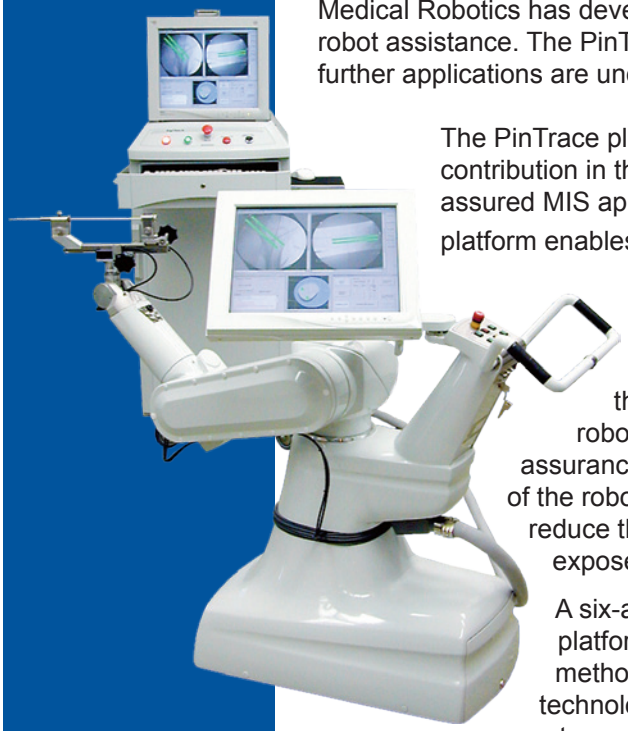
The PinTrace™ method

Quality-assured methodology with robot assistance

The demand for minimal invasive surgery (MIS) with more rapid patient recovery creates an increasing need of high-performance technology, based on computer-assisted orthopedic surgery (CAOS) with access to robot assistance.
Medical Robotics has developed a multi-application platform – PinTrace – based on robot assistance. The PinTrace method is in initial clinical use for hip fractures and further applications are under development.



The PinTrace platform is considered able to make a substantial contribution in the challenge of improving the technology for quality-assured MIS applications. Furthermore, the configuration of the PinTrace platform enables adaption to other navigation systems.

Background

The scientific basis for the PinTrace method is a Thesis from Karolinska Institutet, Sweden (Lindequist 1993). In the initial work aimed at bringing the method into practice, a robot arm was considered to be of key importance in the quality assurance of minimally invasive surgery (MIS). 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.

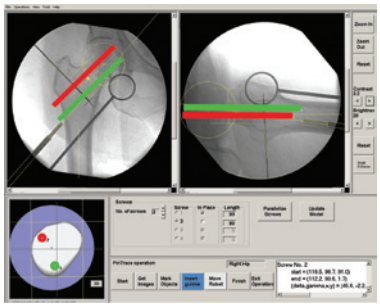
A six-axis free-arm robot was chosen to make the technological platform as flexible as possible for future multi-application methodology. It was assumed that the use of existing robot technology would contribute to low development and production costs as well as access to existing service networks and last available technology in the robot industry.

The key basic requirement in the health service of a cost-effective and user-friendly operative process led to an initial launch of a method that retained the operation process, and involved input data from a C-arm. It was additionally assumed that the choice of input data would ensure high availability, since the C-arm is the most common type of X-ray equipment.

Choice of method and system for quality-assured precision surgery

Available methods for quality-assured precision surgery for MIS is based on the following three fundamental choices of method and system:

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



The compatibility of PinTrace with the C-arm results in a simple and user-friendly operative process and high availability in trauma.

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Technological development historically has largely focused on creating navigation systems without robot assistance. Most existing systems therefore have a limited range of uses since several applications require robot assistance to achieve reasonable quality assurance.

In addition, most system platforms do not support operation processes that require input data from the C-arm. This limits the prospect of high utilisation of system investments, since the high-volume procedures in fracture surgery require input data from a conventional C-arm.

The PinTrace method does not follow the trend described. The method is based on a unique platform with robot assistance combined with an open configuration for input data. This has created the following key benefits:

- Compatibility with the C-arm ensures full access to the high-volume procedures of trauma surgery with a cost-effective and user-friendly method, where the learning curve is steep.
- Robot assistance results in improved quality-assurance due to better conditions for increased surgical precision and reduced cumulative radiation exposure time.

Trauma surgery with PinTrace™

The principal aim of PinTrace is to provide a method with substantially improved precision and cost effectiveness for the most cost-driving group of fractures in the health service – hip fractures. Hip fractures today account for more than 50 per cent of diagnoses in fracture surgery, and an exponential rise in numbers is additionally anticipated in the next few decades.

Another priority objective for Medical Robotics is to minimise the total need for expensive prosthetic operations for cervical hip fractures. With the aid of improved methodology for anatomical fixation, it is assumed that this can be achieved by reducing:

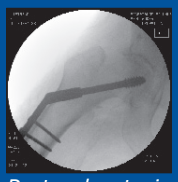
- The proportion of primary prosthetic operations.
- The complication rate and thus the re-operation rate for anatomical fixations carried out.

The initial prioritisation of hip fractures is additionally based on the hypothesis that a high rate of use is a key requirement for user acceptance and a positive attitude towards the implementation of multi-application methodology.

It is therefore assumed that the critical limit for user acceptance can best be achieved by initially introducing the method for hip fractures.

According to above, it is finally the judgement of Medical Robotics that PinTrace method for more complex applications with a lower volume rate will be made simpler and more cost-effective by the initial implementation of hip applications.

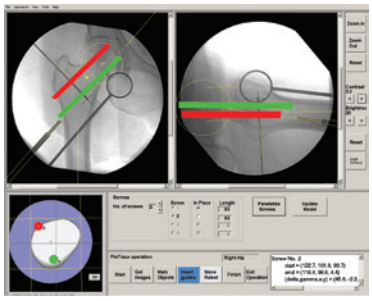
Example of performed surgery with PinTrace



Pertrochanteric hip fracture

Femoral fracture (IM-nail)

Cervical hip fracture



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).

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The PinTrace™ method

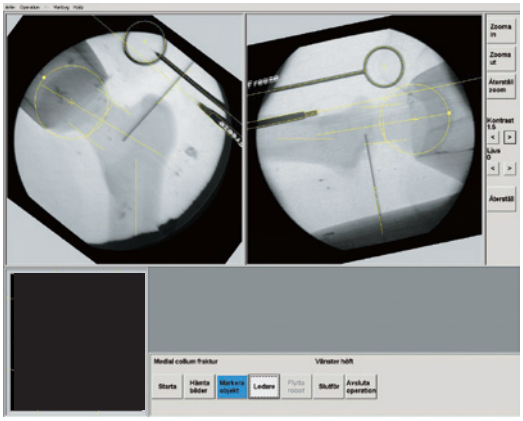
The method is based on support functions for critical sequences demanding high quality assurance. Other sequences are in line with present-day manual methods. The principal stages of the PinTrace process are described below.

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.

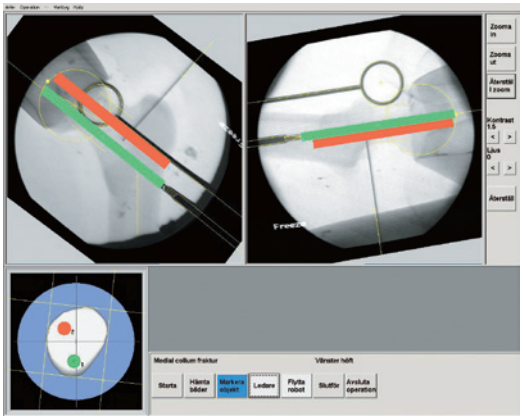


Pre-operative planning

A cross-section of the collum is calculated for cervical hip fractures. The system then calculates optimum 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. To achieve minimally invasive surgery, the main positioning is done non-invasively. 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.

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Key features of PinTrace™

Initial outcome from over 60 PinTrace operations indicates the following advantages of the PinTrace method:

- Improving patient outcome.
- Reduce of cumulative radiation exposure time.
- Easy to CE-mark (The PinTrace system is CE-marked).
- Ease of use.
- Enables development of techniques that are more accurate, less and minimally invasive.
- The surgeon controls the intervention and the surgical tools.
- The surgeon is the end effecter.

A randomised clinical trial is being initiated to further verify the features above.

Multi-application – a demand rather than a vision

Since minimal invasive surgery – executed by CAOS technology with or without robot assistance – both improves patient outcome and decreases cumulative radiation exposure time, the technology is far too beneficial to ignore.

Currently, applications for CAOS systems are limited and the main trend has been towards developing total joint applications. Greater availability and maximum return on investment in this technology demands multiple MIS applications. The multi-application requirement is obvious, since high frequency of use is one of the key features for achieving accuracy, simplicity and cost-efficiency.

Furthermore, it is not a question of navigation with or without a robot arm, but rather of providing the surgeon with the option of combining available technology in a manner optimally adapted to the procedure at hand. Some procedures lend themselves more to navigation, whereas others require more precise execution and thus generate a need for robot assistance.

Based on the above, multi-application methodology for MIS should be widely requested by patients and surgeons – if the challenge of accurate surgical performance is combined with ease of use at reasonable cost. If this challenge is not met, multi-application systems will probably remain a vision.

Medical Robotics believes the PinTrace platform can contribute substantially to meeting this challenge. The reason for this is that the PinTrace system was developed on an open technical platform with a system configuration that enables adaptation to other navigation systems.

Ref: Internal Fixation of Femoral Neck Fractures. Thesis, S. Lindequist, Stockholm 1993.