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A tracker-less image-based, non-invasive, real time, universal navigation system for guide wire positioning

Vijay Panchanadikar[1], Gauri Oka[1]

Abstract

Introduction: Computer-assisted navigation system allows surgeons to obtain a real-time feedback with the potential to decrease intraoperative errors and optimise the surgical result.

Aim: Our aim was to test a novel tracker-less navigation system, a purely image-based, non-invasive, real time, universal navigation system which can predict future position of the guide wire, K wire, screws and plates for fracture fixation.

Methods: Patients with intertrochanteric fracture treated by dynamic hip screw barrel plate fixation were divided into two groups. In one group, the C-arm was used and in the other, the software navigation was used in addition to the C-arm. Parameters such as time to insertion, number of C-arm shoots and number of attempts for guide wire insertion were documented and compared.

Results: Using the navigation software for guide wire positioning in the DHS barrel plate surgery proved beneficial as compared to not using navigation.

Conclusion: Intraoperative use of this navigation system eliminates trial and error thus improving accuracy and reducing the operative time and radiation exposure.

Introduction

Precision in orthopaedic surgery improves the post-operative outcome of the treatment and minimises the risk factors for intra-operative and post-operative complications. For peritrochanteric fractures, a significantly higher risk of cut-out is shown with less than optimum positioning of lag-screw tip, that is, in the upper part of the femoral head in the anteroposterior (AP) radiological view, posterior in the latero-lateral (LL) radiological view, and in the peripheral zones [1]. Favourable results with computer-assisted automated screw placement in the vertebral pedicle were first published in 1998 [2]. Since then, navigation has gained wide acceptance among orthopaedic surgeons and has become an invaluable tool for some orthopaedic procedures such as reconstructive hip and knee surgery, sports injury, trauma, spine and tumour surgery. It allows the surgeons to obtain real-time feedback and offers the potential to adjust the operating technique, decrease intraoperative errors and optimize the surgical result [3]. Computer-assisted navigation systems can be active or passive [4]. Active navigation systems prevent the surgeon from moving beyond predetermined safe zones. Passive navigation systems provide intraoperative information and images are displayed on a monitor, the surgeon is then free to make any decisions he or she feels necessary. Based on the method of referencing information, computer-assisted navigation systems are further classified into, computed tomography (CT) based navigation systems, fluoroscopy-based navigation systems and imageless tracker-based navigation systems in which there is no radiation exposure. Currently, navigation is used for the insertion of pedicle screws in the lumbar spine (its first use), distal locking of the intramedullary nail, femur neck fracture fixation, iliac wing and sacroiliac joint screw fixation, acetabulum fracture fixation, proximal tibia or humerus fracture fixation [7].

In spite of advances, the currently used navigation systems suffer from serious drawbacks. In a review article in 2013, Mavrogeniset al [3] stated that navigation systems are still in their infancy with the following drawbacks:

1. Increase of operative time for arrangement of set up
2. High learning curve
3. Risk of fractures (which is now minimized, but not eliminated, due to smaller pins)
4. An inherent error of 0.1 to 1mm in the tracking system of navigation markers
5. Lack of improvement in clinical outcomes. Many studies show improved accuracy and better postoperative imaging, but they have not necessarily made their patients any better clinically than they would have with conventional technique [5].

Excessive radiation in 3D-image intensifier, its invasive nature (due to the need to drill pins in bones) and its non-universal nature (not useful for all fractures, bones and implants) are additional drawbacks of the current computer navigation systems observed in day to day practice. Also, instruments and systems are not cross compatible. For example Stryker (Stryker ADAPT, a computer-assisted navigation Adaptive Positioning Technology for Gamma 3) navigation system in trauma for position of head screw in proximal femoral nailing is compatible only with the company's own nail. Smith and Nephew system (TRIGEN SURESHOT Distal Targeting System)in trauma for distal interlocking works only for the company's nail (author's disclosure at the end). In India, non-affordability is a significant barrier to the widespread use of

[1]Department of Orthopaedics, Independent research consultant

Address for correspondence:

Dr. Vijay Panchanadikar

Deenanath Mangeshkar Hospital road, near Mhatre bridge,

Erandwane, Pune, 411004. Maharashtra, India.

E-mail: vmpsanjeevan@gmail.com

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navigation systems.

In 2015, Zheng and Nolte2 concluded that even after about two decades since the introduction of the first robot and navigation systems for CAOS, it is still at the beginning of a rapid process of evolution. There is a need to eliminate the drawbacks of the currently available optical tracking systems and to stimulate the development of non-invasive registration methods and referencing tools. All the new techniques and devices will need to be carefully evaluated first in a laboratory setting and then clinically. More prospective and retrospective studies comparing the outcome of CAOS versus non-CAOS procedures with long follow up time will have to be conducted.

Trackerless navigation system: Keeping in mind the drawbacks of the current navigation systems and as per recommendations in literature,6 a passive type fluoroscopy-based navigation system was developed called “System for accurate guide wire and implant positioning”. Being C-arm or X-ray image-based, it is a trackerless, non-invasive and universal system aimed to eliminate the drawbacks of a tracker-based navigation system and to be used for all fractures and bones, and to be compatible with implants of various manufacturers. It was expected that intraoperative use of this navigation tool would reduce radiation to the patient and surgeon, eliminate trial and error, improve accuracy, reduce surgical time, reduce bone loss and reduce complication rates.

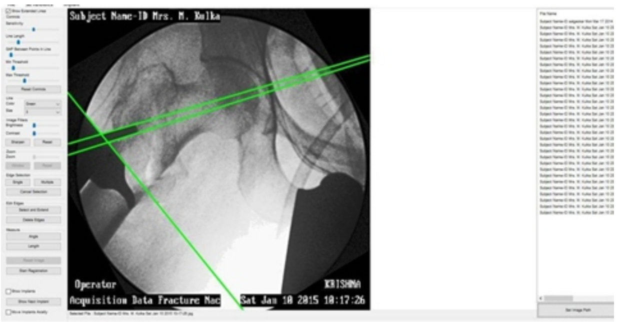

Figure 1: Software displaying (predicting) future position of the guide wire

The navigation software and its functioning

Functioning of trackerless navigation system: Software imaging and image manipulation is the heart of this system. For example, for an intertrochanteric femur fracture, the C-arm or X-ray images are captured. The software then performs the image processing. It predicts and displays the future position of the guide wire inside the bone on a separate monitor based on its current position outside the bone. Based on this feedback, the surgeon can adjust the position of the guide wire outside the bone so that when driven in, the guide wire will assume the ideal position inside bone. The software then superimposes virtual dynamic hip screw on the future guide wire position. Similarly, other implants like the barrel plate and cortex screws are suitably superimposed and displayed. Thus, the surgeon is able to visualize the future position of implants inside the bone even before a guide wire is inserted. By use of an appropriate scaling method, the software helps to predict various parameters of implants like screw length, number of screws required, and appropriate plate angle. The navigation system can be used for other surgeries as well, for example, distal end radius K-wire fixation/plate fixation, proximal femoral nailing, radius ulna shaft plate fixation and

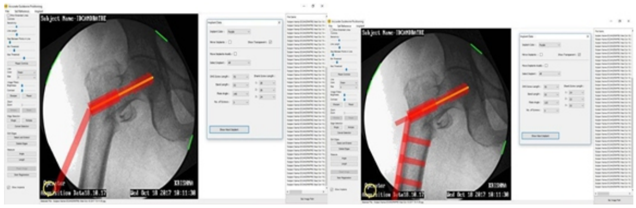

Figure 2: Virtual implant superimposition and templating of DHS barrel plate

proximal humerus plate fixation.

Routinely used orthopaedic guide wires or sleeves form the hardware component (jigs). The software detects in C arm image, the position of guide wire (or sleeve) while its end is touching the bone surface (not driven in) by edge detection and further image manipulation described earlier is effected.

Material & Method

Part 1:

Initially, the system was tested and validated on plastic femur heads, tibia and humerus bone models in the operation theatre environment. Guide wires were passed in bone models in the operation theatre under C-arm control with and without navigation. Benchmark was established by inserting the guide wire without the navigation software and parameters were noted. The results of wire insertion with navigation were compared to this benchmark. For benchmarking, a total of three models were used, one each for the femur, tibia and humerus. For navigation-assisted guide wire insertion, a total of 26 models were used: 20 for the femur, three for the tibia and three for the humerus.

Table1: Use of navigation demonstrates favourable reductions in all parameters

Percentage reduction in time	Percentage reduction in number of shoots	Percentage reduction in number of attempts	Percentage error (antero-posterior view)	Percentage error (lateral view)
68.42	75.17	53.52	2.53	2.49

Results

Improvement was observed in the various parameters of guide wire positioning like number of C-arm shoots, reduction in time, reduction in number of attempts. The percentage error between the predicted guide wire position and actual guide wire position was less than 4% in almost all cases. Two images of predicted guide wire position and actual guide wire position were superimposed using the Photoshop software and measurements taken. Measurements were taken on the anteroposterior and lateral view C-arm images and the maximum difference (in mm) between the predicted guide wire position and actual

Table 2: Results of guide wire insertion in bone models:
Benchmark or no navigation: One femur, one tibia and one humerus.
Navigated guide wire insertion: Twenty femurs, three tibias and three humeri.

Bone model	Total time required (mins)	Reduction in time required (%)	Total number of shoots	Reduction in number of shoots (%)	Total number of attempts	Reduction in attempts (%)
Femur						
Benchmark	**17**		**65**		**4**	
Navigation						
1	6.42	62.23	18	72.3	3	25
2	7.5	55.88	17	73.84	4	0
3	2.45	85.58	16	75.38	1	75
4	6.1	64.11	16	75.38	2	50
5	5.5	67.64	12	81.53	2	50
6	6.09	64.17	15	76.92	3	25
7	5	70.59	15	76.92	1	75
8	7.2	57.65	21	67.69	1	75
9	4.83	71.59	13	80	1	75
10	6.83	59.82	21	67.69	2	50
11	5.22	69.29	23	64.62	3	25
12	4.86	71.41	18	72.31	3	25
13	3.02	82.24	5	92.31	1	75
14	4.46	73.76	15	76.92	3	25
15	3.4	80	8	87.69	1	75
16	7.39	56.53	14	78.46	2	50
17	5.2	69.41	17	73.85	2	50
18	7.6	55.29	19	70.77	2	50
19	5.2	69.41	15	76.92	1	75
20	7.2	57.65	20	69.23	1	75
Tibia						
Benchmark	9		11		3	
Navigation						
1	5.2	42.22	3	72.72	3	0
2	1	72.88	3	72.73	1	66.67
3	0.5	85.47	2	81.82	1	66.67
Humerus						
Benchmark	4.13		6		6	
Navigation						
1	1	75.78	2	66.66	1	83.33
2	1.12	72.88	2	66.67	2	66.67
3	0.6	85.47	1	83.33	1	83.33

guide wire position were expressed as percentage of maximum bone width. The tracking system of commercially available navigation markers has an inherent error of 0.1 to 1 mm for each of the 3 coordinates in space.4 In our tests, the deviation in mm ranged from a minimum of 0 to a maximum of 2.8 mm in one plane (with an average of 1.31mm). This is very much comparable to existing navigation systems.

Part 2:

A non-randomized comparative study on patients:

After validating the system on bone models, a non-randomized comparative study was conducted on adult patients. Approval of Institutional Ethics Committee was obtained. Men and women with intertrochanteric fracture of the femur admitted under a single surgeon at our institute were included. Patient consent was waived by the Ethics Committee as the study was considered to carry minimal or no risk there being no intervention, but only image manipulation and visual feedback. High risk individuals and patients with polytrauma were excluded. Intraoperative standard of care C-arm monitoring was used in all patients. Navigation software was used in patients depending upon the availability of compatible C-arm in addition to C-arm monitoring. Thus there were two groups: one in which the C-arm was used and the other, in which navigation was used in addition to the C-arm.

The following data was collected for each surgery:

1. Number of attempts for guide wire positioning
2. Radiation exposure as measured by number of C-arm shoots for guide wire positioning
3. Time required in minutes for guide wire positioning

We included 27 patients and navigation was used in 8 patients.

Table 2: Compares the various outcome measures between the 2 groups.

Outcome measure	Navigation used (n=8) Mean ± SD	Navigation not used (n=19) Mean ± SD	p value
No. of guide-wire insertion attempts	3 ± 1.7	5.3 ± 2.1	**0.014**
Time for guide-wire insertion (min)	9.9 ± 6.5	19.63 ± 10	**0.019**
Radiation exposure (no. of shoots)	20.9 ± 9.5	37.8 ± 23.2	0.059

Results

We found that the mean number attempts required for guide-wire insertion was significantly less when navigation was used as compared to when navigation was not used (3±1.7 Vs. 5.3±2.1 respectively, p=0.014). Similarly, when navigation was used, it was found that the mean duration (in minutes) required for guide-wire insertion was significantly less as compared to when navigation was not used (9.9 ± 6.5 minutes Vs. 19.63 ± 10 minutes respectively, p=0.019). The number of shoots required was also lesser when navigation was used, but this difference was not statistically significant (20.9 ± 9.5 Vs. 37.8 ± 23.2 respectively, p=0.059).

Discussion

Computer-assisted navigation system has been playing an important role in orthopaedics and traumatology since the last two decades. Navigation systems continue to evolve and improve. With the use of navigation, significant differences were demonstrated in parameters of surgical time, wound size, number of x-ray shoots and accuracy of implant placement in fixing trochanteric fractures with gamma nail8. A study on navigated sub-capital fracture fixation allowed improved screw positioning and reduced radiation to both the surgeon and the patient9. Existing computer navigation systems in practice today have drawbacks of morbidity such as fractures and infections due to the placement of bony reference arrays11, or have excessive radiation exposure10 and are non-universal. The new navigation software works as an add-on to the C-arm images and does not replace the C-arm. Hence, standard of care is provided all the time. The results of our study demonstrate the effectiveness of this navigation software in improving the parameters studied, namely, the time required for guide wire insertion, the number of C-arm shoots and the number of attempts. This trackerless, image-based navigation may have a potential to replace existing tracker-based navigation systems.

Limitations

We agree that our study has some limitations. It is a non-randomized study conducted at a single center by a single surgeon. Our results are based on a small sample size. Moreover, only one fracture type was considered (though, one of the most common ones).

Conclusions

The trackerless navigation system helps achieve a reduction in the number of C-arm shoots, the time to attain ideal guide wire position and the number of attempts. Further long-term multi-centric studies on a larger number of patients and in other fracture types are required to conclusively prove its benefit.

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