The PinTrace system

The demand for minimal invasive surgery (MIS) with more rapid patient recovery creates an increasing need of high-performance technology, based on computer and robot assisted surgery.

Medical Robotics has developed a multi-application platform – PinTrace – based on robot assistance. The PinTrace platform is considered to make a substantial contribution in the challenge of improving the technology for MIS applications in orthopedic surgery. Furthermore, the PinTrace platform has a fully open configuration and therefore enables adaption to different navigation systems.

Background

The scientific basis for the PinTrace system is a Thesis from the Karolinska Institute, Sweden (Lindequist 1993). In the initial work aimed at bringing the system into practice, a robot arm was considered to be of key importance. The significance of the robot arm was boosted further by a concern to significantly reduce the cumulative radiation dose to which the surgeon is exposed.

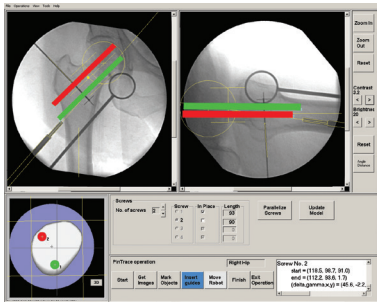
A six-axis free-arm robot was chosen to make the PinTrace platform as flexible as possible for future multi-application methodology. It was further assumed that the use of a standard robot arm, in the long run, would contribute to low development and production costs as well as access to the latest edge robot technologies and existing service networks.

The key requirements – cost-efficiency and user-friendly systems – led to initial launch of a system that retained the manual operation process as far as possible and involved input data from a C-arm. It was additionally assumed that the choice of C-arm as the basic input data would ensure high availability, since the C-arm is the most common type of X-ray equipment worldwide.

Choice of method and system

Available methods for MIS are based on the following three fundamental choices of method and system:

- **Navigation with or without robot assistance.** The PinTrace system is based entirely on robot-assisted navigation.
- **Input data from two-dimensional X-ray, three-dimensional X-ray or other input data.** The PinTrace system has a fully open configuration and therefore supports the two-dimensional C-arm as well as other input devices and different navigation systems.
- **Supportive alternative automatic process function.** The primary purpose of the PinTrace system is to provide a supportive function rather than replace the surgeon by introduction of automatic sequences. However, the PinTrace platform allows development of advanced automatic sequences due to the use of a six-axis free-arm robot and the fully open input configuration.



The compatibility with the C-arm results in a simple and user-friendly system as well as high availability.

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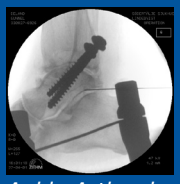
Example of performed surgery with PinTrace

Femoral fracture (IM-nailed)

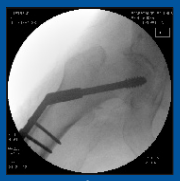


Ankle Arthrodesis

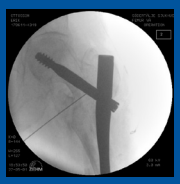
Robot guided saw template for knee prosthesis

Knee Prosthesis

Femoral neck fracture



Pertrochanteric fracture (DHS-nailed)



Pertrochanteric fracture (Gamma-nailed)

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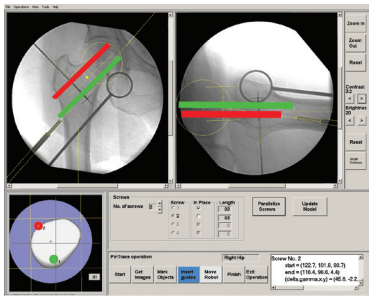
Orthopedic surgery with PinTrace

The principal aim of PinTrace is to provide methods with substantially improved patient outcome and cost-efficiency in orthopedic surgery, including the most cost-driving group of long bone fractures – hip fractures. Hip fractures today counts for a vast proportion of the diagnoses in fracture surgery, and an exponential rise in numbers is anticipated in the next few decades due to an increasing average life expectancy worldwide.

The focus on providing a system that includes hip fractures is additionally based on the hypothesis that high availability and therefore high frequency of use is the key requirement for wide user acceptance and a positive attitude towards implementation of multi-application methodology.

It is therefore assumed that the critical limit for wide user acceptance will be best achieved by initially introducing methods for long bone fractures, where hip fractures accounts for a major part.

According to above, it is finally the judgement of Medical Robotics that initial implementation of long bone applications will lead to far better performance regarding accuracy, simplicity, working environment as well as cost-efficiency for more complex PinTrace applications, both for trauma surgery (e.g.: pelvic fractures, knee fractures and fractures of the upper extremities) as well as for reconstructive surgery.



The picture shows a simulation of an incorrectly placed fixation site – not visible on the X-ray images, but clear in the cross-sectional graph (see red screw position).

PinTrace with input from two-dimensional C-arm

The PinTrace system with input data from two-dimensional C-arm – the most common input source for navigation worldwide – is based on support functions for critical sequences demanding substantially improved surgical accuracy. To increase the availability and therefore the frequency of use the following two softwares are available:

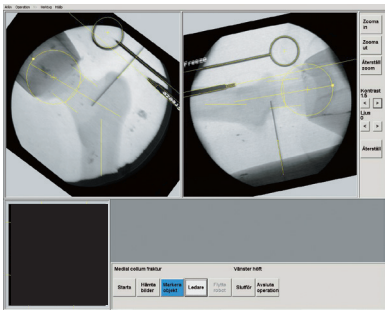
- **Freebone.** A general fracture module for a majority of orthopedic surgery procedures with high precision and substantially reduced cumulative radiation exposure time from the C-arm.
- **Hipbone.** A special software for hip-fractures based on a unique method for simulating 3-D reconstruction of the femoral neck and head. The method, as well as Freebone, substantially reduces the cumulative radiation exposure time from the C-arm.

The principal stages of the PinTrace method for femoral neck fractures are described below.

Input data and initial fracture analysis

Input data is two perpendicular X-ray images from a C-arm. Imaging takes place entirely in accordance with normal routines. The image information is imported to the PinTrace system in standard format and viewed directly on the touch screen. The surgeon can therefore make an initial analysis of the fracture area using expanded analytical aids.

Registration



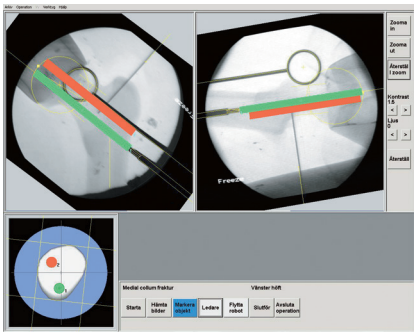
The robot arm is positioned such that the tip of the tool is clearly registered on the two X-ray images. The system of coordinates is then created by marking a few of the most significant parts of the fracture area and the tool on the touch screen. No patient markers or other extra equipment and manipulations are required for registration.

Pre-operative planning

A cross-section of the femoral neck is calculated. The system then calculates the optimal screw positions. The positions are displayed in the cross-sectional graph and on the X-ray images. The surgeon can then simulate alternative positions in real time directly on the screen.

Positioning

When the surgeon has approved the intended fixation sites, the robot arm is positioned. The tool tip is positioned on the correct coordinate but with linear displacement to a point just outside the intended skin incision.



The system is then put in inactive safety mode. The surgeon marks the skin incision with the tool tip and then makes the incision manually according to the normal procedure. The system support allows for precise positioning, with the result that the size of the incision can be reduced. Final positioning for the intended bone penetration is done by manual linear displacement of the tool tip through the incision to the edge of the patient's bone.

Placement of guide wires, pins and screws

Bone penetration is monitored and performed manually by the surgeon using the drilling jig. The surgeon uses normal tools for the procedure concerned. The system is put in inactive safety mode throughout the sequence.

Clinical Trials

The PinTrace system has been used in three hospitals in Sweden (Södertälje Hospital, Karolinska University Hospital and Karlstad Hospital) and approximately 10 surgeons have performed surgery with the system.

Several types of orthopedic surgery have been performed including: Internal hip fixation (more than 60 operations), Intramedullary nailing of the femur, Tibia condyle fractures and Ankle arthrodesis.

A clinical study (non randomized), including 30 femoral neck fractures, has been performed with the PinTrace system at Södertälje Hospital, Sweden. The results are presented below:

Follow-up (months)	**Number**	**Redislocation** (re-operated THR)	**Segmental Collapse** (re-operated THR)	**Dead** (not re-operated)
12	30	1 screw loosening 1 screw penetration	1 segmental collapse	3

Summery

- Total 30 femoral neck fractures preformed in a clinical study (non randomized) with the PinTrace system at Södertälje Hospital, Sweden.
- 3 re-operations = 10 % re-operation rate.
- Re-operation rate for femoral neck fractures treated with standard manual method at Södertälje Hospital during the same follow-up interval = 30 % (20/66).
- Published article regarding the importance of improved accuracy: *Lindequist S1, Törnkvist H.: Quality of reduction and cortical screw support in femoral neck fractures. An analysis of 72 fractures with a new computerized measuring method. J Orthop Trauma, 1995 Jun;9(3):215-21.*

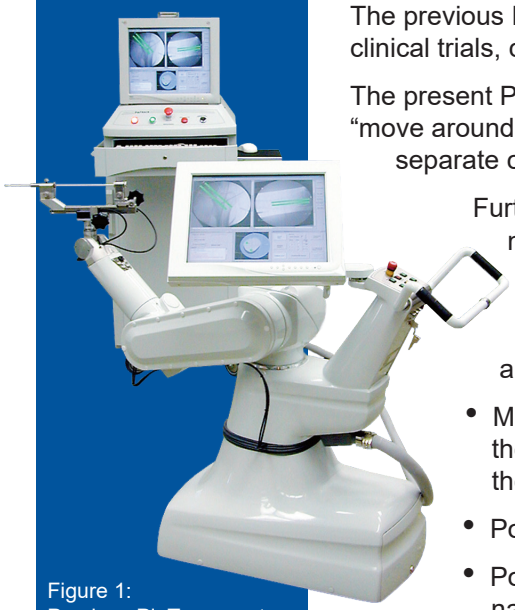


Figure 1:
Previous PinTrace system.

Next generation of PinTrace

The previous PinTrace system (figure 1), used in previously performed surgery and clinical trials, comprises of two units – robot arm and a separate cabinet.

The present PinTrace System (figure 2) is a lot more compact and easy to use and "move around" due to the availability of far better robot arms today and since the separate cabinet is not needed anymore.

Furthermore there are more options for positioning the robot arm. The following alternatives are available:

- Manual positioning by grabbing the robot arm and moving it to the desired position.
- Positioning with joy-stick.
- Positioning with input data from different navigation systems or from other input sources than C-arm will be an option.

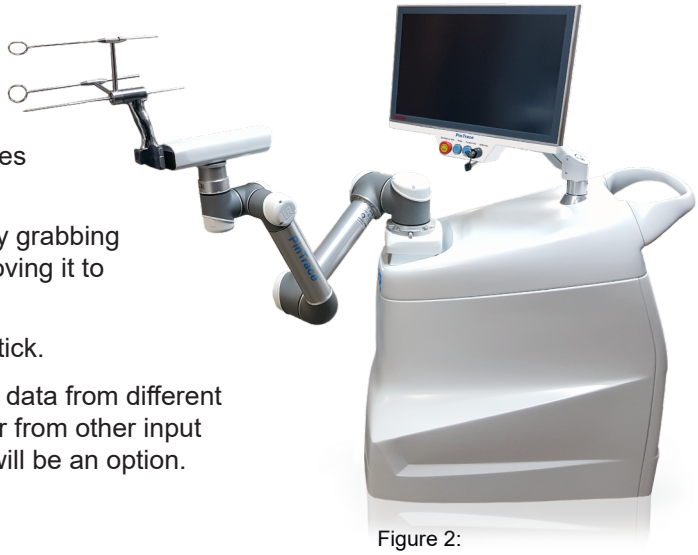


Figure 2:
Present PinTrace system.

Benefits and features

The PinTrace key-benefit is high availability and therefore high frequency of use, which is a prerequisite for substantial improved:

- **Surgical accuracy** (which creates conditions for better patient outcome).
- **Working environment** (due to reduced cumulative radiation exposure time).
- **Simplicity** (easy to use, steep learning curve and compact as well as "easy to move around").
- **Cost-efficiency** (low development and production cost as well as low cost per operation and low maintenance cost).

The PinTrace features that leads to high availability and high frequency of use are:

- Use of standard six-axis free-arm robot.
- Fully open configuration/technical platform supporting input data from two-dimensional X-ray (high-volume procedures in fracture surgery require input data from a conventional C-arm), three-dimensional X-ray or from other input sources and from different navigation systems.
- Special software for hip-fractures and compatibility with C-arm ensures full access to the most cost-driving group of lower extremity fractures in trauma surgery.

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