A sawblade (Synthes, West Chester, Pennsylvania, USA) with a length of 95 mm, a width of 25 mm and a thickness of 1 mm was used (Postl 2017). Then all metal (the reference base, the Schanz screws, the K-wires) was removed. Finally, the wound was closed according to the provisions of the department of forensic medicine.

3.7 Control group (freehand osteotomies)

The bone geometries of the control group's pelvises were identical to the geometries of the study group's (cadaveric) pelvises (Postl 2017). This was achieved by printing the pelvises (figure 20) with a 3D printer (ZPrinter 650, 3D Systems, Rock Hill, South Caroline, USA) according to the CAD data (in STL file format) of the preoperative CT scans (Postl 2017). The 3D printer was located at the Medical Faculty of Johannes Kepler University Clinic in Linz, Austria. Freehand osteotomies were performed with the same oscillating saw as in the study group according to the planning data of the study group (Postl 2017). However, no navigation system was used in this group.

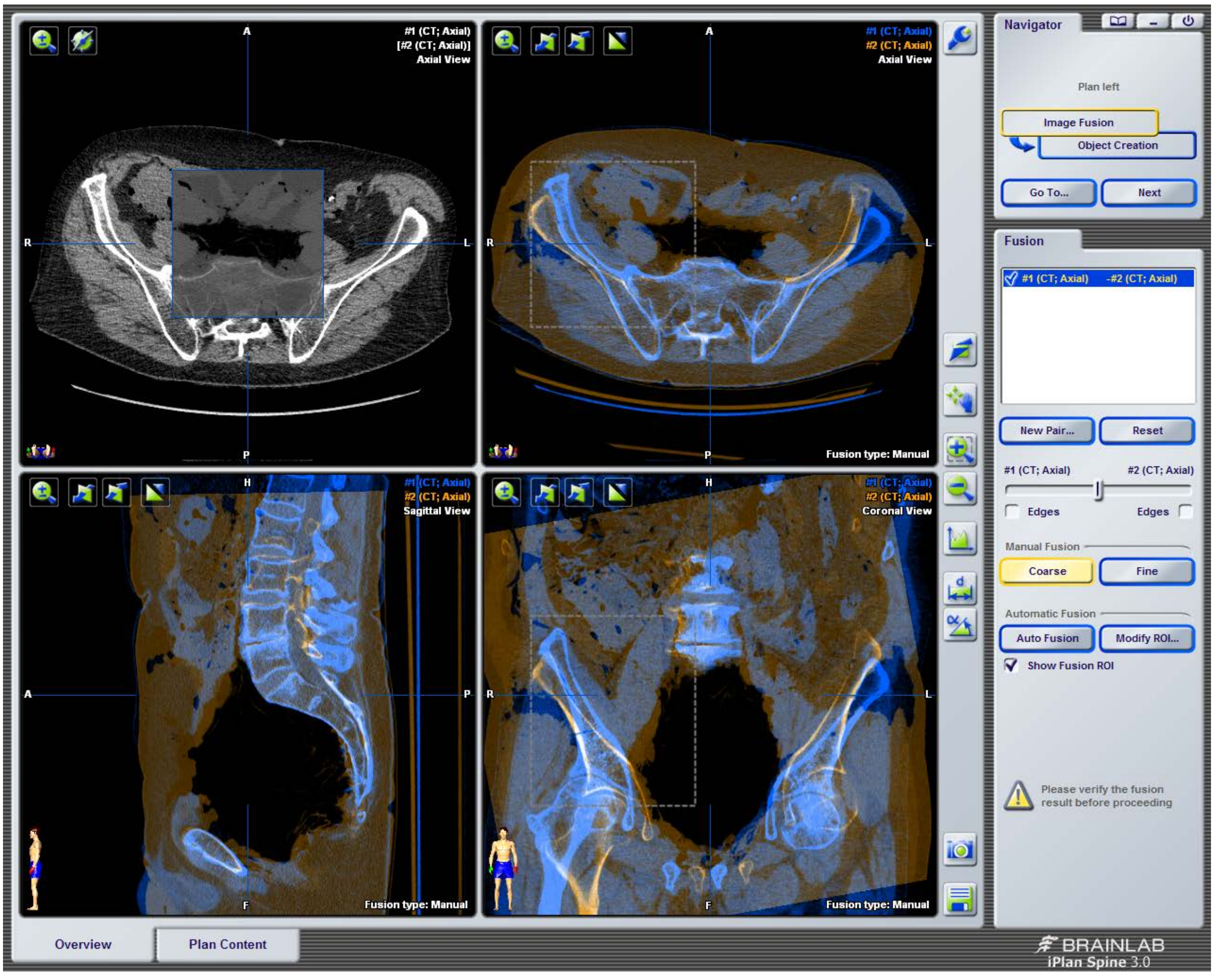
Figure 18 - 3D printer
The figure shows a 3D printed pelvis in the 3D printer.

3.8 Postoperative CT scans

Again, the cadavers were transported from the department of forensic medicine to the department of radiology. The postoperative CT images were performed exactly as the preoperative images (Postl 2017). Straightaway, the cadavers were returned to the department of forensic medicine. Postoperatively, CT scans of the 3D printed pelvises of the control group were also performed. All postoperative CT data was burned to a DVD in DICOM format.

3.9 Evaluation

The postoperative scans of the study group in DICOM format were also transferred to iPlan spine 3.0 (Brainlab, Feldkirchen, Germany). Therefore, the preoperative scans with the planning data (coordinates of the planned osteotomy planes) and the postoperative scans were both available in iPlan spine 3.0 (figure 21).



Fusion type: Manual

Please verify the fusion result before proceeding

Figure 19 – Preoperative and postoperative CT scans before image fusion

The preoperative CT data is depicted in blue. The postoperative CT data is shown in yellow.

Image fusion between the preoperative planning data and the postoperative data was performed (Postl 2017). After this, the preoperative and postoperative data were aligned (figure 22). Thereby the coordinates of the planned osteotomy plane (the planned parallel trajectories of the K-wires) could be determined in the coordination system of the postoperative CT scan.

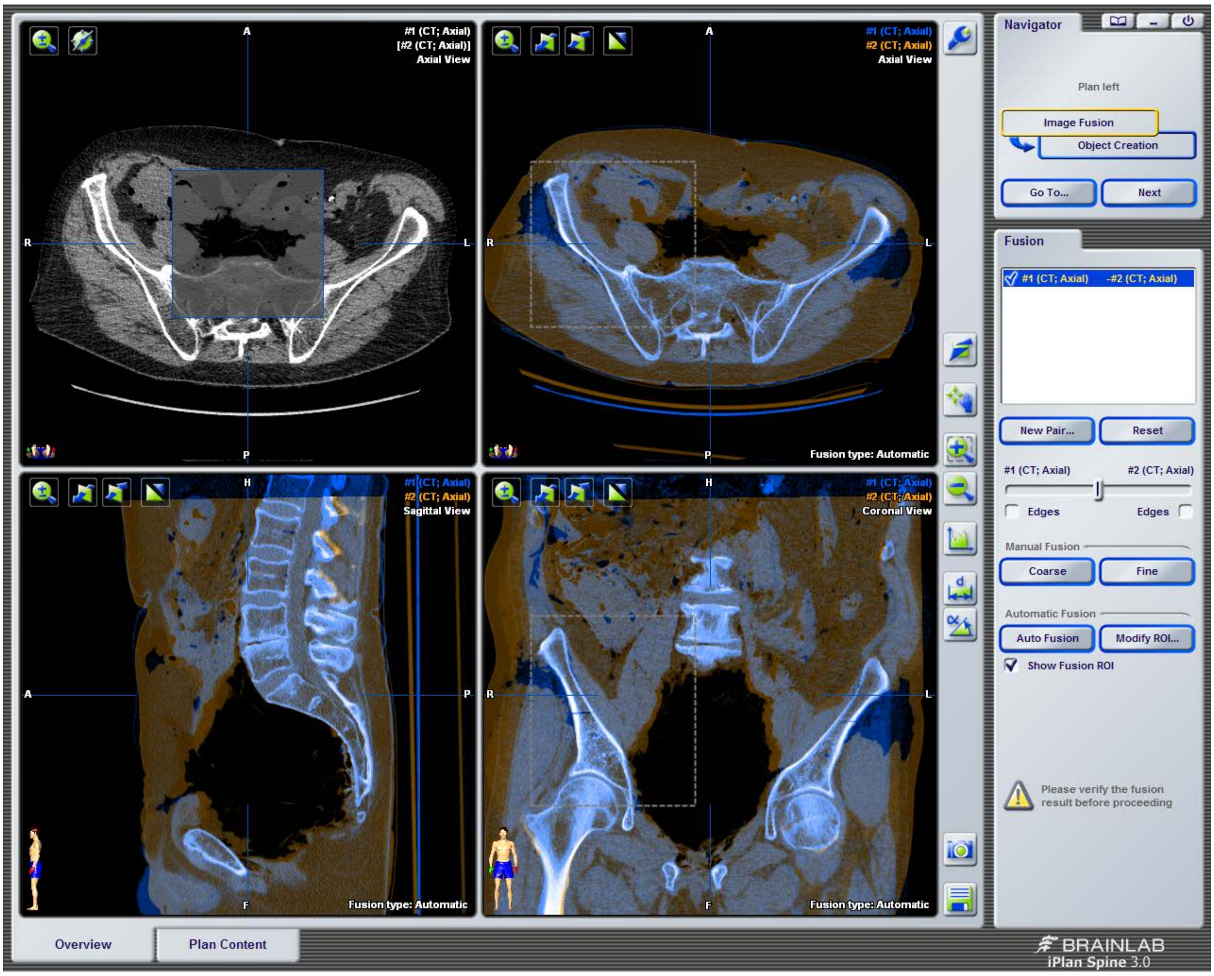


Figure 20 - Preoperative and postoprative CT after image fusion

The preoperative CT data is depicted in blue. The postoperative CT data is shown in yellow.

In the next step the postoperative CT data was segmented to create 3D data (polygonal surface models in STL format) with Amira (Visage Imaging, Inc., San Diego, California, USA). The coordination system of the scans remained available after segmentation with Amira. Afterwards the data were transferred to the 3D CAD software BioCAD

(Technical University Munich, Germany). This is a CAD program for medical purposes. The evaluation of accuracy in BioCAD for the study group was performed with the help of the software programmers and developers Dr. Heiko Gottschling and Dr. Manuel Schröder of the Department of Orthopedics at the Technical University Munich. The planned trajectories were included by drawing rods according to the planned trajectories' coordinates. Best fittings planes of the actual sawed osteotomies were calculated with a least square algorithm (figure 23 and 24).

For the evaluation of the control group the software Mimics Innovation Suite (Materialise, Leuven, Belgium) was used. As in the study group, the preoperative and postoperative data were fused. Again, best fittings planes of the freehand osteotomies were calculated with a least square algorithm.

Fitting planes with a least square algorithm is in accordance with the literature and ISO standards (Cartiaux 2009) (Cartiaux 2013) (Postl 2017).

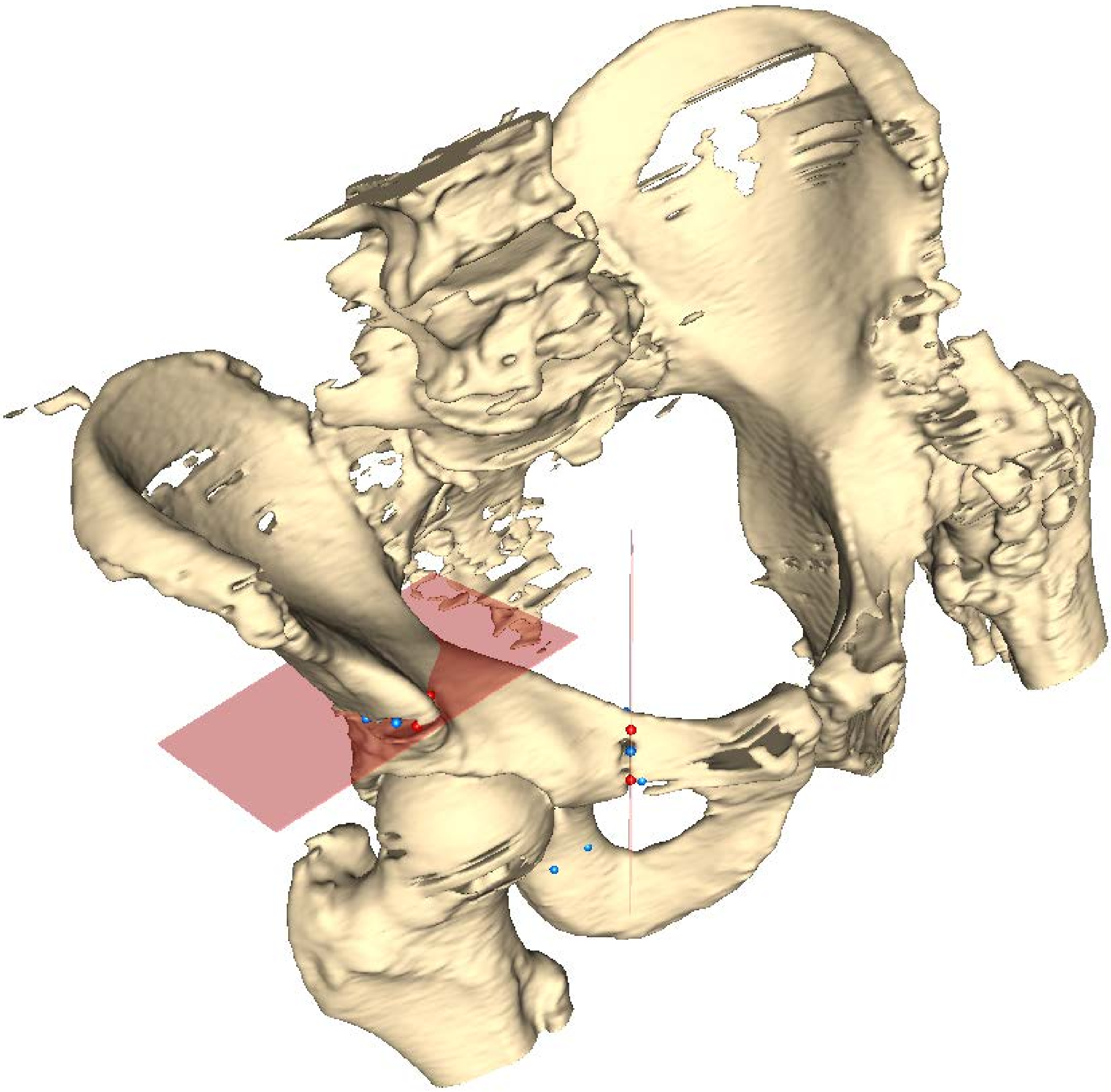


Figure 21 - Evaluation of accuracy at the ilium

The segmented data of a pelvis. The best fitting planes of the actual osteotomies are depicted in red. The planned trajectories are shown as blue rods.

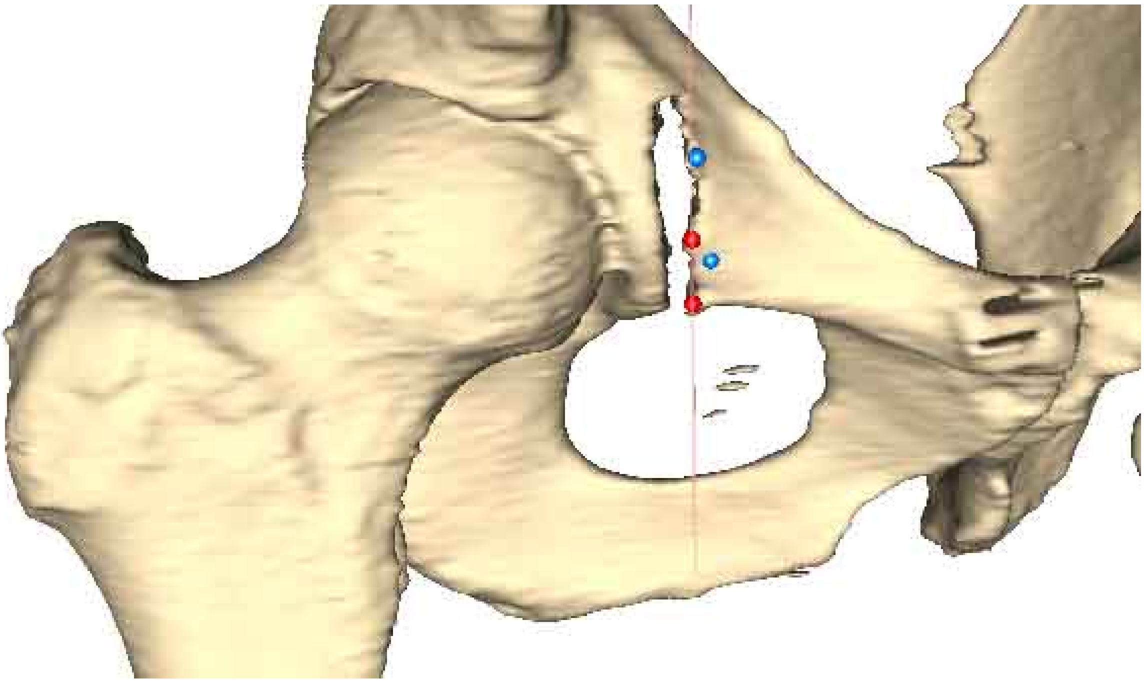


Figure 22 – Evaluation of accuracy at the pubis

The best fitting plane was calculated with a least square algorithm and is shown in red. The planned trajectories are depicted in blue.

The target planes (planned planes) could easily be drawn based on the planned trajectories. This meant that both the planned planes and the actually sawed planes were then available for evaluation.

Cartiaux et al. have evaluated the ISO 1101 standard regarding bone osteotomies and they found that the location (L) was the most relevant parameter for cutting errors (Cartiaux 2009) (Postl 2017). Therefore, in accordance with the ISO 1101 standard (ISO 2005) and the literature (Cartiaux 2009) (Cartiaux 2013) (Cartiaux 2014) the accuracy was described by the location (L) (Postl 2017). The location (L) is defined as the maximum distance (in mm) between the target (planned) plane and the actual osteotomy plane (Cartiaux 2009) (Postl 2017).

3.10 Statistics

Data is given in mean values ± standard deviation, which were calculated with IBM SPSS Statistics 22 (IBM, Armonk, New York, USA) (Postl 2017). Normal distribution was proofed with the software Sigma Stat 3.1 (Systat Inc, Chicago, IL, USA) (Postl 2017). In case of normally distributed data QuickCalcs (GraphPad Software Inc., La Jolla, California, USA) was used for comparison of navigated and freehand osteotomies with two- sample unpooled t-test for unequal variances (Welch's t-test) (Postl 2017). In case of an arbitrarily distributed data the Mann Whitney U test was performed with Sigma Stat 3.1 (Systat Inc, Chicago, IL, USA). The graphs were produced with IBM SPSS Statistics 22 (IBM, Armonk, New York, USA) (Postl 2017).

4. RESULTS

4.1 Specimen

A total number of eight hemipelvises could be included. After the preoperative scan one hemipelvis showed a bone tumor and was excluded. Therefore, seven hemipelvises were finally used in this study. These hemipelvises showed intact bone in the preoperative CT scan and there was no evidence of a history of fractures, tumor or surgery. On average the cadavers were 59.4 ± 21.8 years of age, the height was 173 ± 4.6 cm and the weight was 77.3 ± 12.5 kg (Postl 2013).

4.2 Adapting a navigation system for pelvic tumor resections

4.2.1 Choice of navigation system and its adaptation

Since software solutions for navigated osteotomies of the pelvis were rare we firstly had to find a system which would still allow navigated osteotomies at the pelvis. In previous studies, navigation systems for other areas such as the spine were adapted for use in pelvic tumor surgery (Krettek 2004, Wong 2007a, Wong 2007b). After several tests and with the help of the manufacturer, we also adapted a navigation system that was developed for navigated procedures at the spine (VectorVision with iPlan spine 3.0, Brainlab, Feldkirchen, Germany).

4.2.2 K-wires as guidance

The system provides instruments that can be visually located and therefore direct navigation of certain surgical steps is often possible. However as described above it is not promising to directly navigate an oscillating saw. The flexibility of the sawblade and its jerking movements and vibrations impede this aim (Postl 2017). Furthermore, it is extremely hard to precisely start an osteotomy due to the initial drifting of the saw blade on the bone surface (Postl 2017). For this reason, a solution was sought to increase the potential accuracy. Prof. Dr. med. Rainer Burgkart remembered that K-wires were already used decades ago as guidance for osteotomies. The idea was born to insert K-wires into the bone by navigation and to use it as guidance for the oscillating saw. Under the condition of constant contact between the saw blade and the K-wires, a possible initial drift could be avoided. It was also not necessary to track the saw directly, which seemed problematic due to the vibrations. To our best knowledge this method was not described in the literature for navigated pelvic osteotomies at the time this study was accomplished.

K-wire as guidance for osteotomies could be used for resections without any problems. All K-wire guided cuts could be performed with continuous contact of the saw blade with both K-wires (Postl 2017).

4.2.2 CT-fluoro registration for pelvic osteotomies

CT-fluoro registration has been seen as an innovative registration method and is very promising in terms of accuracy, however there was very little experience regarding its application for pelvis osteotomies. Comparison of the accuracy of resection margins in a study of tumor resections at various sites showed that CT fluoroscopy matching was significantly more accurate than a combination of paired point and surface matching (So 2010). This is why we decided to use this new, promising method in this work.

In our series, the registration process could be accomplished without any problems for all seven hemipelvises.

4.3 Supraacetabular Osteotomies

The deviation as described by the location (L) accounted for 1.9 ± 1.0 mm (n=7) for the navigated group and 9.2 ± 3.2 mm (n=7) for the freehand control group (Postl 2017). Both datasets (table 1 and figure 25) turned out to normally distributed. The two-sample unpooled t-test for unequal variances (Welch's t-test) showed a p-value of less than 0.0001 (Postl 2017). As the p-value was lower than the alpha level (0.05) the null hypothesis was rejected (Postl 2017). This means that the difference between the group was considered as statistically significant. The accuracy of the navigated procedures was significantly higher than the accuracy of the freehand procedures.

Hemipelvis	Navigated osteotomies Deviation [mm]	Freehand osteotomies Deviation [mm]
I	3,8	6,8
II	1,2	11,4
III	1,5	9,3
IV	1,7	13,2
V	1,2	4,5
VI	2,9	11,9
VII	1,0	7,1
Mean	1.9 ± 1.0	9.2 ± 3.2

Table 1 - Deviations of supraacetabular osteotomies at the ileum

Deviation values in mm as described by the location (L) for both groups (Postl 2017). Data has already been published in (Postl 2017).

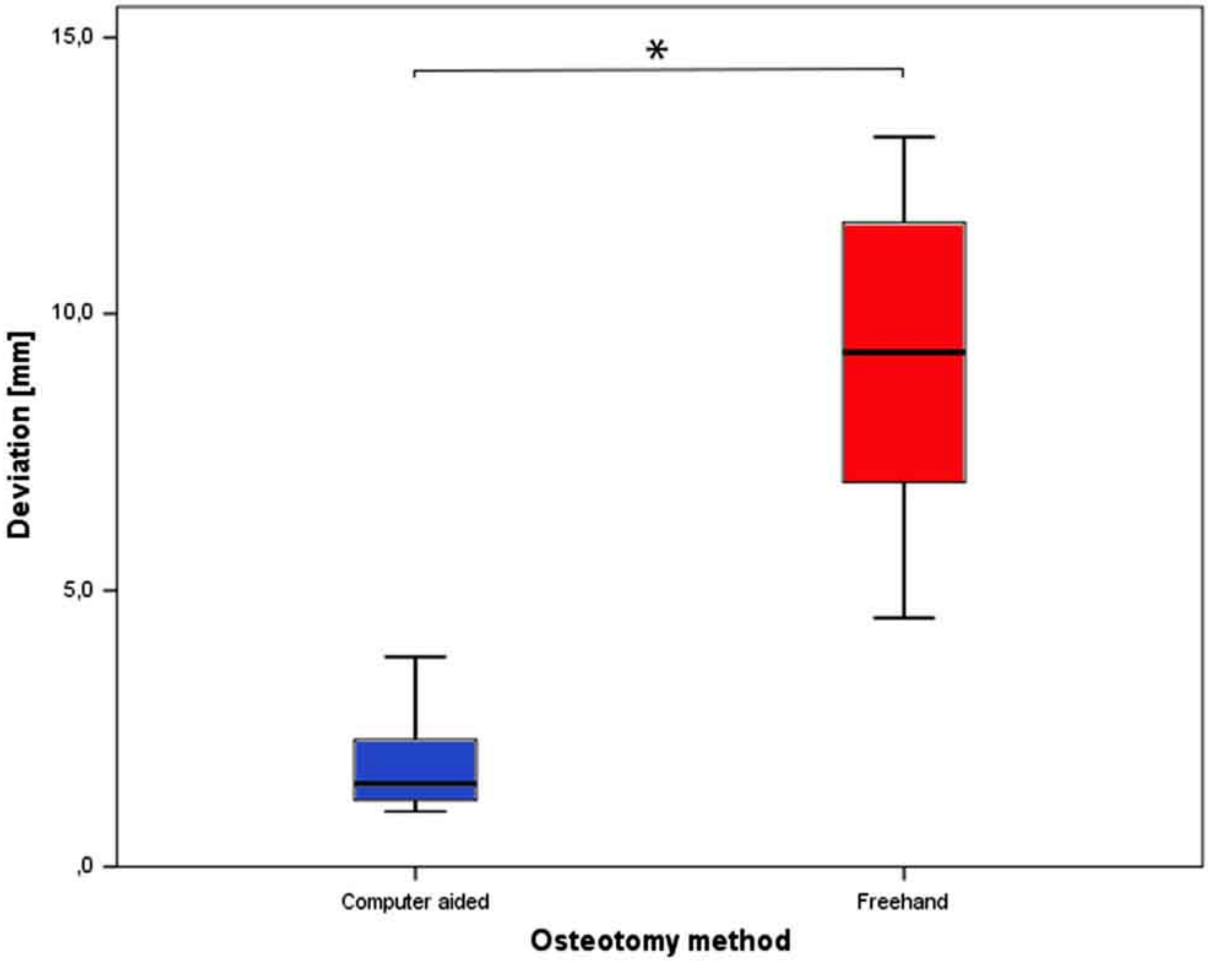


Figure 23 – Accuracy of supraacetabular resections

The figure contains box plots comparing the navigated group with the freehand group by means of deviation values described by the location (L) as defined in the materials section (Postl 2017). The boxes range from the first to the third quartile of values. The symbol “*” indicates a significant difference with a p-value of less than 0.0001 according to Welch’s t-test.

Reprinted from “Potential accuracy of navigated K-wire guided supra-acetabular osteotomies in orthopedic surgery: a CT fluoroscopy cadaver study” by Postl LK, Kirchhoff C, Toepfer A, Kirchhoff S, Schmitt-Sody M, von Eisenhart-Rothe R, Burgkart R, 2017, The international journal of medical robotics and computer assisted surgery, page number 5. Copyright 2016 by " John Wiley & Sons, Ltd". Reprinted with permission.

4.4 Infraacetabular Osteotomies

The Location (L) was 3.2 ± 1.9 (n=7) for the navigated group and 7.9 ± 4.2 (n=7) for the freehand control group. Normal distribution was found for both groups and the Welch's test revealed a p-value of 0.019. The null hypothesis was rejected. Again, the significant difference between the groups suggested that navigated osteotomies were significantly more accurate than freehand procedures (figure 26 and table 2).

Hemipelvis	Navigated osteotomies Deviation [mm]	Freehand osteotomies Deviation [mm]
I	1,4	8,7
II	3,2	5,2
III	6,2	7,9
IV	1,7	3,1
V	1,4	15,6
VI	5,4	4,8
VII	2,9	10,3
Mean	3.2 ± 1.9	7.9 ± 4.2

Table 2 - Deviations of infraacetabular osteotomies at the pubis

The location (L) is given for each procedure in mm.

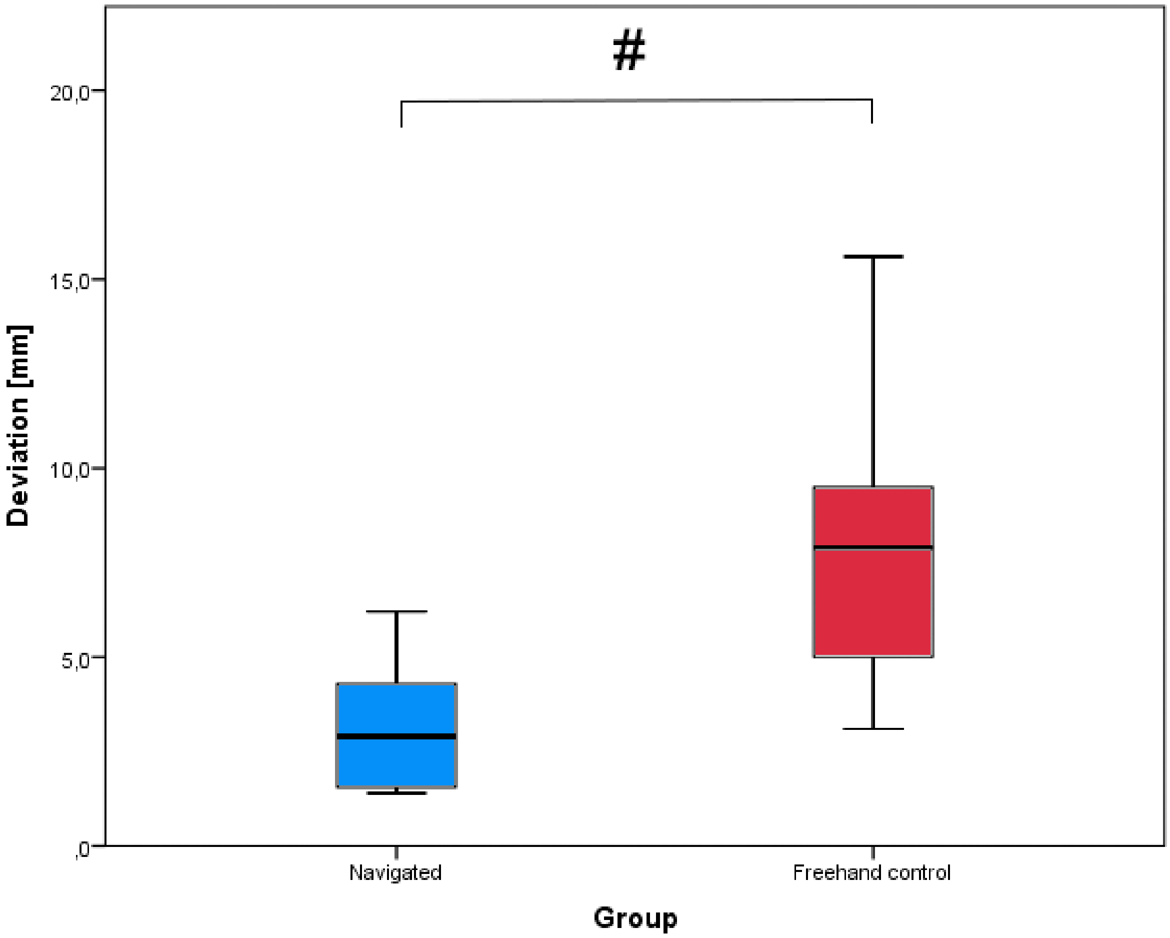


Figure 24 – Accuracy of infraacetabular resections

The figure contains box plots showing the data of the infraacetabular osteotomies. The boxes range from the first to the third quartile of values. The symbol "#" indicates a significant difference with a p-value of 0.019 according to Welch's t-test.

4.5 Comparison of groups

Comparing the supraacetabular navigated osteotomies (1.9 ± 1 mm; n=7) with the infraacetabular navigated osteotomies (3.2 ± 1.9; n=7) with Welch's t-test revealed a p-value of 0.135. The supraacetabular freehand osteotomies (9.2 ± 3 mm; n=7) were compared to the infraacetabular freehand osteotomies (7.9 ± 4.2; n=7) with Welch's t-test and a p-value of 0.518. Thus, there was no evidence against the null hypothesis in both comparisons. A significant difference could not be found (figure 27).

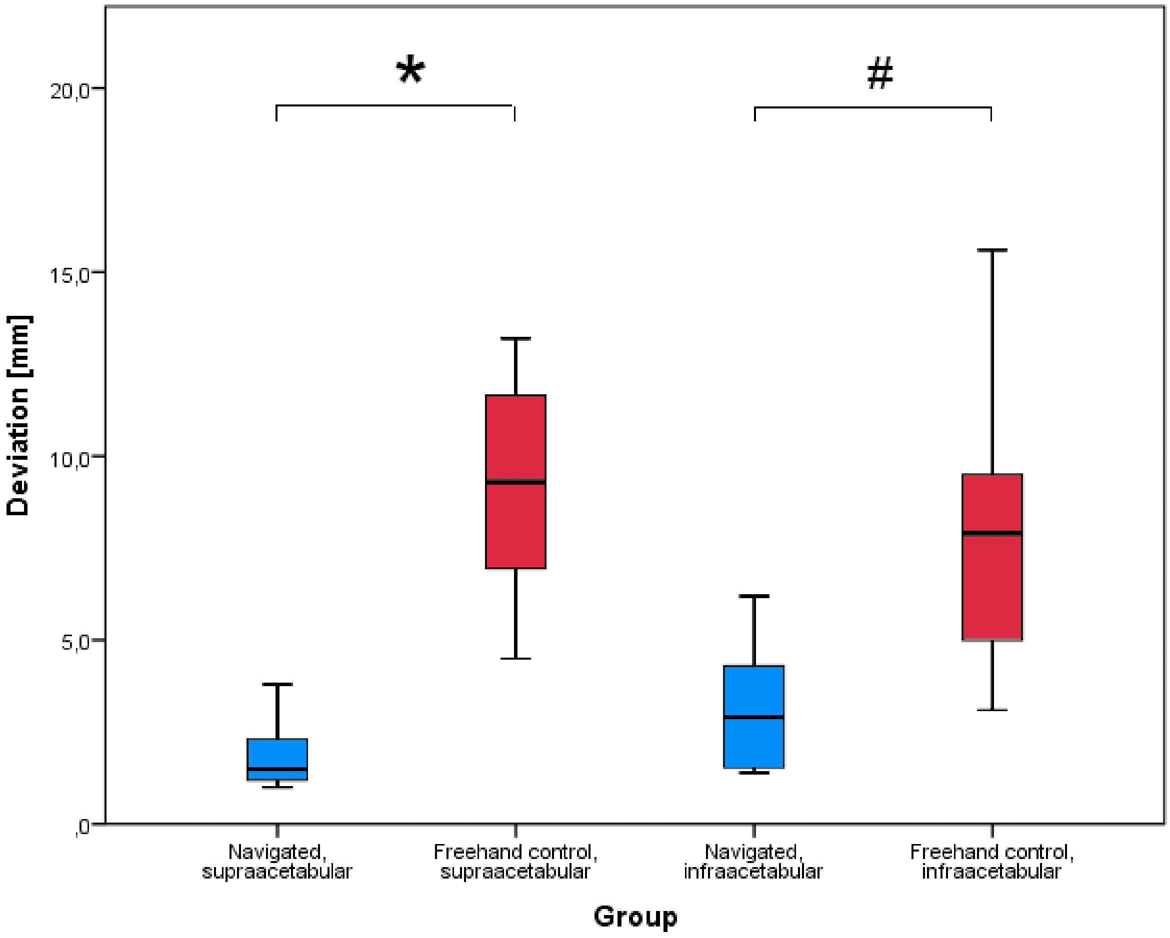


Figure 25 - Accuracy of supraacetabular and infraacetabular resections

The figure contains box plots showing the data of all groups. The boxes range from the first to the third quartile of values. The symbol “#” indicates a significant difference with a p-value of 0.019 according to Welch’s t-test. The symbol “*” indicates a significant difference with a p-value of less than 0.0001 according to Welch’s t-test.

4.6 Overall

The Location (L) turned out to be 2.5 ± 1.6 mm (n=14) for all navigated osteotomies and 8.6 ± 3.6 mm (n=14) for all freehand osteotomies. The navigated dataset was not normally distributed. The Mann Whitney U test revealed a p-value of less than 0.001. Accordingly, the null hypothesis was rejected and the difference was considered as statistically significant. Overall, the navigated procedures were significantly more accurate than the freehand procedures (figure 28 and table 3).

Osteotomy Number	Navigated procedures Deviation [mm]	Freehand procedures Deviation [mm]
1	3,8	6,8
2	1,2	11,4
3	1,5	9,3
4	1,7	13,2
5	1,2	4,5
6	2,9	11,9
7	1,0	7,1
8	1,4	8,7
9	3,2	5,2
10	6,2	7,9
11	1,7	3,1
12	1,4	15,6
13	5,4	4,8
14	2,9	10,3
Mean	2.5 ± 1.6	8.6 ± 3.6

Table 3 - Deviations of all resections

Summary of all procedures (osteotomies). The location (L) is given in mm.

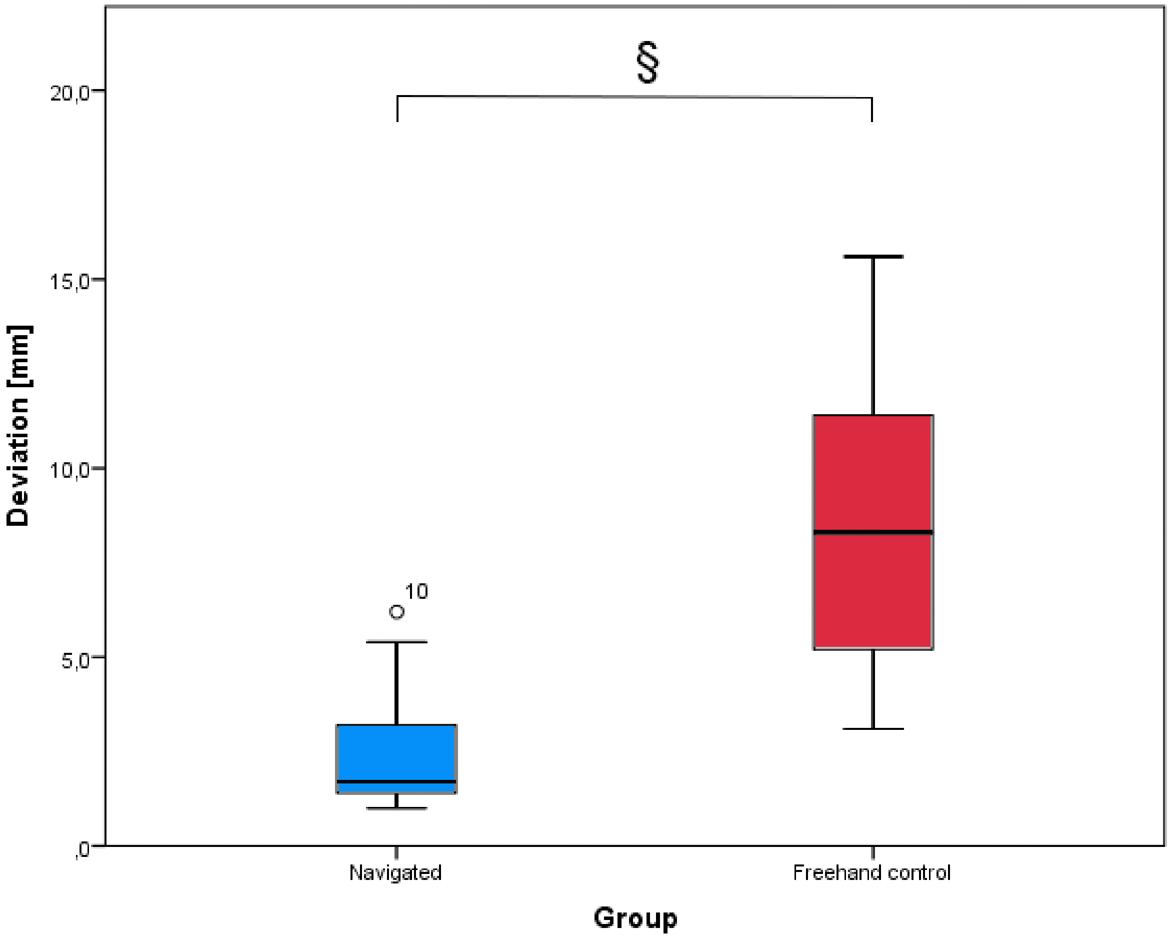


Figure 26 - Accuracy of all resections

The figure contains box plots showing the data of all navigated procedures in light blue and of all freehand procedures in red. The boxes range from the first to the third quartile of values. The symbol “§” indicates a significant difference with a p-value of less than 0.001 according to the Mann Whitney U test.

5. DISCUSSION

The present work investigated the accuracy of computer-assisted tumor resections at the pelvis using human full-body cadavers and under realistic operation room conditions. In this context, K-wires were inserted with the aid of a navigation system, which served as a guide for an oscillating saw.

The same planning was used for 14 computer-assisted resections on human full-body cadavers and for 14 freehand resections on 3D printed customized pelvises with identical geometry. Seven resections were carried out supraacetabularly and infraacetabularly respectively. The evaluation showed that in both supraacetabular and infraacetabular resections the accuracy in the computer-assisted group was significantly higher than the accuracy in the free-hand control group. Overall, computer-assisted osteotomies were also significantly more accurate than freehand osteotomies.

The subsequent study thus delivers promising results and suggests that a clinical application of the method is useful at least in terms of accuracy. Before transferring the presented technique to the clinic, it must be discussed in detail. This is the subject of the following subsections:

5.1 Human full body cadavers in operation room setting

In the present study, full-body cadavers that were over 18 years of age at the time of death were used for the evaluation (Postl 2017). The minimum age ensured that adult pelvises could be used and special characteristics of children's pelvises (such as bone areas that had not yet been ossified) were avoided. In addition, adult corpses are more frequently available at the Institute of Forensic Medicine. Exclusion criteria were bony defects, fractures, a history of surgery, tumors or cysts in the respective hemipelvis (Postl 2017). Corpses that were previously used for study purposes were also excluded (Postl 2017).

In this context, it should be noted that the pelvic bone quality may have affected visualization on fluoroscopic images (Postl 2017). Especially in the area of the pelvis, which has a very complex geometry, bony anomalies could have caused problems due to superposition (Postl 2017). Implants or other foreign bodies with high radiopacity could have caused artifacts in both fluoroscopic images and CT images. Thus, especially implants or foreign bodies could have influenced the accuracy and robustness of CT-fluoroscopy matching (Postl 2017).

The experimental setup for the computer-assisted resections was very similar to the clinical setup of orthopedic surgeries (Postl 2017). Only anesthesiologists were not present and anesthesia was not simulated. The navigation system and the C-arm were brought by truck to the Institute of Legal Medicine, which was very difficult. However, this was still reasonable because it allowed us to gain relevant data for the clinical use of navigation systems in tumor surgery of the pelvis and the effort was necessary from a legal and ethical point of view.

5.2 3D printed pelvises with identical geometry as controls

In order to be able to use the planning of the computer-assisted group for the freehand group, 3D printed pelvises with identical geometry as the pelvises of the human cadavers were produced (Postl 2017). This is certainly a limitation of this work. The printed pelvises did not have soft tissue (Postl 2017). The bony shape was clearly visible and all areas of the pelvises were easily accessible (Postl 2017). In summary, the control group had ideal laboratory conditions (Postl 2017). Therefore, it has to be assumed that freehand resections in a human cadaver control group would have been more difficult and that the accuracy might have been lower for this reason (Postl 2017). Based on this assumption, it could therefore be assumed that the accuracy of the control group used in this study was higher than the accuracy that could have been achieved with a human cadaver control group (Postl 2017). Since the accuracy of the control group was found to be significantly lower in this study than in the computer-aided group, it should be permissible to conclude that a significant difference could have also been observed if a cadaver control group had been used. As the control group did not have soft tissue, as mentioned above, a surgical approach was not necessary. Thus, a comparison of the duration of the procedures was not reasonable and was therefore not made.

On the other hand, the use of 3D printed pelvises with geometries identical to the pelvises of the study group also has advantages. Due to the identical geometry, it was possible to use the same planning in the control group as in the study group (Postl

2017). This reduces potential errors, which could have been caused by another geometry or planning (Postl 2017).

In a control group with free hand resections in human cadavers it would have been advisable to perform the free hand resections on the contralateral side. Compared to this study design, our design has also been able to avoid potential errors due to the handedness of the surgeon (Postl 2017). It should also be kept in mind that only a limited number of human cadavers were available. Also, from an ethical point of view, the number of experiments should have been limited to the minimum necessary. The use of 3D printed pelvises with identical geometry supported these demands.

5.3 Navigation system with planning software

The Brainlab VectorVision navigation system (VectorVision with iPlan spine 3.0, Brainlab, Feldkirchen, Germany) was developed for use in spine surgery, as the name of the software suggests. As already mentioned above, special navigation solutions for tumor surgery of the pelvis were hardly available. Since previous studies have already successfully adapted navigation systems that were developed for the spine for pelvic osteotomies, the VectorVision system was also used for this study. (Krettek 2004, Wong 2007a, Wong 2007b).

5.4 CT-fluoro registration

According to Oliveira et al., image registration in the medical field means aligning two or more images (Oliveira and Tavares 2014). In the case of computer-assisted bony resections at the pelvis, registration was a process that allowed the navigation system to align the preoperative CT data with the corpse on the surgical table (Cleary and Peters 2010). For this purpose, the preoperative CT images were loaded onto the navigation system. The navigation system automatically reconstructed the bony structures from the CT data via segmentation. The system had two cameras and was therefore theoretically able to detect the position of objects in the operating area. However, since the bony pelvis was covered with soft tissue, the system could not determine its position by an optical procedure only. To solve this problem the system required a reference base with three marker spheres, which was attached to the iliac crest with screws. Now two X-ray images were made with the C-arm in different orientation. This allowed the navigation system to complete the registration process by aligning the CT images with the X-ray images from the C-arm. The position of the pelvis at the time of registration was thus determined by CT-fluoro matching. The position could now also be tracked (in case of movements) via the three marker spheres. This required that the three marker spheres were visible for the two cameras. The CT-fluoro registration used in this study, is a rigid registration method.

Generally, two different types of registration can be distinguished: rigid registration and nonrigid/deformable registration (Cleary and Peters 2010, Zheng 2007). In rigid procedures, only rotations and translations are used for alignment (Cleary and Peters 2010). While rigid procedures are suitable for bone surgery, nonrigid methods are interesting for surgery of highly deformable organs such as abdominal surgery (Cleary and Peters 2010)

Commonly used rigid methods are paired-points and surface matching (Zheng 2007). However in a study by So et al, several rigid registration methods in tumor resections were evaluated in different localizations (So 2010). It was found that CT-fluoro registration was significantly more accurate than a combination of paired point and surface matching (So 2010). For this reason, this registration procedure was selected for this study, although little experience with this procedure has been gained so far. In our series the method could be used without any problems. The satisfactory final results with significantly more accurate computer-assisted resections than freehand resections qualify this method for further studies in pelvic tumor surgery. In this regard it should be noted that the errors of the individual steps (such as registration, insertion of the K-wire, errors during guided resection) were not detected (Postl 2017). This is a limitation of this study. However, the total deviation is clinically most important and the evaluation of the intermediate steps is very difficult and therefore these were not determined (Postl 2017).

5.5 K-wires as guidance for oscillating saw

As mentioned above, the use of oscillating saws for osteotomies is an established method in orthopedics (Baumgart 1998). However, there are some points that can reduce the accuracy of osteotomies using oscillating saws. Although thin saw blades can be mounted, the initial drift of an oscillating saw makes it difficult to precisely start an osteotomy on the bone surface. (Postl 2017). The navigation system is able to track instruments using marker spheres, but in the case of an oscillating saw this is difficult due to the vibrations (Postl 2017). In addition, the thin saw blades of an oscillating saw can be bent easily (Postl 2017). This would lead to a large deviation if the navigation used marker spheres on the saw handle for tracking. According to the first aim of this thesis the osteotomies should be performed as accurate as possible. Potential sources of error such as the points mentioned above should therefore be avoided. In this context, customized osteotomy guides have already been used clinically in tumor orthopedics of the pelvis (Holzapfel 2014). The osteotomy guides were produced by the manufacturer of the prostheses and it was described that the method simplified tumor resection and that the clinical and oncological outcomes were acceptable (Holzapfel 2014). A determination of the accuracy of resections and a comparison with a freehand control group were not performed and but this seems difficult to realize in a clinical study. Certain disadvantages of commercially produced osteotomy guides are additional costs and the fact that their production takes some time. When using a prosthesis, the production time is probably not a disadvantage, as the prosthesis also has to be produced first. However, in the case of other reconstruction methods, the production of osteotomy guides could lead to delays. A Belgian study on synthetic bone recently used customized saw guides made of polyamide, which were produced via rapid prototyping before the operation (Cartiaux 2014). This is an interesting approach. However, prior to our work considerations were made as to how a saw can be guided without preoperatively producing osteotomy guides. K- wires as guidance for osteotomies with oscillating saws had already been used decades ago by orthopedic surgeons. It was decided to adapt this method for the use in this study. The K-wires should be inserted with the aid of the navigation system. This method has certain advantages, since no customized osteotomy guide has to be manufactured. Provided that a navigation system with the corresponding instruments is available, low additional costs arise and also a time delay for the production of osteotomy guides is avoided. When using K-wires as guidance for the saw, a direct tracking of the saw was not necessary and errors due to the initial drift did not have to be feared. This method could be used in our series without problems. It could therefore be a promising method, but further studies are necessary to confirm our results.

5.6 Discussion of results

A mean deviation of 1.9 ± 1 mm was found for the supraacetabular computer-assisted resections. This was significantly more accurate than the mean deviation of 9.2 ± 3.2 mm in the freehand control group. Postl et al state that ‘the supra-acetabular osteotomy at the ileum is of central and outstanding clinical importance in endoprosthetic procedures’. This seems also true for other reconstructions methods such as allografts. The reason for this statement is that the position of an implant and thus the position of the rotation center of the hip joint is mainly determined by the supraacetabular resection. (Postl 2017). While implants in periacetabular tumors require stable anchorage in the ileum or sacrum, the pelvic ring does not necessarily have to be closed (Postl 2017) (Windhager 2003) (Rechl 1998b). The load transfer from the lower extremity to the skeleton takes place mainly via the supracetabular anchorage (Postl 2017). For these reasons, the accuracy of supraacetabular resection affects the biomechanics of the hip joint including load transfer and muscle forces (Postl 2017). An average accuracy of less than 2 mm for supracetabular osteotomies can be considered as clinically acceptable, also in comparison with the results of synthetic bone studies in the literature (Cartiaux 2013, Cartiaux 2014).

In this study infraacetabular resections were also performed. Here, a mean deviation of 3.2 ± 1.9 was found for the computer-assisted osteotomies. This was again significantly more accurate than the freehand resections in this area, which showed a mean deviation of 7.9 ± 4.2 mm.

In a study of Cartiaux et al on synthetic bones supraacetabular computer-assisted resections at the ileum were significantly more accurate than computer-assisted infraacetabular resections. In our series the nominal deviation is more than twice as high as in supraacetabular computer-assisted osteotomies compared to infraacetabular ones, but no significant difference was found in the comparison of the groups. Due to the small number of osteotomies, a type II error may have been occurred. This would mean that a larger sample size could have shown that, for example, that the supraacetabular osteotomies were actually more accurate than the infraacetabular ones. If this was the case, the question should be asked why the infraacetabular resections should have been less accurate than the supraactebular ones. One reason could be the distance of the reference base with the marker spheres from the osteotomies. The reference base had been attached to the iliac crest before the registration process and was left at this position for both the supraacetabular und the infraacetabular procedures. Due to the greater distance between the reference base and the infraacetabular area, errors during registration would have had a greater effect here. In addition, it is theoretically imaginable that the insertion of the supraacetabular K-wires has influenced the reference base: Although only little vibration occurred when inserting the K-wires in the supraacetabular region, it cannot be completely excluded that a slight misalignment of the reference base had taken place as a result of this process.

No significant difference could also be found between supracetabular and infraacetabular freehand resections. Here too, however, it cannot be ruled out that a type II error occurred due to the small sample size. This means that a larger sample size might have shown that there was a difference between the groups.

Overall a mean deviation of 2.5 ± 1.6 mm was found for all computer-assisted resections. This was again significantly more accurate compared to all freehand resections, which showed an average deviation of 8.6 ± 3.6 mm. The overall results confirm, as do the partial results, that the used method is promising in terms of accuracy.

5.7 Further limitations

Several other limitations of this study should be mentioned (Postl 2017). First, it should be noted that the number of resections was limited (Postl 2017). However as stated above, human corpses are rare. Although the comparison of the study group with the control group was also significant with the number used here, further research in larger human cadaver studies or clinical research would be of great value (Postl 2017). Another limitation is that radiation exposure has not been studied. (Postl 2017). This should be included in future study designs.

6. CONCLUSION AND OUTLOOK

6.1 Conclusion

The first objective of this work was the adaptation of a navigation system for pelvic tumor resections. The second aim was to compare supracetabular computer-assisted and freehand resections. Thirdly, infra-acetabular resections should also be compared accordingly. Fourth, the supracetabular computer-assisted resections should be compared with the infracetabular computer-assisted resections and the supracetabular freehand osteotomies should be compared with the infraacetabular freehand osteotomies. Finally, all computer-assisted resection should be compared with all freehand resections.

For this purpose, a total of 14 computer-assisted resections were performed on seven hemipelvises and 14 freehand resections were performed on seven 3D printed pelvises with identical geometry.

With regard to the objectives of the study, the following conclusions can be made:

I. A navigation system for the spine (VectorVision with iPlan spine 3.0, Brainlab, Feldkirchen, Germany) was adapted for the use in pelvic tumor surgery. CT-fluoro registration was performed (Postl 2017). K-wires were inserted with the help of the navigation system and served as guidance for the oscillating saw.

II. The computer-assisted pelvic supracetabular tumor resections turned out to be significantly more accurate than the corresponding freehand resections (Postl 2017).

III. Computer-assisted resections were also significantly more accurate in infraacetabular procedures.

IV. No significant difference between supraacetabular and infraacetabular computer-assisted resections could be found. Also, no significant difference was found between supraacetabular and infraacetabular freehand procedures.

V. The comparison of all 14 computer-assisted resections with all 14 freehand resections showed again that the computer-assisted procedures were significantly more accurate.

The present study was able to show that under realistic operation room conditions the above described navigation system can be successfully used for tumor resections at the pelvis and that computer-assisted resections are more accurate than freehand resections. These were important findings to facilitate the clinical application of the method.

6.2 Outlook

In the area of pelvic tumor surgery, the results of this work have shown that the accuracy of computer-assisted resections is significantly higher than the accuracy of freehand resections. These were important results to justify the clinical use of computer-assisted resections. Today (2018) computer-assisted resections are already evaluated on patients at the Clinic of Orthopedics and Sportorthopedics (Klinikum rechts der Isar, Technische Universität München). Several advantages of navigation will also become evident in clinical use. However, computer-assisted surgery today is certainly still more complex than freehand surgery. Nevertheless, it is also certain that technical development will not stand still, and many disadvantages of computer-aided surgery will be addressed in the future. Due to continuous further development in the field of imaging, CAD/CAM technology and navigation, computer-assisted surgery will become increasingly important in the future.

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8. APPENDIX 1: PUBLICATION

The following publication arose from this thesis and is included in the following:

Postl, L. K., Kirchhoff, C., Toepfer, A., Kirchhoff, S., Schmitt-Sody, M., Eisenhart-Rothe, R., & Burgkart, R. (2017). Potential accuracy of navigated K-wire guided supra-acetabular osteotomies in orthopedic surgery: a CT fluoroscopy cadaver study. *The International Journal of Medical Robotics and Computer Assisted Surgery*, *13*(2).

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ORIGINAL ARTICLE

Potential accuracy of navigated K-wire guided supra-acetabular osteotomies in orthopedic surgery: a CT fluoroscopy cadaver study

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Abstract

Background The aim of this study was to evaluate the accuracy of supra-acetabular pelvic tumor resections in human, full-body cadavers and under realistic operation room conditions with the help of a navigation system and K-wires as guidance for the oscillating saw.

Methods Seven hemipelvises from fresh, human, male, full-body cadavers were used. A preoperative and a postoperative CT was performed. Under control of the navigation system K-wires were inserted and served as guidance for the oscillating saw to reduce the error by vibration and jerking movements. The accuracy of the computer aided resections was compared with the accuracy of freehand resections in customized 3D printed pelvises with geometries identical to the cadavers used.

Results The mean deviation of the navigated osteotomies was 1.9 mm (standard deviation 1.0 mm) significantly ($P < 0.001$) lower than the mean deviation of freehand osteotomies at 9.2 mm (standard deviation 3.7 mm).

Conclusion Navigated K-wires for supra-acetabular osteotomies allow significantly higher accuracy than freehand procedures under simulated operation room conditions. Copyright © 2016 John Wiley & Sons, Ltd.

Keywords tumor; pelvis; navigation; computer-assisted; accuracy; K-wire

Introduction

Pelvic malignant tumors are often large in size at the time of diagnosis and the complex anatomy of the pelvis makes accurate osteotomies demanding (1–6). But accuracy is crucial for finding the balance between achieving a radical, curative resection and preserving tissue which is important for achieving good functional results.

In pelvis resections, three main types have to be distinguished (Figure 1). These are iliac wing resections (type I), periacetabular resections (type II) and infra-acetabular resections at the Os pubis or Os ischium (type III) (7,8). In type I and III resections, a reconstruction is not mandatory, but in type II (periacetabular) resections, the force transmission from the lower extremity to the axial skeleton has to be reestablished (9). It still remains unclear which

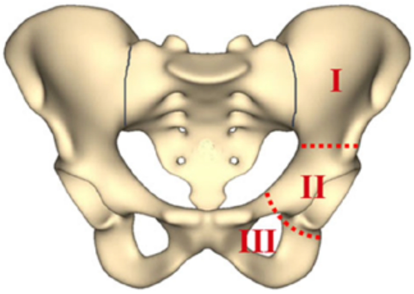


Figure 1. **Classification of resections at the pelvis according to Enneking and Dunham**

reconstruction method is best, but in terms of functional outcome, reconstruction with allografts and pelvic endoprostheses is superior to hip transposition, arthrodesis or even flail hip (10).

Endoprostheses require stable anchoring in the remaining Os ilium for the force transmission between the lower extremity and the axial skeleton (9). Closure of the pelvic ring is not compulsory and some authors are dissuaded from fixation of the prosthesis at the Os pubis or Os ischium due to a reported higher loosening rate (11–13). Therefore, in a periacetabular (type II) resection, the supra-acetabular osteotomy at the Os ilium is of central and outstanding clinical importance in endoprosthetic procedures. An inaccurate supraacetabular osteotomy at the Os ilium leads to a wrong position of the custom-made implant, which is manufactured according to the preoperative planning data. The position of the implant is critical because it determines the rotation center of the hip joint and the biomechanics related to load transfer to the skeleton as well as the muscle forces. In summary, accuracy is mainly important in supra-acetabular resections at the Os ilium in periacetabular resections (type II resection). These supraacetabular resections at the Os ilium were evaluated in this study.

A recent study on saw bone models reported that navigation significantly improves the accuracy of osteotomies in pelvic resections compared with freehand procedures in the saw bone setting (14).

The aim of this study was to evaluate the accuracy of supra-acetabular pelvic tumor resections in human, full-body cadavers and realistic operation room (OR) conditions with the help of a navigation system and K-wires as guidance for the oscillating saw. The accuracy of the navigated resections was compared with the accuracy of freehand resections in customized 3D printed pelvises with geometries identical to the cadavers used. The null hypothesis (H_0) was that there is no difference between the accuracy of navigated osteotomies and freehand osteotomies of the control group. The level of significance α was set to 0.05.

Materials and methods

Seven hemipelvises from fresh, human, male, full-body cadavers from the department of forensic medicine were used after explicit informed consent of the explored subject had been ensured. The cadavers had not been used for other purposes before. The entire cadavers were unrestrainedly placed on a radiolucent table and OR conditions were simulated. The mean age of the cadavers was 59.4 years (standard deviation 21.8 years), the mean height was 173 cm (standard deviation 4.6 cm) and the mean weight was 77.3 kg (standard deviation 12.5 kg). This study was approved by the Ethical Review Board of the Medical Faculty of the Technical University Munich (reference number 113/16 S). Exclusion criteria were morphological osseous pathologies detected via the preoperative CT scan at the pelvis. The navigation process was performed using the Brainlab VectorVision^2 device (Brainlab, Feldkirchen, Germany). All osteotomies in the study and control group were performed by a single, experienced surgeon.

Preoperative CT scans and planning

Preoperative CT scans of the lumbar spine and the entire pelvis including the proximal femur were performed on a GE LightSpeed VCT XTe CT scanner (140 kV, 40 mAs, collimation 0.6 mm, pitch 0.75 mm). DICOM (Digital Imaging and Communications in Medicine) data were transferred to a workstation for segmentation and resection planning (Brainlab iPlan spine 3.0, Brainlab, Feldkirchen, Germany). The supra-acetabular osteotomies at the Os ilium were planned to be oriented from the spina iliaca anterior inferior towards the incisura ischiadica major (Figure 2).

Because of the inherent tool vibrations, direct tracking of an oscillating saw is unstable and leads to immanent inaccuracies due to marker misdetection. Furthermore,

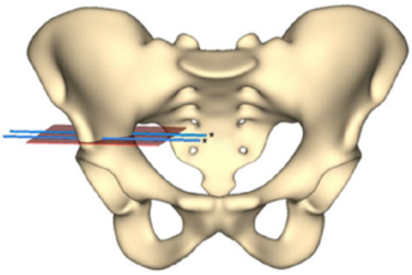


Figure 2. **The figure shows an AP-view of the bony pelvis onto the symphysis. The supra-acetabular osteotomy of the Os ilium is depicted as a red plane. The axes of the K-wires are visualized by blue rods for better understanding (marked with *)**

starting to cut with an oscillating saw on the bone surface is challenging and might result in deviation caused by vibration and jerking movements of the saw. To avoid this, two K-wires inserted in parallel were used to serve as guidance wires for the oscillating saw blade for each osteotomy. After the first K-wire was planned, the second K-wire's position was determined parallel to the first K-wire to create the sawing plane (Figure 2). The distance between the K-wires was 2 cm to ensure stable guidance for the saw blade. While planning a resection, it had to be considered that the whole diameter of the K-wire had to be positioned in the part of the pelvis that was not resected. This is necessary to avoid an offset, which would have been caused by the wires. If the K-wires had been placed centrally at the resection line, an error of half the diameter of the k-wire and the thickness of the saw blade would have occurred.

Operation set up and CT-fluoro registration

Each cadaver was placed on a radiolucent table in a supine position (see Figure 3 for study setup). For the fluoroscopic (CT-Fluoro) registration system, a C-arm (Ziehm Vision Vario C-arm, Nuremberg, Germany) was used. The registration kit (Brainlab, Feldkirchen, Germany) was mounted on the image intensifier of the C-arm (Figures 3 and 4) according to the manufacturer's guidelines. It is needed for calibration of potentially distorted X-ray images and for tracking the C-arm position. According to the manufacturer's guidelines two parallel Schanz screws (diameter 3.5 mm, Synthes, Solothurn, Switzerland) were inserted in the ipsilateral crista iliaca. With a specific mounting device the reference base with three marker spheres (Brainlab, Feldkirchen, Germany) was stably attached to the two Schanz screws (Figures 3 and 4). The whole study setup was arranged specifically to guarantee a steady intervisibility of both navigation cameras to the reference base and the registration kit.

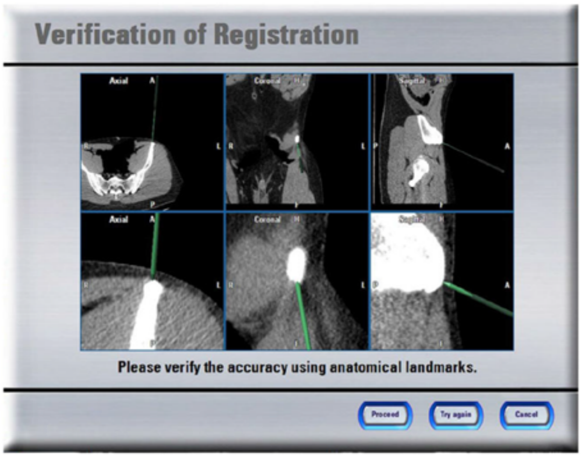
Figure 3. The cadaver (marked with #) was placed on a radiolucent table in supine position. The registration kit was mounted on the C-arm (marked with *). The Brainlab VectorVision2 device (marked with +) is on the left side of the picture. The reference base was fixed with two Schanz screws to the ipsilateral crista iliaca (right to >)

Figure 4. Reference base and registration kit in enlarged view

For an accurate matching process the system requires at least two X-ray images with a minimum of a 30° angle difference between the images. In the present study a vertical posterior–anterior X-ray image and a 40° tilted, oblique medio-lateral X-ray image was used for all operation procedures. The pre-operative CT scan was referenced to X-ray images of the pelvis with the CT-Fluoro matching algorithm. The Brainlab navigation system offers the possibility to evaluate the plausibility of the registration process by aiming with the pointer tool at the surface of different anatomical landmarks of the pelvis. Prominent and precisely detectable anatomical landmarks – the bilateral spinae iliacae superiores and inferiors – were chosen (Figure 5). After we tightly contacted the bone surface with the navigated pointer tip at the specific anatomical landmarks we started an evaluation process of the navigation system using the distance between the virtual pointer tip and the virtual bone surface. If this distance between the displayed virtual pointer tip and the virtual bone surface was larger than 1.5 mm, we restarted the registration process.

Navigated osteotomy

An ilioinguinal approach according to Letournel was performed (15). The K-wires (Kirschner wires, diameter 2 mm, length 310 mm, Aesculap, Tuttlingen, Germany) were inserted (see Figure 6 depicting the procedure) using the navigated drill guide (drill guide 55839-10 with 2.0 mm reduction sleeve, Brainlab, Feldkirchen, Germany). The


Verification of Registration

Please verify the accuracy using anatomical landmarks.

Figure 5. **Checking the registration at the right ipsilateral spina iliaca anterior superior**

Figure 6. **Inserting a K-wire with the navigated drill guide**

oscillating saw was equipped with a saw blade of 95 mm length, 25 mm width and 1 mm thickness (Synthes, West Chester, Pennsylvania, USA).

Postoperative CT scan

After removing the reference base and the K-wires, postoperative CT scans were performed under the same conditions as the preoperative scans and on the same CT scanner in order to quantify the deviation between the planned virtual trajectories and the surgical outcome precisely.

Evaluation

The planning data and the postoperative data (both in DICOM format) were uploaded to iPlan spine 3.0 for image fusion. The fused data were converted into the STL (Standard Tessellation Language) file format, a common CAD (Computer-Aided Diagnosis) format. With a 3D-CAD Software (BioCAD, Technical University Munich, Germany) the best fitting planes of the actually sawed planes were calculated by a least squares algorithm. Fitting planes with a least squares algorithm is a common procedure for evaluation according to the ISO standard (14,16). The deviations of the actually sawed planes from the planned planes were described by the location (L) in accordance with the ISO 1101 standard (17). The location (L) is defined as the maximum distance in mm between the actually sawed plane and the planned (target) plane (16). The ISO 1101 standard was evaluated by Cartiaux *et al.* in 2009 for bone osteotomies and the location turned out to be the most relevant parameter for cutting errors (16).

Control group

To achieve identical bone geometries customized bone models of the cadavers' pelvises were produced by a 3D printer (ZPrinter 650, 3D Systems, Rock Hill, South Carolina, USA) according to the CAD data (STL) of the cadavers' preoperative CT data. Freehand osteotomies were performed according to the preoperative planning. After this procedure a CT scan of all customized bone pelvises was performed under the same conditions as the preoperative scans. Then the deviation of the freehand osteotomies was evaluated exactly as described for the cadaver procedures.

Statistics

The statistical analysis was performed with the support of the Institute of Medical Statistics and Epidemiology of the Technical University Munich. Statistical description was performed by calculating mean values (arithmetic mean) and standard deviations with the software IBM SPSS Statistics 22 (IBM, Armonk, New York, USA). The proof of normal distribution for the study and the control group was provided with software Sigma Stat 3.1 (Systat Inc, Chicago, IL, USA). For comparison of the navigated osteotomies and the freehand osteotomies, Welch's t-test (two-sample unpooled t-test for unequal variances) was performed with the QuickCalcs software (GraphPad Software, Inc. La Jolla, California, USA).

Results

The seven bony hemipelvises showed no osseous pathology on the preoperative CT scan. 14 K-wires were inserted and served as guidance wires. All seven saw cuts were accomplished with continuous contact of the saw blade with both k-wires. On the geometrically identical 3D printed control group pelvises analogous osteotomies were performed. There were no complications during surgery in both the navigated and the control group.

The mean deviation as described by the location (L) according to the ISO 1101 standard (17) accounted for 1.9 mm (standard deviation 1.0 mm, n = 7) for the navigated osteotomies and 9.2 mm (standard deviation 3.7 mm, n = 7) for the freehand control group (Table 1 and Figure 7).

Statistical comparison of the navigated dataset and the free hand group was then performed by Welch's t-test (two-sample unpooled t-test for unequal variances) after a normality check of both datasets has been passed. Welch's t-test revealed a *P*-value of less than 0.001.

As the *P*-value was lower than the alpha level (0.05), the null hypothesis was rejected. A highly significant difference between the accuracy of the navigated group compared with the control group was found ($P < 0.001$). Our data showed that the accuracy of navigated, K-wire-guided supra-acetabular osteotomies under OR conditions was significantly higher than the accuracy of freehand osteotomies in customized 3D printed pelvises.

Discussion

In this feasibility study under realistic OR conditions, the accuracy of navigated supra-acetabular osteotomies in human cadavers was evaluated by comparing the virtual osteotomy planes planned on the basis of preoperative CT scans with the actually, surgically performed osteotomies in the post-operative CT scans. A navigation system was used for K-wire positioning and the K-wires served as guidance for the oscillating saw to perform the osteotomies.

Table 1. Deviation values described by the location (L) in the navigated group and the freehand control group

Osteotomy No,	Navigated group	Freehand group
1	3.8 mm	6.8 mm
2	1.2 mm	11.4 mm
3	1.5 mm	9.3 mm
4	1.7 mm	13.2 mm
5	1.2 mm	4.5 mm
6	2.9 mm	11.9 mm
7	1.0 mm	7.1 mm
Mean	1.9 mm (SD 1.0 mm)	9.2 mm (SD 3.7 mm)

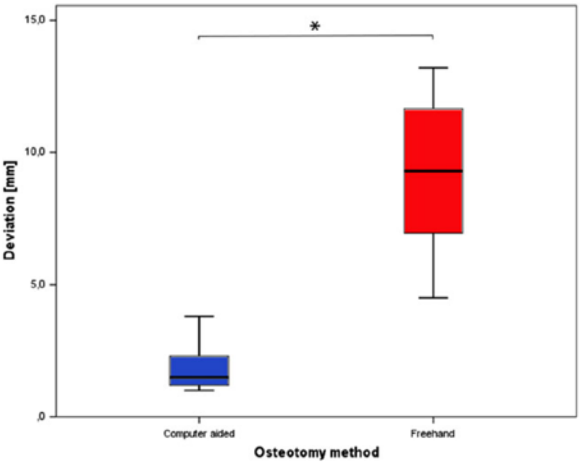


Figure 7. The image shows a box plot of the deviation values described by the location (L) for the navigated group and the freehand control group. The boxes show the range from the first to the third quartile (* $P < 0.001$)

Computer-assisted navigation techniques have been improved continuously over recent years and are nowadays commonly used in spine surgery as well as for distinct steps in knee and hip arthroplasty (18–26). Interestingly, software solutions for navigated pelvic surgery are rare. In previous pelvic studies, the navigation techniques were adapted from other areas such as the spine to the pelvic area (27–30).

A recent study by So *et al*. of navigated tumor resections in various locations using a CT fluoroscopy matching algorithm showed that this CT matching process is superior to other algorithms in terms of accuracy (31). Therefore, this matching method was chosen for navigation of the pelvic area in the presented study, although no comparable human cadaver study has used CT-fluoroscopy matching before. In this regard, it should be mentioned that the pelvic bone quality could affect visualization of bony structures on fluoroscopic images. This could influence the accuracy and robustness of CT fluoroscopy matching. Especially in pelvic applications, this could lead to problems due to superposition, which complicates the feature recognition of matching algorithms. Consequently, morphological osseous pathologies on the preoperative CT scans were defined as exclusion criteria.

Our experimental setup was very close to the clinical setting of orthopedic periacetabular osteotomies at the pelvis, as OR conditions were simulated. This enabled us to provide relevant data with regard to future clinical use. The present study shows that navigation with CT fluoroscopy matching may be performed with an accuracy of approximately 2 mm in a human whole-body cadaver model under simulated OR conditions. From a clinical point of view, these results are adequate when considering the standard tools and procedures used so far – such as freehand procedures or saw templates. In addition, our results show that the accuracy of navigated, K-wire-guided osteotomies under OR conditions is higher than the accuracy of freehand osteotomies in 3D printed control group pelvises.

To use 3D printed pelvises instead of cadavers as a control group presents a clear limitation of this study. The 3D printed pelvises were without soft tissue. Free visibility and accessibility ensured ideal laboratory conditions. Hence, it can be assumed that freehand osteotomies in a cadaver control group would be even more demanding and therefore the accuracy would have probably been even less. On the basis of this assumption the measured deviation values of the present freehand control group are presumably equal or even slightly lower than a cadaver control group.

On the other hand, our customized 3D printed pelvises were geometrically identical to the pelvises of the navigated group and allowed use of the same planning for the navigated group and the control group. This reduces potential bias due to different planning and handedness differences. Cartiaux *et al*. reported a mean deviation of 2.8 mm for computer aided osteotomies and a significantly higher mean deviation of 11.2 mm for freehand osteotomies in their study with a pelvic saw bone model (14). The results of the present study, which were acquired under operation room conditions are comparable with this data from the literature.

The maximum error detected in our study for navigated, K-wire-guided osteotomies was 3.8 mm and therefore we suggest a resection margin of at least 5 mm when using this method.

Of course, several further limitations of this study have to be mentioned. First, the number of osteotomies was limited and further research is needed in terms of larger human cadaver studies as well as in terms of adapting this navigation process to the clinical patient setting. Second, the error of each single step (e.g. registration error) was not evaluated – we intended to analyze the error of the entire navigation process as it is clinically relevant for the end result. And the operation time and radiation exposure were not evaluated.

In conclusion, the results of our whole-body cadaver study provide evidence that navigation allows higher accuracy than freehand procedures and clinical acceptance under simulated OR conditions. The K-wires as guidance wires for the oscillating saw blade were proven to be a precise solution for osteotomies. However, our *ex vivo* cadaver results need to be validated in clinical procedures for tumor patients.

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Conflict of interest

This study was funded by the Wilhelm-Sander Foundation, which is a charitable, non-profit foundation whose purpose is to promote cancer reasearch. Due to the non-profit and charitable nature of the foundation, it may not gain or lose financially from the publication of the article in any way, neither now nor in the future. Therefore, the authors declare that they have no conflict of interest.

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9. APPENDIX 2: ACKNOWLEDGEMENTS

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