Concept for General Improvements in the Treatment of Femoral Shaft Fractures with an Intramedullary Nail

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Abstract: The gold standard for femoral shaft fracture treatment is intramedullary (IM) nailing. This principle has gained acceptance because of the good fracture healing rate and the rapid return to full weight-bearing of the leg. Nevertheless, a significant number of patients suffer from impairments in everyday life years after treatment. This paper discusses various causes and presents possible solutions: a) Improving the IM nailing procedure by developing a new intraoperative assistance system to precisely restore length and rotation angle of the injured femur. b) Improving rehabilitation after IM nailing treatment, through home monitoring. c) Increasing data safety, standardization, and centralization along the entire patient pathway, enabling analytics to statistically verify improvements in IM nailing treatments.

1 INTRODUCTION

Thanks to modern medicine, a femoral shaft fracture can be treated with few complications. Nevertheless, 20% of patients still suffer from after-effects three years post-treatment, reducing their quality of life. These include pain in the lower limbs or an altered gait pattern. One identified cause is an incorrect reconstruction of the rotation angle or length of the femur during surgery. This relationship and possible improvements are presented in more detail below.

Treatment Challenges

Intramedullary (IM) nailing is the most successful treatment for a femur shaft fracture in adults, due to high healing rates with low complication (Rommens & Hessmann, 2015). During treatment with an IM nail, the soft tissue is minimally affected, enabling rapid healing (Fantry et al., 2015). In addition, interlocking with screws provides rotational and longitudinal stability and thus ensuring the conditions for an early return to full weight bearing and a high likelihood of fracture union (Jaarsma & van Kampen, 2004; Paterno & Archdeacon, 2009). Nevertheless, it is still a surgical procedure that carries risks, such as infection or neurovascular injury. Another disadvantage of the minimally invasive procedure is the difficulty to ensure anatomical realignment under direct vision, which leads to less control of rotation and length compared to the classical method of plate fixation (Jaarsma et al., 2004). Deviations from the original position, greater than 5° in frontal or sagittal plane, 15° in the axial plane and 2 cm in length, are regarded to be deformities (Ricci et al., 2008). It originates from a poor choice of nail entry point or incorrect positioning of nail fixation during surgery. The occurrence varies between 22.7 - 28% of the cases (28% (Jaarsma & van Kampen, 2004), 26%

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(Strecker et al., 1996), 22.7% (Rommens & Hessmann, 2015), 25% (Papachristos, 2019)). In general, a not correctly reconstructed femur leads to arthritis and pain of back, hip and knee, limping, restrictions in range of motion and daily life. These complications scale with the severity of the malalignment. (Jaarsma & van Kampen, 2004; Papachristos, 2019). In summary, developing a way to correctly restore the rotation (also known as (ante-) version or (ante-) torsion) and the length of the femur, malalignments could be reduced and therefore the patient's quality of life improved. Common techniques used by surgeons to correctly restore the anteversion angle of the fractured femur are based on determining the anteversion angle of the uninjured leg at beginning of surgery. This angle is used as reference for the injured leg. One well known method to determine a reference for the anteversion is the lesser trochanter method (Deshmukh et al., 1998). Alternatively, the anteversion angle can be measured by using the inclination scale of the C-arm to measure the C-arm angle between the positions required for taking a true lateral image of the knee and a true lateral image of the femoral head-neck junction (Tornetta et al., 1995). Other possible methods for assessing femoral rotation are the cortical step sign method (Langer et al., 2010) and computer tomography (CT) based navigation (Weil et al., 2014). Although several different methods for measuring anteversion exist none of the methods is widely accepted. The fluoroscopy-based methods significantly increase the number of necessary x-ray images and the time needed for surgery (Deshmukh et al., 1998; Tornetta et al., 1995). Additionally, these methods have limited accuracy (Ju et al., 2021). The cortical step sign method has limited value for patients with comminuted fractures, and CT-based navigation causes high costs and long setup time. In conclusion, a widely accepted method to control for anteversion and length of the femur is needed.

Rehabilitation

The following common impairments after IM nailing are identified: Hip abduction and knee extensor weakness, knee and hip pain, decreased hip movement, decreased walking endurance, and gait abnormalities, especially Trendelenburg gait pattern. Rehabilitation focuses on reversing these through physical exercises improving range of motion, strength, weight bearing and gait. However, it is described in literature that 20% of the patients could not return to normality 3 years after surgery (Paterno & Archdeacon, 2009; Noor, 2019). Therefore, it is important to consider follow-up issues caused by malrotation. Researchers found that up to 72% of a present malrotation could be compensated (Jaarsma et al., 2004). However, day-to-day monitoring of the musculoskeletal system and its mobility is necessary to assess individual stress caused by a given malrotation. The collection and analysis of the monitoring data can enable individual therapy interventions, to improve patient's healing in a sustainable way. In addition, interventions can be made comparable, and their success evaluated. Lastly, new information about the compensation can be gathered, for example when it sets in or how it progresses. Physiotherapy could start directly at this point and support with targeted training.

2 METHODS AND PRELIMINARY RESULTS

Within the Secur-e-Health project (Secur-e-Health, 2021) the German subproject Smart Fracture Care funded by the German Federal Ministry of Education and Research (BMBF) is focusing on a new approach for dealing with femur shaft fractures. The main project goals are:

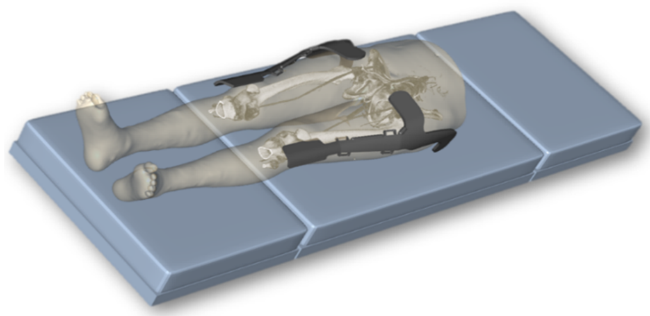
1. Improving the IM nailing procedure by developing a new intraoperative assistance system to precisely restore length and rotation angle of the injured femur.
2. Improving rehabilitation after IM nailing treatment, through home monitoring.
3. Increasing data safety, standardization, and centralization along the entire patient pathway. This will enable Big Data analytics to statistically verify improvements in IM nailing treatments.

2.1 Intraoperative Assistance System

There is no widely accepted method controlling anteversion and length of the femur shaft.

To address this issue, we propose a computer aided surgery system that allows intraoperative reconstruction of the 3D shape of the uninjured femur using a small number of fluoroscopic images recorded before surgery. The mirrored 3D shape is used as a reference for restoring the rotation and length of the injured femur.

The Length Alignment Rotation (LAR) system consists of a tablet computer with built-in frame grabber and touch screen. The tablet computer is placed in the sterile field close to the surgeon allowing interaction with the LAR software. It also obtains fluoroscopic images using a frame grabber



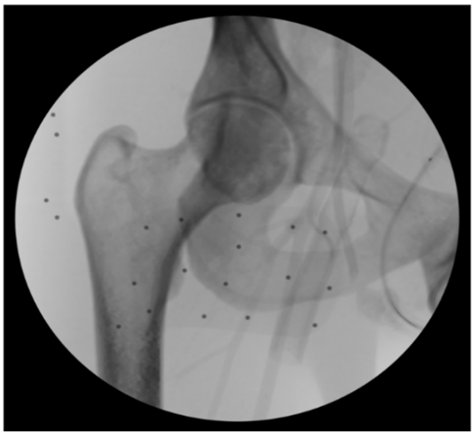


Figure 1: Placing (left) and radiographic image (right) of reference bodies attached to the patient, used for the LAR system.

and a connection to the C-arm. Additionally, reference bodies are attached to the patient (see Figure 1). These markers are based on polymer-bodies with small, embedded steel beads. Using computer vision software, the viewing orientation of fluoroscopic images can be computed by analysing the pattern of the projected beads in the image.

The reference Image is created at the beginning of the surgery. The LAR system is used to compute the 3D shape of the unaffected femur by the following steps:

1. A reference body spanning the length of the femur is placed on the unaffected limb.
2. Two fluoroscopic images of the proximal area of the unaffected femur are taken.
3. Two fluoroscopic images of the distal area of the unaffected femur are taken.
4. The LAR system computes a 3D approximation of the unaffected femur from the images taken in step 2 and 3.

For rotation and length control of the injured femur, the approximation of the 3D shape of the unaffected bone can be used as reference for the injured bone. For this, the following workflow step are required:

1. A reference body spanning the length of the femur is placed on the affected limb.
2. Two fluoroscopic images of the proximal area of the affected femur are taken.
3. The LAR system computes a 3D approximation of the proximal part of the affected femur. 4. The mirrored 3D shape of the unaffected femur is matched to the proximal part of the 3D shape of the affected femur.
5. The contour and axes of the mirrored unaffected femur will be presented as an overlay on top of the fluoroscopic images of the affected femur. This can be used as a reference by the surgeon (see Figure 2).
6. Using two images of the distal area, the system can also reconstruct the entire 3D shape of the affected femur. Now angle and length of the affected femur can be directly compared to the unaffected femur (see Figure 2).

One of the main technical challenges in the LAR system is the reconstruction of the 3D shape of the femur from 2D fluoroscopic images. To compute the 3D shape of the femur, first the relative orientation of the fluoroscopic images is computed using the projections of the reference body beads in the fluoroscopic images. A convolutional neural network (CNN) for 3D segmentation is used to compute an approximation of the proximal and distal femur shape from the fluoroscopic images. The network architecture used for this is similar to the architecture described in (Milletari et al., 2016). The proximal and distal approximation of the femur are fused into an overall shape by fitting a 3D active shape model (Cootes et al., 1995) to the distal and proximal approximations.

An early version of the LAR system has been tested in a cadaver lab on two specimen and in several sawbone labs. The tests showed that the system can be used to obtain a 3D reconstruction of a femur bone from 2D images. The accuracy of the estimated angles was ± 8 degree and ± 4 mm in length, when compared to the ground truth obtained from a CT scan. The objectives of further research are to improve the workflow, to facilitate the work with reference bodies and to enhance the robustness of the 3D reconstruction.

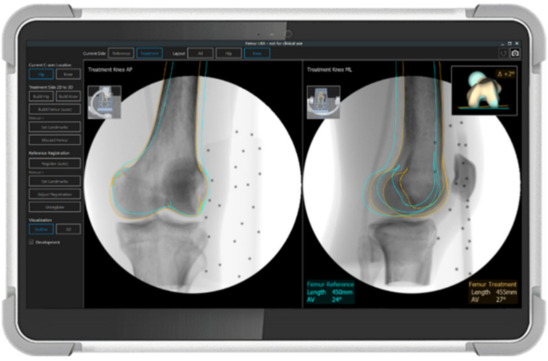


Figure 2: Tablet computer showing the LAR system.

2.2 Rehabilitation Improvement

The healing process is determined either in sessions with the physiotherapist or by patient self-reports. In the first case, only a small insight into the treatment progression is generated and not a continuous picture. In the second case, documentation is often inaccurate due to the patients' tendency to misjudge themselves (Komaris et al., 2022). Therefore, an objective, continuous measurement method may be helpful to obtain a more accurate picture of the patient's healing progress to further customize treatment. In addition, such system could enable intercomparability, allowing treatment methods to be compared. number.

2.2.1 Concept for Improvements

To overcome the difficulties described above, we propose the usage of a sensor array, which can be worn during rehabilitation in a wearable. Used for this purpose are Force Sensing Resistors (FSRs), inertial measurement units (IMUs) and Electromyography (EMG) sensors. Collected data is then processed and statements about the course of healing can be made.

To improve individual treatment and to create the possibility of easy intercomparability, the following objectives are established:

a) Check for the common residual impairments after IM nailing, hip abduction weakness, decreased hip and knee movement, knee extensor weakness, pain, gait abnormalities, decreased walking endurance. If these are identified, targeted countermeasures can be taken during rehabilitation.
   Since hip abduction and knee extension weakness affect the patient's gait pattern and daily routine, they can be detected by combining a specific questionnaire and a gait analysis. The range of motion (ROM) can be measured allowing to conclude about mobility. Which in turn allows deductions about hip and knee joint movements. Pain is a subjective perception and needs to be assessed by questionnaires. Information about changes in walking endurance can be obtained in a trend analysis.
b) Collecting information about ROM and pain tolerable load on the leg in everyday life. This additional information can be used by the physical therapist to customize exercises or to properly assess the use of assistive devices.
c) A malrotation of the femur is followed by a compensation mechanism of the body. This effect is well known and documented, but information about the onset of compensation is not yet available. Continuous measurements could provide further knowledge.
d) Visualization of the healing process. A visibly positive progression could motivate the patient to continue or even intensify the exercising and thus accelerate the healing.
   To meet these objectives (a-d), information about the status of mobility, ROM, gait, activity, malrotation, compensation, status of demanding activity, pain, managing everyday life and the before surgery state must be generated from collected patient data. This will be accomplished using wearable sensors as well as patient self - assessments e.g., filling out questionnaires (about pre-surgical status, pain and satisfaction with healing).

2.2.2 Sensor Systems

In the following, three sensor systems (EMG, IMU and FSR) proposed in chapter 2.2.1 for integration into a wearable are described. After a functional introduction, the data evaluation methods to generate relevant information are described.

Electromyography (EMG) can be used to measure the onset of a muscle activation. Surface electrodes can measure the electronical potential differences, which are due to the activation of muscles. The EMG-signal changes in amplitude and frequency depending on the induced motion (Wang et al., 2021). The following information must be determined from the recorded sensor data:

Rotation: A gait pattern is created by the interaction of several muscles. In case of deformed bones in the lower limbs, gait pattern changes and therefore the activity of the muscles. The change can be measured externally with the help of EMG sensors. Since the sensors are to be worn above the knee, the vastus medialis and the vastus lateralis seem to be suitable muscles for such measurements. Mohammad & Elsais, 2020 found significant negative correlations between hip internal rotation angle and EMG activity for the gluteus maximus and vastus medialis obliquus. Significant positive correlations were observed between hip internal rotation angle and EMG activity for the vastus lateralis obliquus (Mohammad & Elsais, 2020). Those findings indicate that the EMG measurement could be used to draw conclusions about malrotation. A study to determine this relationship is being planned.

Load and Muscle Strength: The load on the leg influences the muscle force required for walking. E.g., if the patient uses a walker, less load is placed on one leg and less muscle force is required. Since musculoskeletal electrical activity correlates with muscle force, EMG sensors are useful for detecting different loads. In fact, and Mokri et al., 2022 showed that neuromuscular activation is a major contributor to muscle strength (Mokri et al., 2022). However, the research also showed that a direct model cannot be created because muscle force also depends on muscle volume, fiber length, and velocity (Roberts & Gabaldon, 2008), which means that EMG calculations can only be used as an indicator of the healing process. For example, if the EMG detects an increase in activity, improvement can be assumed. Calculating absolute load values remains a challenge. To gain more insight, a study will be conducted to examine different loads and corresponding EMG signals.

Inertial Measurement Units (IMUs) are available in small sizes and for a low cost. They can be used to obtain position and orientation. It usually consists of an accelerometer, gyroscope and magnetometer. We propose wearing at least two sensors. The following information must be determined from the recorded sensor data:

ROM: At least two sensors are needed to determine a joint angle, quantifying the ROM. If the sensor axes are perfectly aligned with the object axes the joint angle can be computed by integrating the difference of both angular rates (Seel et al., 2014). The positioning of the sensors will be supported by wearables, but it cannot be guaranteed, that the positioning accuracy will repeatedly be sufficient. To overcome this issue a joint is considered as a hinge joint and therefore creating constraints allowing the position and direction vector of the knee to be determined. Concluding, only the individual orientation of the sensors is required, directly resulting in an accurate flexion/extension angle (Favre et al., 2008). Seel et al., 2014 could achieve an accuracy of 3° when measuring the knee joint (Seel et al., 2014). This concept is suitable to be integrated in the wearable.

Activity: Information on the patient's activity can be derived from the calculations of ROM, e.g., step count. Another important aspect that should be sensorially detected is the performance of physiotherapeutic exercises in the home environment. Komaris et al., 2022 have already presented a working concept in which exercise sequences are recorded and processed during supervised training (Komaris et al., 2022). These recordings can now be compared to home training, identifying exercises and detecting changes in execution.

Gait: Insights into Gait irregularities are an indicator for the healing process. To put as little additional strain on the patient as possible, the aim is to use a unilateral sensor fitting. This limits the ability to detect gait differences based on lateral differences. However, it is still possible to observe the change of spatio-temporal gait parameters unilaterally (Shahar & Agmon, 2021), allowing conclusions to be drawn about gait irregularities. From this, e.g., Trendelenburg gait could be detected, a study is planned to gain further insight.

Pressure sensors are one of the simplest methods to measure the force under the foot while walking. In example, Force Sensing Resistors (FSRs), are suitable for this purpose. These consist of a conductive polymer between two electrodes. If a force is applied from outside, its conductive properties change along with the resistance between the electrodes. This change correlates with the applied force (Abdul Razak et al., 2012). The following objectives are to be measured:

Load: The load can be estimated, by real-time pressure sensors worn inside the shoe sole. After a calibration with the help of a scale, a threshold value can be set, which is considered as a limit for the load of the leg. This can be used to provide direct feedback for the patient to assist in loading the leg accordingly. In addition, the data shows the objective course of the tolerable load allowing for exercises to be adapted accordingly. Bril et al., 2016 showed the possible usage of such threshold to directly support the patient (Bril et al., 2016).

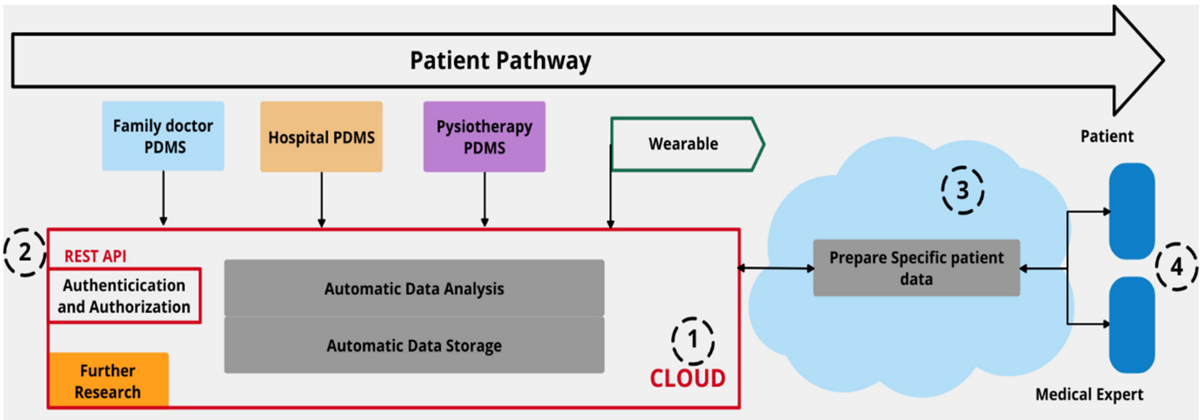


Figure 3: Concept of digital patient pathway.

Mobility: Step frequency can be investigated to derive information about the patient's mobility. Since steps are recognizable in recorded pressure data, a Fast Fourier Transformation can provide information about the step frequency. Also, classifying pressure patterns while being active can help to differentiate events such as stair climbing. Chakraborty & Dendou were able to detect whether a patient was climbing up or down stairs, with an accuracy of 100% (Chakraborty & Dendou, 2014). Implemented in this approach, it could provide additional information about healing progress.

2.2.3 Overall Sensor Concept

A concept, to achieve the above-mentioned goals has been created. It is based on a sensor set built into wearables and a data collection unit. The wearable will hold multiple sensors (FSR, IMU, EMG) while keeping the additional burden on the patient to a minimum. E.g., the sensors must be easy to place and remain stable to ensure measurement reliability. To meet these requirements, the sensors are divided into two systems. System A is used on the thigh and holds the EMG sensors and a single IMU sensor. It is designed as a bandage, starting just below the knee, and extending 15 cm above. A hole at the position of the patella helps the patient to position it. System B is built into the shoe and holds the pressure sensors and a single IMU sensor. Because it is firmly installed in the sole, it cannot be applied incorrectly or slip during examination. To gather data from system A and B, a gateway is needed that automatically connects to the wearable and receives, encrypts, and forwards the collected data to a server. The server stores, processes and evaluates the data.

2.3 Digital Patient Pathway

The success of a treatment is influenced by many factors, e.g., concomitant diseases, nail types, nail techniques and interlocking methods. Thus, the choice of the most suitable method for an individual patient becomes a challenge. Additionally, there are issues with data flow and accessibility, as not all stakeholders, such as treating specialists, have access to all the data generated during the treatment process. Leading to two main problems, to be solved by improved data handling. On the one hand, a concept has to be developed, which allows to conduct studies on the success of different treatment methods. On the other hand, the availability of patient information as a basis for individual treatment must be enhanced.

For an improved individual outcome patient data is digitalised and stored in a centralized entity, making the entire patient pathway traceable, see Figure 4. A cloud (1) provides the ability to automatically collect patient data and to process it generating further information, cf., section 2.2.

This concept ensures security by providing a REST API (2) and de- and encrypting data traffic. Additionally, data will be standardized generating comparability. Authentication and authorization management is used to ensure that only the patient can view, and share collected data. Neither patient nor medical specialist is in need to always be able to view all stored data. This creates the need for an interface between the data cloud (1) and the user (4). In Germany, the introduction of the electronic patient record (ePA) has created a basis for solving such issue (Bundesminesterium für Gesundheit, 2021). For our proposed concept, the principle is abstracted, which allows to build a demonstrator on a known base while being compatible with other concepts of electronic patient data storage. The myoncare application, an approved medical product, is used in this case (Oncare GmbH, 2022). It offers a communication platform for healthcare providers and patients in a way that information on health status, exercise videos, questionnaires or educational sheets can be exchanged directly between specialist and patient. The platform can be connected to the central cloud (1) via an interface. Thus, the patient's healing process can be monitored continuously, creating a basis for improved individual outcome.

To enable further research, the data stored in the cloud (1) can be utilized. With the patient's consent, the data is anonymized, standardized and made accessible, providing the opportunity to evaluate the success of different treatment methods in patient cohorts.

3 CONCLUSION AND DISCUSSION

LAR System

The LAR system is a good alternative to existing techniques for intraoperatively measuring femoral anteversion angle and length. Compared to existing solutions the proposed system is designed to save radiation, time, costs while increasing accuracy. Initial experiments have had promising results and have shown that the overall system design is viable. Future work will concentrate on streamlining the workflow and the handling of reference bodies to make the system more usable. Additionally, the algorithms for 3D reconstruction from 2D fluoroscopic images will be made more accurate and robust.

Wearable

Analysis of sensor data allows each of the objectives described in section 2.2.1 to be addressed. The home exercise will be monitored objectively, a continuous picture of the healing process will be drawn, different treatment methods will be comparable. This will be an important improvement because, to our knowledge, there is no universal standard for rehabilitation after IM nailing. Further studies on the concept in terms of feasibility and usability need to be conducted.

Digital Patient Pathway

Limitations, identified in section 2.3, concerning the data handling, can be improved with the proposed idea. All information about the patient's history will be available for each treating specialist. In addition, the data will be automatically processed so that patient and specialist receive a comprehensive overview of the treatment. In addition, treatment methods can be compared and evaluated as data from multiple patients is available. Big data analyses, for example, can then be carried out. The addition of the myoncare application enables to process all data in a user-friendly way, while maintaining a certified standard. Since the data handling concept is abstracted from the established ePA, our proposed concept is exchangeable and additionally transferable into the ePA or other patient data management concepts. Aspects of data privacy and security remain to be discussed before the proposed concept can be integrated into everyday clinical practice.

The proposed concept of a secure medical data repository that facilitates both individual outcome and further research is highly consistent with the goals of the Secur-e-Health (ITEA) project.

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