Master's Thesis
석사 학위논문

Non-radiative & Precise Navigation System for Distal Locking in Intramedullary Nailing

Jaesuk Choi (최 재 석 崔 宰 碩)

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by

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A thesis submitted to the faculty of DGIST in partial fulfillment of the requirements for the degree of Master of Science in the Department of Information and Communication Engineering. The study was conducted in accordance with Code of Research Ethics[1).

November. 10. 2016

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[1) Declaration of Ethical Conduct in Research: I, as a graduate student of DGIST, hereby declare that I have not committed any acts that may damage the credibility of my research. These include, but are not limited to: falsification, thesis written by someone else, distortion of research findings or plagiarism. I affirm that my thesis contains honest conclusions based on my own careful research under the guidance of my thesis advisor.

Non-radiative & Precise Navigation System for Distal Locking in Intramedullary Nailing

Jaesuk Choi

Accepted in partial fulfillment of the requirements
for the degree of Master of Science

November. 25. 2016

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Abstract

Intramedullary nailing has been one of the most commonly used surgical procedure for treating long bone fracture in orthopedic surgeries. Intramedullary nailing consists of several procedures such as guide-wire insertion, reaming, nail insertion and distal locking. In particular, the distal locking has been known as one of the most challenging steps in this surgery. Because the nail is inserted and located in medullary canal so it is invisible to surgeon. For finding the position of nail and distal hole, in conventional method, surgeon uses large amount of radiography. In addition, while drilling and screw interlocking, since the nail is designed to have a longitudinal shape slightly bent by several millimeters so that it can conform to the bone canal shape, the exact position of the distal locking nail hole's axes cannot be easily determined and the operating time becomes longer.

This paper proposes a novel smart surgical navigation system for solving conventional limitations of intramedullary nailing. Using handle-integrated Laser guidance module, it can target the point onto the skin which indicates invisible distal nail hole. Owing to the characteristic of line-laser intersection, laser guidance module has a significant advantage of self-laser emitting toward distal nail hole without radiography. Additionally, through its fixation mechanism, the proposed laser guidance system does not need an additional tracking device for compensating disturbances from external impact. Not only to distal hole localization, for guiding the direction toward distal nail hole to surgeon while drilling, we proposed real-time drilling orientation measurement system. Handle and Drill integrated inertial sensors and Bluetooth communication module provide real-time angle data so that drill's angle error toward center of distal nail hole is calculated in real-time. Our systems featured removing usage of fluoroscopic image and low-cost compared to conventional systems.

Keywords: Intramedullary nailing, Non-radiation, High-accuracy, Laser guidance, Orientation measurement

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INTRODUCTION

1.1 The introduction of Intramedullary Nailing

Distal femur fracture is the secondly most common fractures for elderly patients following the hip fragility fracture in orthopedics [1]. Fractures of the distal femur mainly occur either as severe fractures in young men, and mild fractures in elderly women [2]. Especially, as aging proceeds, the importance of the distal femur fracture treatment has been increased due to the low bone density in the elderly patient.

In order to treat the distal femur fracture, broken bone should be prevented to rotation and movement. For securing the fractured bone, implantable instruments are already commercialized and prevalent. Implantable instruments are used for joining the broken parts of the bone by inserted into the intramedullary canal. Commercialized implantable instruments for securing the fractured bone are sorted depending on the fractured site; iron-plate (Figure 1) and iron-rod (Figure 3). As shown in Figure 2, the iron-plate is used at the difficult insertion site such as fingers, wrists, back of the hand and toes etc. It is attached to the outside of the broken bone so that join the broken parts and prevent rotation. In Figure 4, the iron-rods called nail is being used for thick bone such as thigh and the shin bone etc. However the intramedullary nailing which is considered as the most frequent in orthopedic surgery operation has several critical defects in its operation procedure; hazard and low-accuracy. So in this paper, the navigation system for solving defects of conventional intramedullary nailing is mainly discussed. Before we discuss about the way of solving defects, for understanding of intramedullary nailing, the intuitive intramedullary nailing procedures are followed.

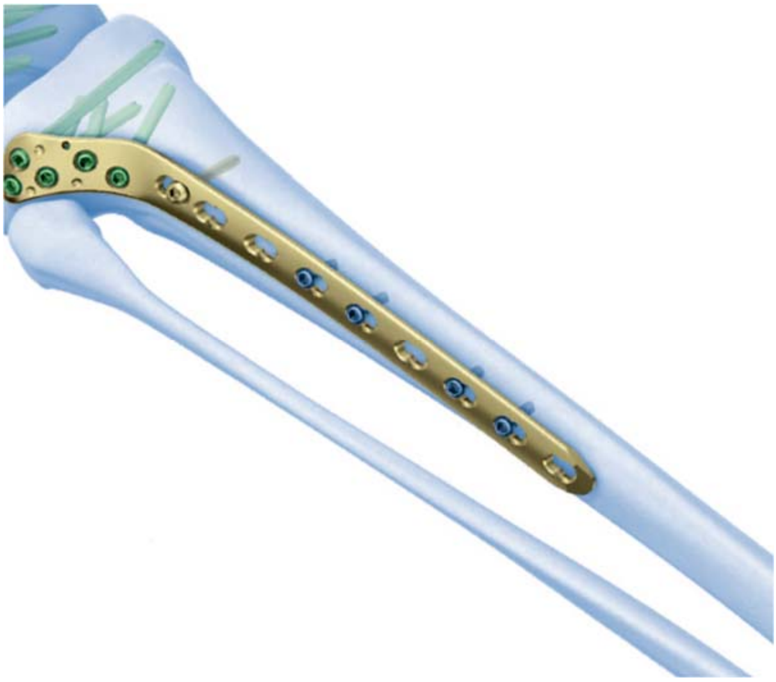

Figure 1. Iron plate for fracture treatment [SYNTHES®]

Figure 2. Practical usage of iron plate

Figure 3. Iron rod for fracture treatment [SYNTHES®]

Figure 4. Practical usage of iron rod

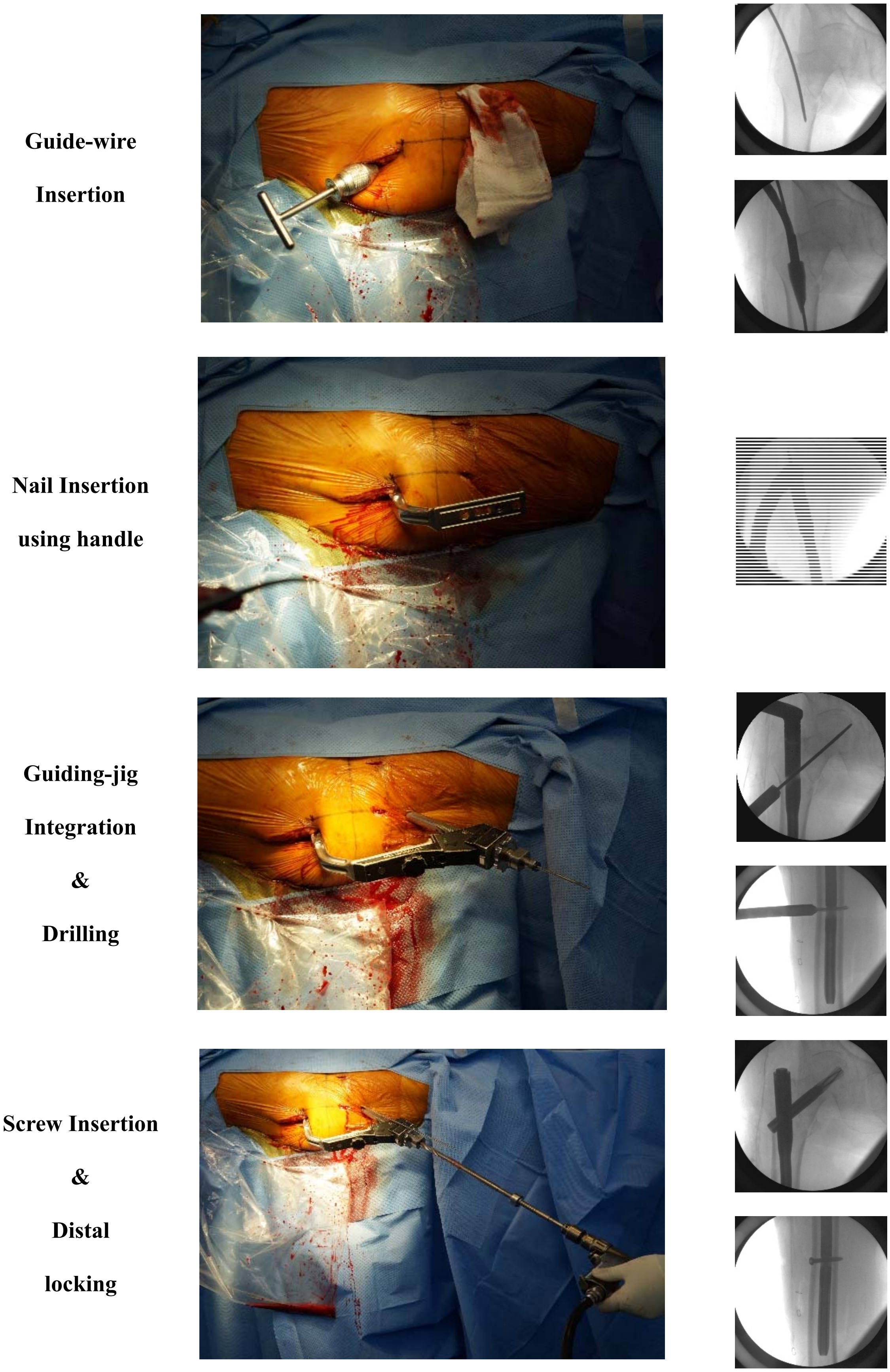

Figure 5. Procedure of intramedullary nailing

The process of intramedullary nailing

1. To secure the route of the nail, insert the guidewire to the head of the femur.
2. Along the guide wire, reamer is inserted to secure the size of the nail route.
3. The nail and the handle are integrated.
4. Using the handle, the nail is inserted.
5. For secure the path of locking screw, drilling procedure is proceeded differently in accordance to the proximal and distal position.
    - 5.1 For proximal interlocking, the guiding jig which points the proximal locking hole is mechanically integrated with the handle.
        - 5.1.1 Drilling is performed in accordance with the guiding zig pointing the proximal locking hole.
    - 5.2 In distal interlocking, since the guiding zig which points the distal locking hole is not exists, few times of C-arm is taken for identification of the distal hole location.
        - 5.2.1 After identification of the distal nail hole location, the drilling-guide jig is inserted.
        - 5.2.2 While inserting the drilling-guide jig, in order to determine the direction of the drilling-guide jig toward distal hole, C-arm is taken.
        - 5.2.3 Along the drilling-guide jig, the drilling is performed.
6. Locking screw insertion toward nail hole.
7. Interlocking with nail and outside inserted screw.

1.2 The necessity of Navigation system in Intramedullary Nailing

The nailing procedure is carried out for minimizing the rotation and displacement of a patient's fractured bone by inserting a hollow nail into the medullary canal and locking the holes of the nail with screw. However, since the nail is inserted into a bone, the surgeon cannot see the locking area. Therefore, the locking procedure has been considered a challenging step in intramedullary nailing.

For finding the locking area, there are many commercial targeting-arm devices (TADs). However these devices mainly feature a jig to guide the proximal hole; no method to guide the distal hole exists. To solve this problem, most orthopedic surgeons use radiography with distal interlocking, which exposes the patients as well as the surgeons to radiation. However, conventionally used radioscopy-based distal interlocking is not sufficiently accurate, because it is conducted by trial and error using two-dimensional (2D) fluoroscopic images, leading to the possibility of excessive errors and medical accidents. Furthermore, determining the distal nail hole using radiography requires more extensive imaging compared with other orthopedic procedures. Because the human femur is slightly bent in the longitudinal direction, a nail is designed to have inclination and a curvature of several millimeters, to conform to the bone canal shape. The curvature and the inclination of such a twisted nail make it difficult for a surgeon to find the distal nail hole using one fluoroscopic image. Thus, determining the exact position of the distal nail hole is inaccurate and requires acquiring and analyzing several fluoroscopic images.

In addition to difficulties in distal nail hole localization, robust combination of the nail with the screw should be conducted for successful intramedullary nailing. However, while drilling toward distal nail hole, securing the path of screw insertion, the real-time drill bit insertion angle toward distal nail hole may occur the error. Since the static 2-dimensional fluoroscopic image cannot accurately convey the real-time drilling angle, if there is an error in the orientation of the drilling toward distal nail

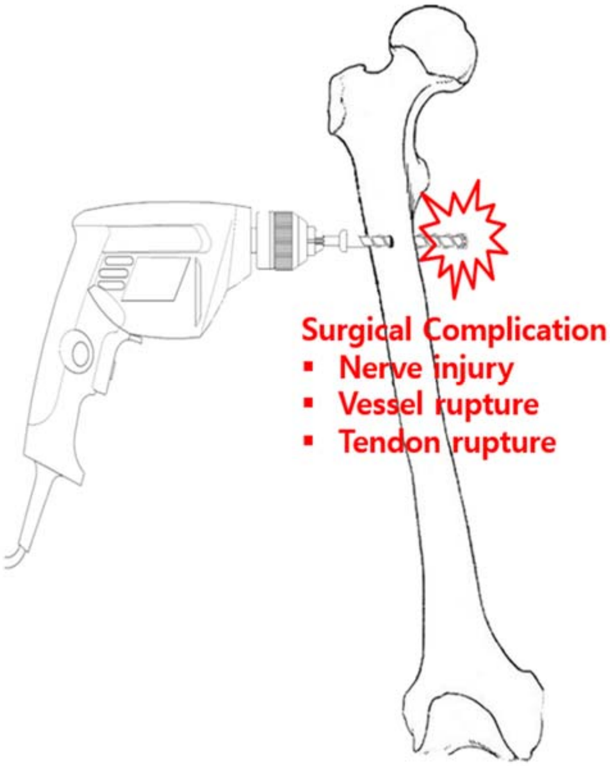

Figure 6. Medical accidents

hole, locking screw will not be integrated with distal nail hole robustly and cause a split to the nail. Also, over drilling occurs the rupture of blood vessels, nerve and tendon as depicted in Fig 6. So both of distal nail hole localization and drill-bit orientation have inaccuracy problem owing to the static characteristic of fluoroscopic image.

In addition to the inaccuracy problem, the radiography-based approach has the following drawbacks. 1) It increases the operation time. A surgeon has to analyze a significant amount of visual data to align the direction of drilling toward the distal nail hole. Since in distal locking both targets (distal nail hole) and tools (drilling equipment and screws) are related to each other in the three-dimensional (3D) space, while the surgeon is performing the procedure based on 2D fluoroscopic images, a relatively large amount of radiography data is required, thus increasing the operation time [3]–[5]. 2) It involves significant exposure to radiation, for both patients and surgical teams. Hence concerns has been expressed regarding the effect of radiation exposure on human body during intramedullary nailing procedure. Large amount of exposure to radiation can have deterministic (i.e., hair loss, skin burns, nausea, and cataract) and stochastic effects (i.e., carcinogenesis and teratogenesis). And the organs sensitive to radiation include the gonads, bone marrow, breast, cornea, gastrointestinal tract, lung, and thyroid. Even though radioactive materials are denoted hazardous by the World Health Organization (WHO), most of surgeons still widely use radiography in medical imaging. The reason for this is significant gains in the resolution of imaging, compared with the radiation damage that is incurred. So the technique which can reduce the need of radiation exposure associated with 2D radiography for visualizing the position of the nail and drilling orientation is being required.

1.3 Research Goal

Intramedullary nailing is a representative orthopedic surgery to fix broken bones by combining the locking screw which is inserted from the outside of the tissue with the distal or proximal nail hole. As mentioned earlier, since the nail is positioned in the medullary canal, surgeons cannot determine the position of the distal nail hole and the real-time displacement of exterior inserted drill bit. So conventional intramedullary nailing method employs a fluoroscopic image to visualize surgical instruments. However fluoroscopic image is thereby continuously exposed to high levels of radiation for medical staff and patients. And also, the fluoroscopic image which is output of the C-arm is based on static 2-dimensional image. It is unable to reflect real-time displacement data of the nail and the drill bit to be inserted in the image so as the surgical operation is in progress, it will require more radiography and causes error which results in medical accidents. In order to solve the problems of the intramedullary nailing, many systems are proposed. But most systems were not achieve general acceptance due to the low precision, cost competitiveness and inconvenience in use.

In this paper, we present a novel system that is low cost, high accurate and reliable owing to handle-integrated line-laser markers and instrument-integrated smart module. Using the proposed system, a distal nail hole can be accurately localized on skin, and a surgeon can verify the real-time angle of surgical drilling, which corresponds to the orientation of the screw toward the distal nail hole. Most of all, the proposed system conducts successful distal interlocking without any radiation exposure. The results of this study demonstrate that the proposed system is easy to use, precise, low-cost, and radiation-free, compared with previously proposed systems.

1.4 Thesis Organization

In chapter 2, we analyze the existing surgical navigation system which was attempted to address the limitation of intramedullary nailing. Chapter 3 will describe the new developments of proposed navigation system. In chapter 4, the experimental results of proposed navigation system will be addressed and the future problems to be improved will be referred through the chapter 5.

Chapter 2

CONVENTIONAL NAVIGATION SYSTMES FOR INTRAMEDULLARY NAILING OPERATION

2.1 Radiography based navigation systems for obtaining accuracy

The representative system using fluoroscopy is free-hand technique. Free-hand technique is the commonly used in intramedullary nailing operation. This technique is based on image intensifier which exposes radiation for finding the position of distal nail hole and visualizing the displacement of the drill bit. The point which is indicated by the image intensifier reflects the coaxial path which means the way from the drill insertion point to distal nail hole. In the free-hand process, for the successful distal interlocking, the image intensifier should be adjusted for positioning circles (output image of image intensifier and distal nail hole) are in the center of the screen (2-dimensional fluoroscopic image). For the precise distal nail hole localization, output circles of image intensifier and distal nail hole should be appeared perfectly round on the screen as the alignment is correct. However, it is not easily achieved so it has no choice to take large amount of radiation exposure hence it becomes a critical disadvantage [11]. The next step after distal nail hole localization is the drilling for securing the screw insertion path. For drill bit insertion, cortex should be incised then drill is adjusted to visually align with the circles of intensifier. There are three points of the drill that matches the circle of the intensifier; center of the drill bit, drill tip and the drill but. Kelly et al. performed successful distal locking through the alignment of these three points of drill [23]. The drawback of free-hand technique is that it needs large amount of fluoroscopic images. As already well known, the radiation gives a harmful influence on the human body. So most of surgical teams try to avoid and begrudge the radiation exposure. Not only to high dose of ionizing radiation exposure to medical team and patient, but also the inaccurate distal nail hole localization becomes critical defect. If an accurate position which indicates the position of distal nail hole has not been achieved, it may occur the new hole's being drilled in a corrected screw insertion path. So until a complete circle is on the 2-dimensional fluoroscopic image, intensifier should be aligned to coronal and transverse planes. Furthermore, even though the accurate position of the distal hole is positioned, through intensifier, drilling procedure should be repeated until the drill bit is inserted through the right path. So this procedure still requires additional use of radiography and repeated drilling. And repeated drilling procedure reduces the density of the bone and loosen the locking screw.

The traditional method for compensating the inaccurate drilling presented in the free-hand technique, guide instruments such as Steinmann pin, Kirschner wire or Guide-pin are inserted prior to inserting the drill bit into the bone. Kundsen et al. [24] proposed a technique using a 3mm Kirschner wire, air drill and image intensifier. This technique does not require additional assistant and aiming devices. A fluorescent substance coated drill or drill-guide instruments also proposed. These instruments can also be seen on the fluoroscopic images while locating in the path of the distal nail hole. However this technique makes the operation more difficult that reinserting of drill bit and longer operation time. To sum up, free-hand technique is a method by using an image intensifier, identify the location of the distal nail hole to the incision point on 2-dimensional fluoroscopic image. However, it continuously requires large amount of the radiography in order to identify the drilling path from drill bit insertion point to distal nail hole. Moreover, it has low accuracy so that repeated drilling operation should be performed.

For increasing drilling accuracy during distal interlocking procedure, hand-held system was proposed. The hand-held system uses a targeting device (guiding-jig) at the point which is indicated by the image-intensifier to prevent slipping of the drill bit during drilling procedure. The guiding-jig is designed for tipping the position of distal nail hole and fixing the orientation of the drill bit. After contacting the tip of hand-held guiding jig to the distal nail hole position indicated by image-intensifier, the axis of guiding-jig and the distal nail hole are aligned with co-axial by hand. Through the hand-held system operation time can be reduced than the conventional free-hand technique. However hand-held system cannot be a straightforward solution to decrease use of radiography and improve the drilling accuracy. In order to hold the initial position of guiding-jig, as free-hand technique does, intensifier should be used for localizing the position of distal nail hole hence it still requires radiography. And also, drilling accuracy cannot be improved prominently. Because the guiding-jig is fixed by the hands of the surgeon during drill bit insertion and the variable real-time drilling path is not visually realized to surgeon. Also, the operation time is being longer due to the use of targeting devices.

Liao et al. proposed an autostereoscopic image overlay device combined with a laser guidance system [4]. This system can reproduce display 3D autostereoscopic images and reproduce motion parallax by superimposing the images of surgical anatomic structures on to the patient using integral videography. It specified acquiring better accuracy by laser guidance based surgical instruments alignment method. Nakdhamabhorn et al. proposed a 4-DOF laser guidance robot which is high accurate owing to fluoroscopic image based image processing unit for calculating surgical path, and optical tracking system for identifying position and orientation. The robot guide the surgeon to perform high accurate intramedullary nailing[7]. However, these systems, while aiming to improve the operation accuracy, still rely on radiography and the costs of configuring these systems are high [4], [7], [8].

To summarize, for accurate intramedullary locking procedure, first of all, the position of the distal nail hole which is located in the medullary canal should be identified. And the drilling path (screw insertion path) must be secured from the insertion point to distal nail hole. However, these procedures are not stable because all of instruments are located in the medullary canal. It makes the operation time longer and still has limitation that of dependence on surgeon’s sense. For improving limitations of intramedullary nailing procedure, many technique has been presented. However they require repeated procedures to obtain a view of anterior, posterior and lateral image of patient’s femur. And it is hard to determine the precise distal nail hole position and real-time orientation of the drilling through the 2-

dimensional static fluoroscopic image. Consequently, radiation exposure should be high. Not only the defects of radioscopy but also the involuntary movement of the surgeon's hand occurs the medical accident in intramedullary nailing. If a hole is missed due to the inaccurate drilling, cortical defects can be occurred hence re-drilling is necessary. This can lead to bone weakening, or inadequate screw fixation. There is also the problem of the high occurrence of drill-nail contact. So they did not improve the localization of distal nail hole and drilling accuracy. Despite these problems, fluoroscopy based systems, for many surgeons, remain the favored technique for distal interlocking.

2.2 Low radiation targeted navigation systems

Conventional systems that rely on radiography are not only harmful to the human body but also unstable and obstructive. Due to the static 2-dimensional image characteristic, in order for the surgeon to confirm the real-time displacement of the surgical instruments, it is necessary to secure several fluoroscopic images of the anterior, posterior, and lateral of surgical sites. Therefore, the dependency or radiography becomes higher. In addition, since the accuracy is not high enough to detect errors in the real-time displacement of a changing medical instruments, the system that minimizes the radiation dose and minimizes the error currently becomes a main topic. For the first example of minimizing the dose of radiation and obtaining high screw drilling accuracy, a laser guidance system is proposed by Goodall et al [9]. The 632.8nm wavelength of helium/neon laser is mounted on the image intensifier and its output beam is emitted coaxially towards x-ray source. By using the laser guidance system, the drill insertion point is marked as a dot on the skin and the drilling is proceeded with several fluoroscopic image. Even though Goodall et al. found the method to reduce the use of radiography and increase the accuracy of distal interlocking, this system still requires additional fluoroscopic image to be taken when the surgical sites are changed. Like Goodall proposed system, there are many systems which are minimally used with the radiography. However these are not certain the successful distal interlocking when the movements of the instruments occur so most of them are not take general acceptance. In order to fully eliminate the dependency of radiography and to increase the accuracy of screw insertion, a nail-mounted systems have been proposed. The nail-mounted system is designed to device consists a targeting structure (guiding-bar), placed in a vertical position of the distal nail hole by combining a support structure with a proximal guide which is designed to the handle for proximal locking. A representative nail-mounted device is the T-handle of Orthofix®. T-handle is an instrument which is integrated guiding-bar. Since the guiding-bar of the T-handle is parallel to the nail, by inserting a graduated trocar through the guiding-bar, the alignment of the nail and handle is fixed. According to Gugala et al. the T-handle drastically reduced the time requirement of radiography during distal interlocking [25]. However, proximally mounted aiming devices, such as T-handle, are not as popular as the free-hand method. Because the position of the guiding-bar differs from the distal nail hole by 90 degrees, the handle slightly sags due to its weight when the guiding-bar is in the supine position to the floor. Also, the guiding-bar is located on the extension of the drilling path (screw insertion path), so it causes a restriction on the behavior of the surgeon during drilling procedure. These situations can lead to misalignment of the distal nail hole and guiding-bar.

Magnetic-field-sensing-based techniques also have been proposed for determining the distal nail hole location without using radiography [3], [6]. Lee et al. proposed a nail-embedded permanent magnet and an electrical conductive board [3]. The drawback of this system is that the magnetic field can change when the conductor is adjacent to the nail. In addition, this system requires custom nails with a permanent magnet inside. Chu et al. proposed a nail-embedded endo-trans illuminating system [5], which emits light while a nail is positioned in the bone. This system uses a light-emitting diode (LED) that emits light with wavelength in the visible range of 700–1000 nm, thus eliminating the need of using radiography. However, even though the operator can see the light emitted from inside of the bone, the guiding light is scattered owing to tissue reflection, requiring an additional optical device. The critical defects in both of the proposed systems is requirement of specially manufactured nails, thus increasing the cost.

To sum up, most of the proposed systems achieved their own goal (high accuracy, low radiation exposure). However, they unwillingly endured other disadvantage while acquiring their goal. High accuracy targeted systems missed cost-effectiveness in system construction and radiation hazard. Low radiation targeted systems require specially manufactured nails which increase the cost and could not prevent the naturally occurred distortion such as magnetic field distortion or light scattered of tissue reflection.

Chapter 3

DESIGN OF PROPOSED NAVIGATION SYSTEM

3.1 Handle-integrated line-laser markers

3.1.1 Methodology

For highly precise localization of the distal nail hole and no use of radiography, we propose a handle-integrated laser guidance module. Conventionally, many laser guidance systems have been proposed which used dot-pointed laser modules. However, in characteristic of dot-pointed laser, the output position of the laser beam varies in accordance with the height of a medium. Thus, if a dot-pointed laser is simply adopted for intramedullary nailing, the drill bit insertion point changes according to the thickness of the patient's tissue. In our system, we made use of the fact that the output beam planes of two line lasers have a line of intersection. As shown in Figure 7, the laser guiding module includes two line lasers, projecting two individual lines on the skin surface. When the lasers are controlled to emit light toward the distal nail hole, the line of intersection of the corresponding beam planes is normal to the plane of the distal nail hole. When this normal line crosses the patient's skin, an intersected point is formed, indicating the precise insertion point of a drill bit. It means the target distal nail hole can be perpendicularly accessed, regardless of the tissue thickness. In addition, the proposed laser guidance module is coupled to a handle that is used when inserting the nail. The advantage of coupling the laser guidance module to the handle structure is discussed in next paragraph. To mathematically interpret the principle of the laser guidance system in Figure 8, we assume that the reference plane is located on the patient's skin into which the drill bit is inserted, by translating parallel plane of distal nail hole plane. Then, the two laser markers are adjusted in such a way that the beam

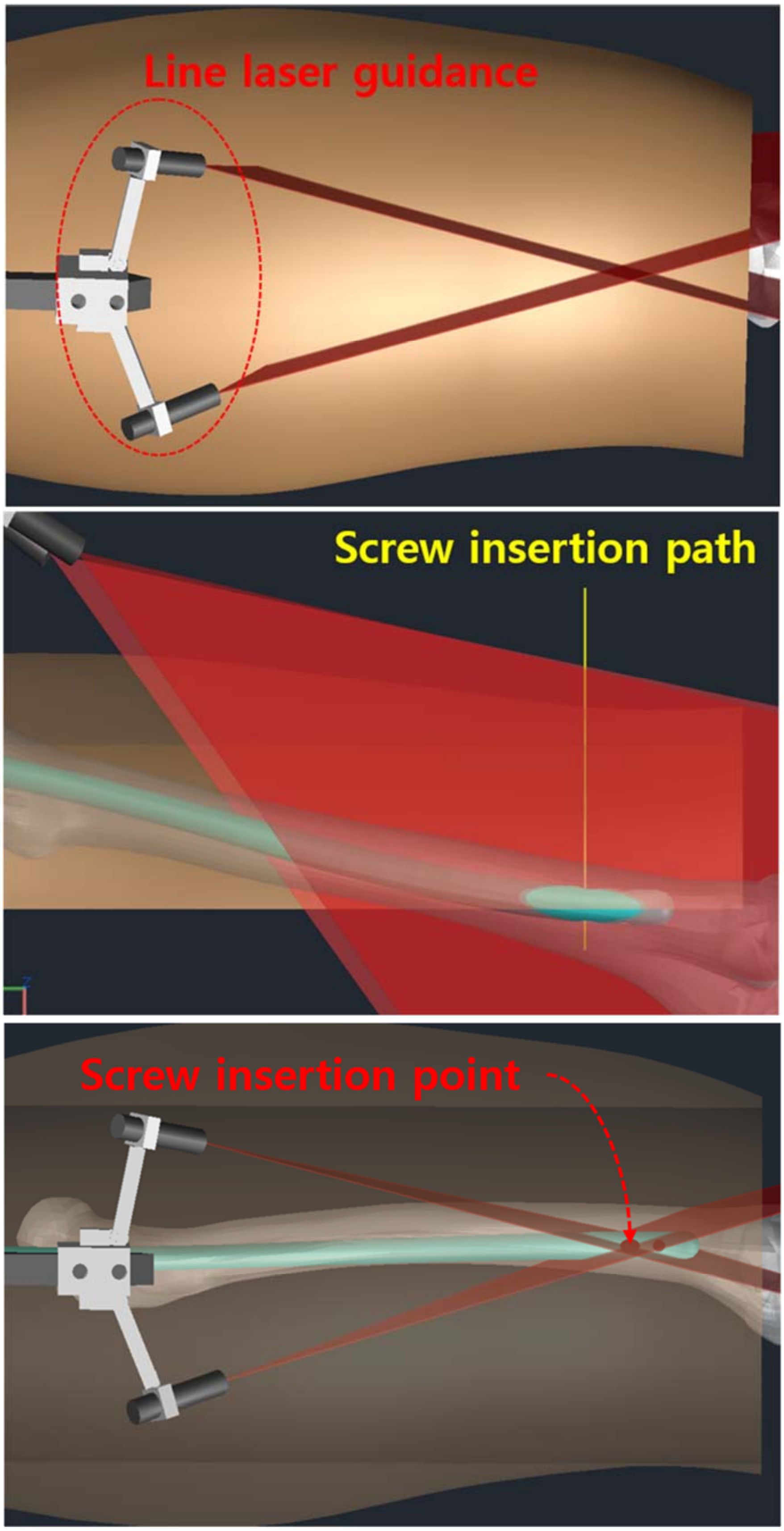

Figure 7. The proposed navigation system: Laser guidance

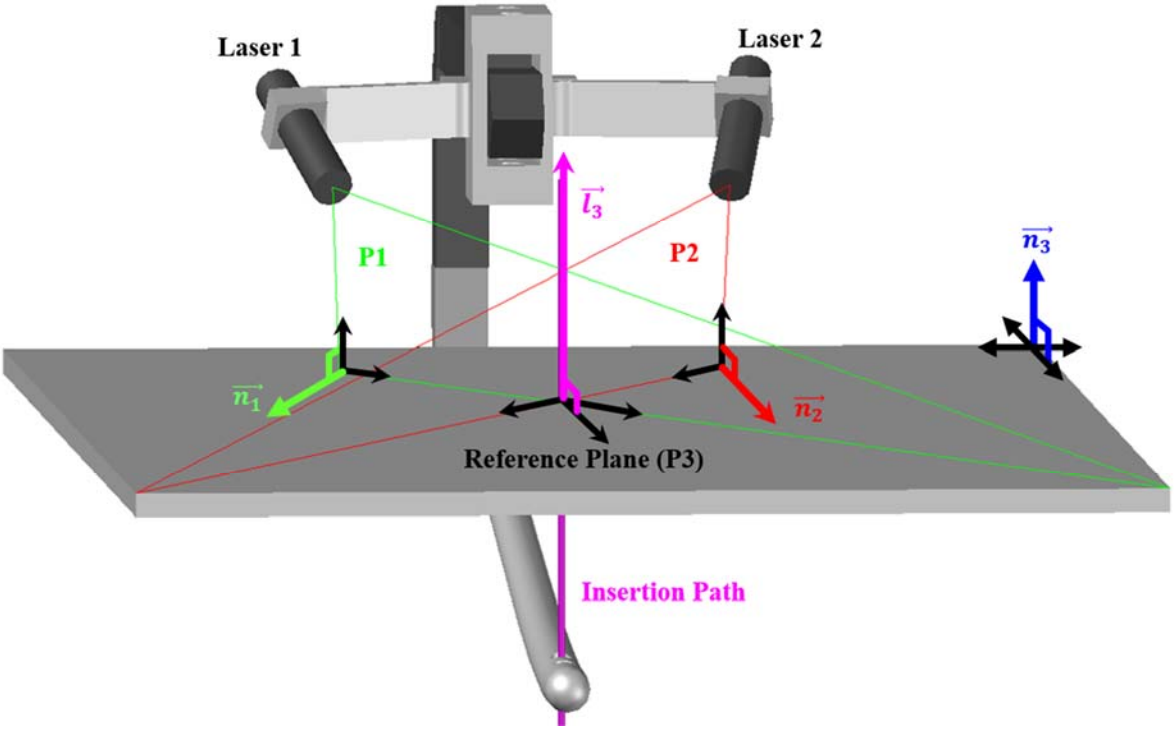

Figure 8. Theoretical illustration of the proposed laser guidance system

planes (P1, P2) formed by the light beams emitted toward the distal nail hole are perpendicular to the reference plane. Through the above condition, each normal vector of beam planes $(\vec{n_1}, \vec{n_2})$ become perpendicular to normal vector of reference plane.

$$\vec{n_1} \cdot \vec{n_3} = 0 \tag{1}$$

$$\vec{n_2} \cdot \vec{n_3} = 0 \tag{2}$$

$$\vec{n_1} = \textbf{Normal vector of plane 1} \tag{3}$$

$$\vec{n_2} = \textbf{Normal vector of plane 2} \tag{4}$$

$$\vec{n_3} = \textbf{Normal vector of the reference plane} \tag{5}$$

The intersection vector of the two laser beam planes $(\vec{l_3})$ is located on the insertion point; the intersection line is always normal to the distal nail hole.

$$\vec{n_3} \times \vec{l_3} = (\vec{n_1} \times \vec{n_2}) \times \vec{l_3} = \mathbf{0} \tag{6}$$

$$\vec{l_3} = \textbf{Vector of crossing beam planes} \tag{7}$$

Using the set of locational relations above, we developed a high accurate, low-cost distal nail hole localization and drilling guide for distal interlocking.

However, laser marker based conventional systems for intramedullary nailing have a practical drawback; these systems are sensitive to possible surgery site displacement during operation. Conventionally, laser guiding modules are positioned with no fixed relation to the location and orientation of the nail, and disturbance of the patient's femur owing to an external physical impact displaces the surgical site, yielding localization errors. For example, even when the reference plane (surgical site) is tilted, projection angles do not changed along with the reference plane because the laser guidance device is separated from the nail and handle. Thus, after the displacement, the normal vectors of the laser beam planes are not perpendicular to the reference plane anymore. Let us denote the normal vectors of the three planes (P1, P2, P3) by $\overrightarrow{\boldsymbol{n_1}}$, $\overrightarrow{\boldsymbol{n_2}}$, and $\overrightarrow{\boldsymbol{n_3}}$:

$$\overrightarrow{\boldsymbol{n_1}} = (\boldsymbol{a_1}, \boldsymbol{b_1}, \boldsymbol{c_1}) \tag{8}$$

$$\overrightarrow{\boldsymbol{n_2}} = (\boldsymbol{a_2}, \boldsymbol{b_2}, \boldsymbol{c_2}) \tag{9}$$

$$\overrightarrow{\boldsymbol{n_3}} = (\boldsymbol{a_3}, \boldsymbol{b_3}, \boldsymbol{c_3}) \tag{10}$$

If the distal nail hole plane, and hence the reference plane are tilted by $\boldsymbol{\theta}^\circ$, the normal vector of the reference plane ($\overrightarrow{\boldsymbol{n_3}}$) becomes

$$\overrightarrow{\boldsymbol{n_3}} = (\boldsymbol{a_3},\ \boldsymbol{b_3 cos\theta} - \boldsymbol{b_3 sin\theta},\ \boldsymbol{c_3}) \tag{7}$$

Then, the intersection line of the beam planes ($\overrightarrow{\boldsymbol{l_3}}$) is not parallel to the normal vector of the reference plane.

$$\overrightarrow{\boldsymbol{n_3'}} \times \overrightarrow{\boldsymbol{l_3}} \neq \boldsymbol{0} \tag{8}$$

Thus, the point of intersection of the laser-beam planes does not indicate the distal nail hole location, i.e. a guiding error occurs. To solve this problem, previously proposed laser marker based systems have used additional optical devices and data processing devices for calculating proper lasers' projection angles [4], [7]. Additional devices are used for tracking the operating site's movement and for

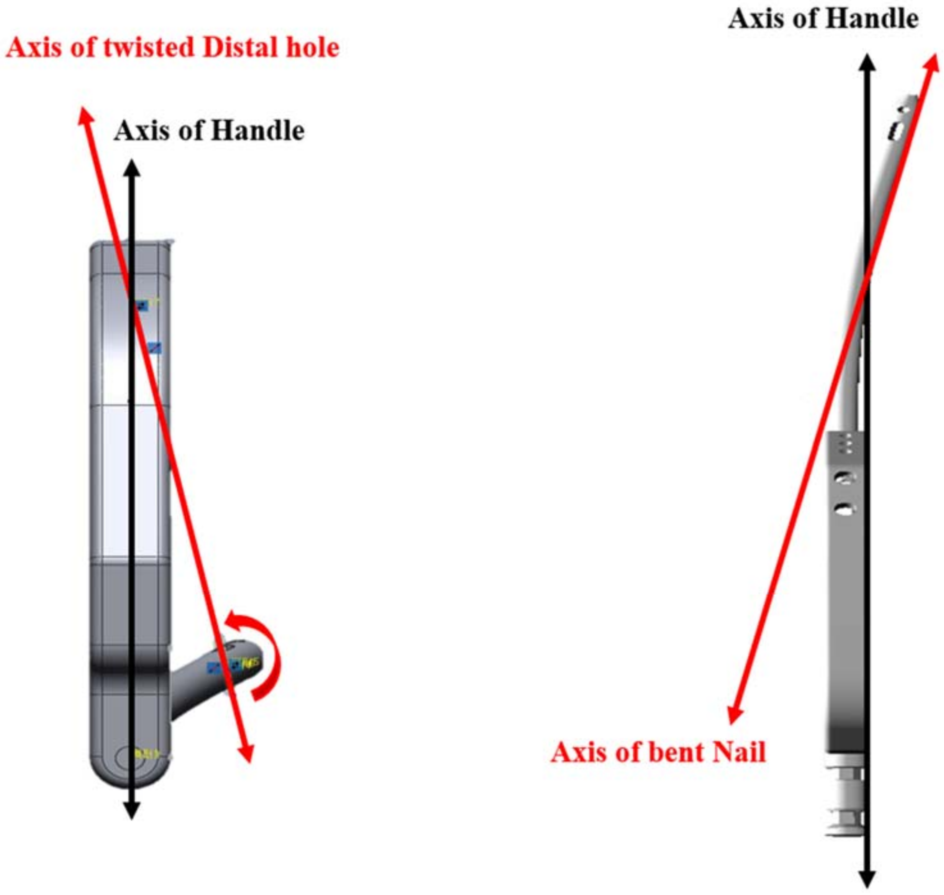

Figure 9. The 3-dimensional models of the handle and a nail, for measuring mismatches between the axis and the insertion angle

calculating the resulting errors, so that the lasers' projection angles can be properly controlled. It makes the system more expensive and obstructive. On the other hand, our system uses a robust fixation mechanism with mechanically integrated handle and laser-guidance module. As a result, the laser guidance module is automatically adjusted, offsetting the surgical site displacement. Thus, the module always locates a correct drill bit insertion point, which is perpendicular to the center of the distal nail hole.

3.1.2 Axis alignment

For properly localizing the distal nail hole, it is also important to compensate the axial mismatch between the distal nail hole and the handle. Because the nail is driven into the bone, the nail has a slightly bent curvature to conform to the patient's anatomy; thus, the axis of the handle is tilted relative to the axis of the distal nail hole. This axial mismatch should be accounted for when calculating

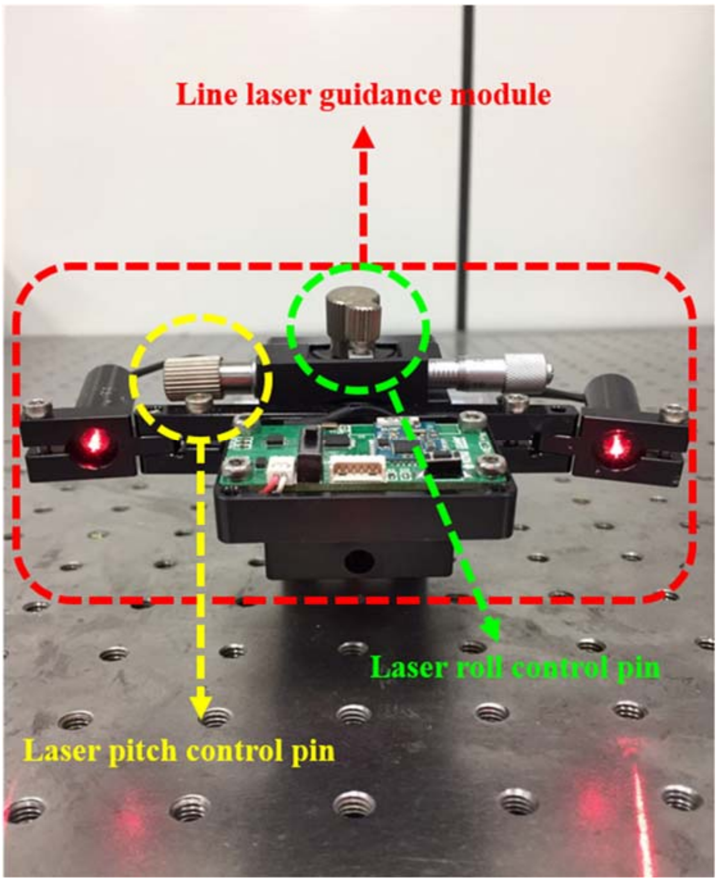

Figure 10. The designed line-laser guidance module

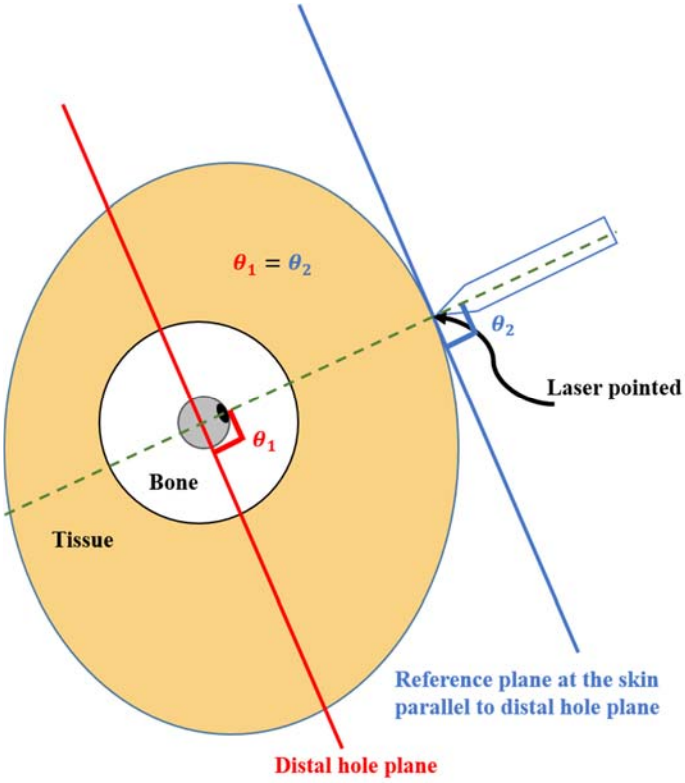

Figure 11. Cross-sectional diagram showing the geometrical relation between the screw insertion point guided by the system and the distal hole of nail

the lasers' emission angles. As shown in Figure 9, to resolve these issues, accurate 3D models of the nail and handle structures were constructed. By compensating the lasers' emission angles according to the measured tilting and bending angle (axis mismatch), the laser mounting structure prevented the effects of axial mismatch from occurring. To control the angle and the direction of laser guiding, as shown in Figure 10, the module structure was designed to be direction-controllable. In the present work, the module was hand-controlled, but automatic control will be implemented in the future. And nails are classified into several types, depending on the size of the patient's femur. However, the present system employs only one type of the nail, because the present study focuses on validating the proposed laser guidance module.

3.1.3 Novelty

In our system, the laser markers easily localize the distal nail hole which means precise screw insertion point using the proposed handle-integrated structure. Because the system contains a robust integration mechanism and uses accurate geometric calculations, the projection angles of laser markers are automatically controlled along with the nail movement, alleviating the need to use additional devices for tracking and compensation. The proposed structure ensures that the laser guided point is always located on the line perpendicular to the center of the distal nail hole, as shown in Figure 11. The operating surgeon is conveniently find the correct point toward distal nail hole which is the surgical instrument(locking screw) is to be inserted. The proposed system is cost-efficient.

3.2 Drilling direction guidance smart module

3.2.1 Methodology

In intramedullary nailing, after localization of the screw insertion point (distal nail hole), drilling is performed as a next step for successful distal interlocking. It is important not only to ensure precise distal nail hole localization but also to provide an accurate drilling direction guidance, because inaccuracy in drilling can result in a drill bit crash and unstable distal interlocking. So, conventionally, surgeons verify the drilling orientation while drilling using 2-dimensional fluoroscopic image. However, in addition to being based on radiography, this approach is time-consuming. Verifying a real-time drilling orientation is a challenge, and many approaches have been proposed for implementing a real-time navigation system to solve this issue [3], [6]. However, as already mentioned in introduction, most of these approaches did not find general acceptance, owing to their high associated cost. Employing a conventional navigation system incurs an excessively higher cost in performing nailing procedures. Given the cost constraint, we focused on implementing a non-radiative, low-cost and precise drilling orientation guidance system.

As shown in Figure 7, our proposed system which relies on the laser guidance module, ensures that the screw insertion point is always located on the line that is perpendicular to the plane of the distal nail hole. This allows to successfully perform the surgery, as long as the drill is kept heading in perpendicular direction. In our approach, as shown in Figure 12, the drilling angle is measured using inertial sensors, for allowing the surgeon to ensure that the drilling orientation is perpendicular to the plane of the distal nail hole. Therefore, our system does not require fluoroscopic imaging for real-time validation of drilling orientation. However, the drilling angle should be adjusted in real time to offset any potential displacement of the surgical site. Thus, the drilling orientation with respect to the plane of the handle that is embedded into the nail should be measured in real time. To achieve this, as shown in Figure 13, we employ two angle measurement modules – one integrated with the body of the drill and the other with the handle of the nail. For implementing each angle measurement module, a 9-axis inertial sensor chip, a Bluetooth communication module, and a microprocessor unit are used. Each module measures the tilting angle in real time and transmits the measured data to a host computer having a display panel. The host computer then processes the data received from two modules to calculate the drilling orientation with respect to the plane of the handle and displays the results. By observing the information on the display panel, the surgeon can perform real-time verification of the drill's current position and the tilting angle of the drill bit relative to the plane of the distal nail hole, so that the actual

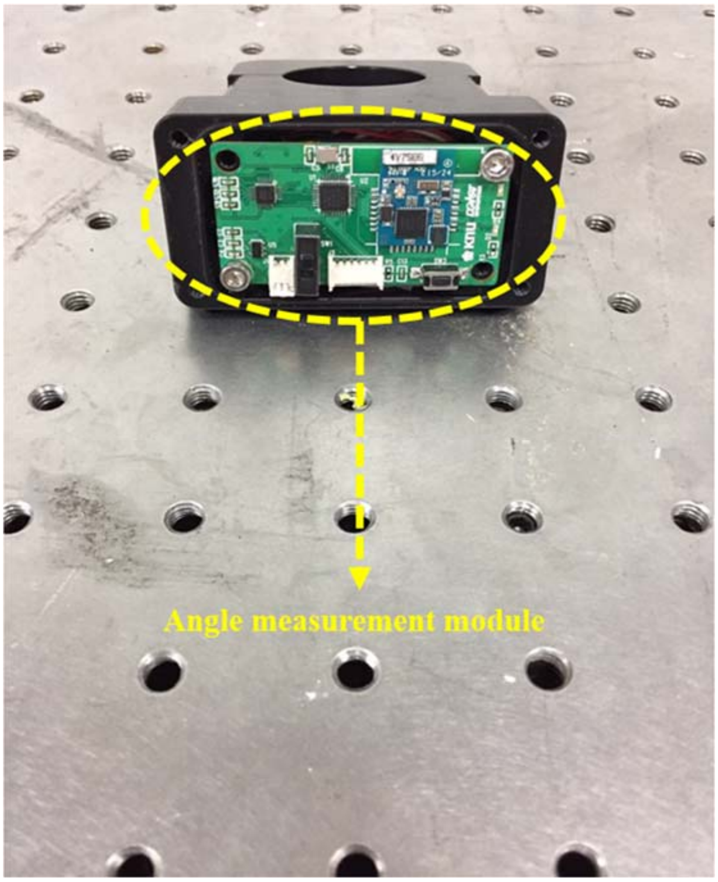

Figure 12. The designed modules of the real-time drilling angle measurement

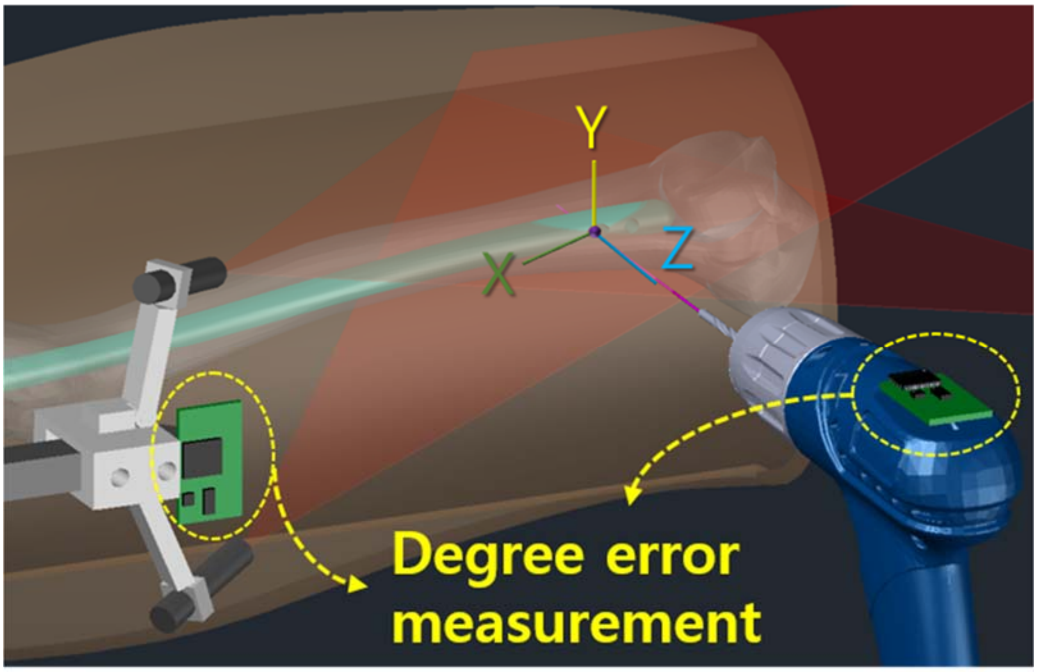

Figure 13. The proposed real-time screw drilling angle measurement system

drilling path can be aligned with the target path, as in Figure 7.

3.3 Interface circuit design

The circuit module (Figure 14) of the provided drilling orientation guidance system consists of a sensor circuit for angle measurements, a communication circuit for wirelessly communicating with the host computer, and a power management circuit for providing proper power to all circuit blocks. In the sensor circuit, a 9-axis inertial sensor (MPU-9250), containing a gyroscope, an accelerometer, and a magnetometer, is used for measuring displacement data in real-time. In addition, the system features a micro-processor (ATmega-168) module for converting raw displacement data into degree data, using a custom algorithm. A Bluetooth communication module (BOT-CLE110) is used in the communication circuit to transmit real-time angle information measured from the handle and drill integrated modules. The transmitted information is processed in the host computer to provide the real-time visualization on the display panel. The Galaxy Tab is used in this work.

3.3.1 Circuit design consideration

When choosing the electronic circuit chip for our system, we considered its size, power consumption, and temperature limitation. For surgeons not to feel obstructive, the module size should be as small as possible, and the operating time should be long. The circuit board that was implemented in this study was 48×25 mm^2 as shown in Figure 14, and starting with a fully charged battery, the operating time was about 20 hours.

Importantly, for sterilization of medical devices, the circuit should withstand sterilization temperature. Medical devices are usually sterilized using the autoclave method, which requires the temperature of 120 ^{o}C, which can be too high for the circuit to withstand. To be on the safe side, we therefore propose to use a different sterilization method, utilizing the EtO (ethylene oxide) gas. The EtO gas sterilization method does not require the temperature higher than 60 ^{o}C.

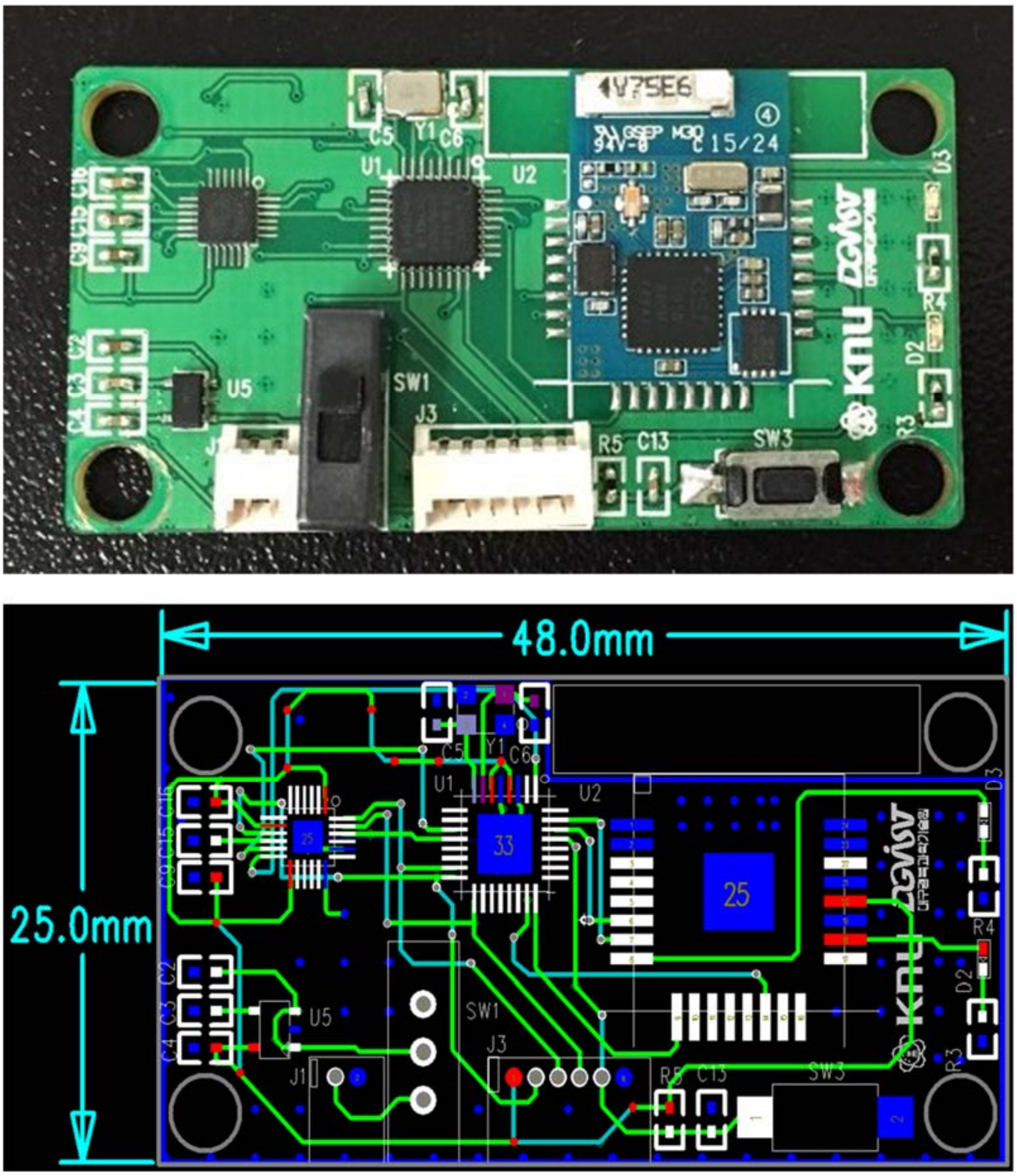

Figure 14. Electronic circuits implemented on the printed circuit board for the angle measurement module

3.3.2 Practical drill alignment method

The practical method of drill bit direction alignment for drilling is shown in Figure 15. As the plane of the handle (P2) and the plane of the distal nail hole (P1) are interconnected structurally, the angles between the planes are always same. Since successful distal interlocking requires the drill to be inserted perpendicularly, the drilling orientation with respect to the distal nail hole plane should be measured in real-time. When the drilling orientation is tilted relative to the distal nail hole plane (P1), an error is registered by the integrated angle measurement modules. Then, as shown in Figure 16, the

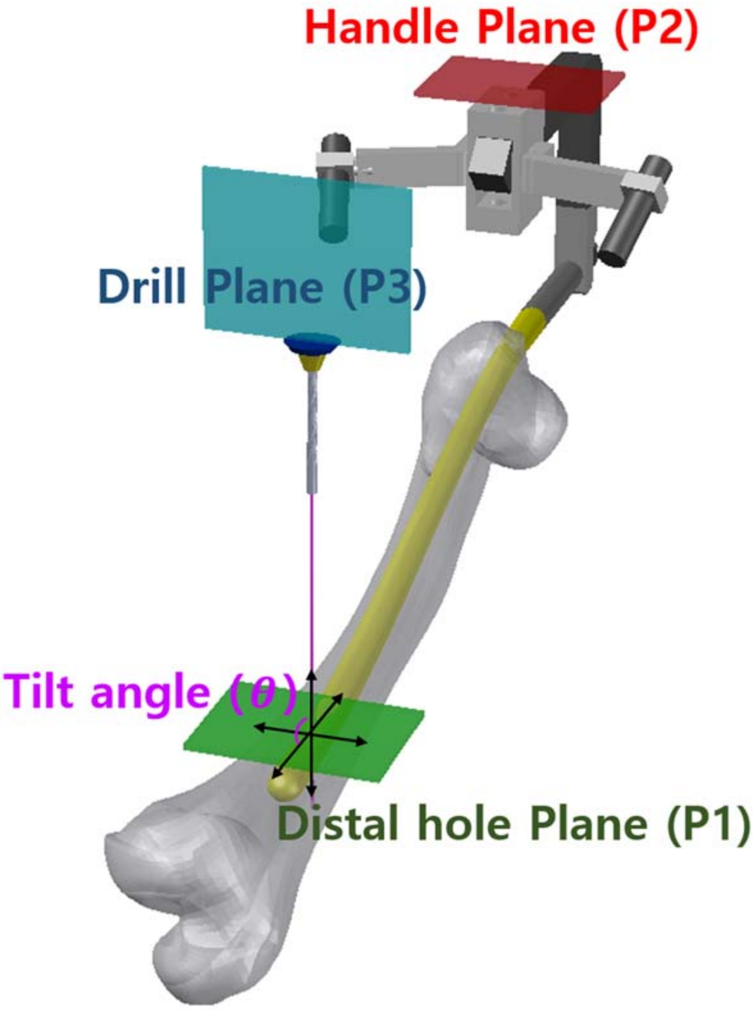

Figure 15. Alignment of different planes for ensuring perpendicular insertion of the screw

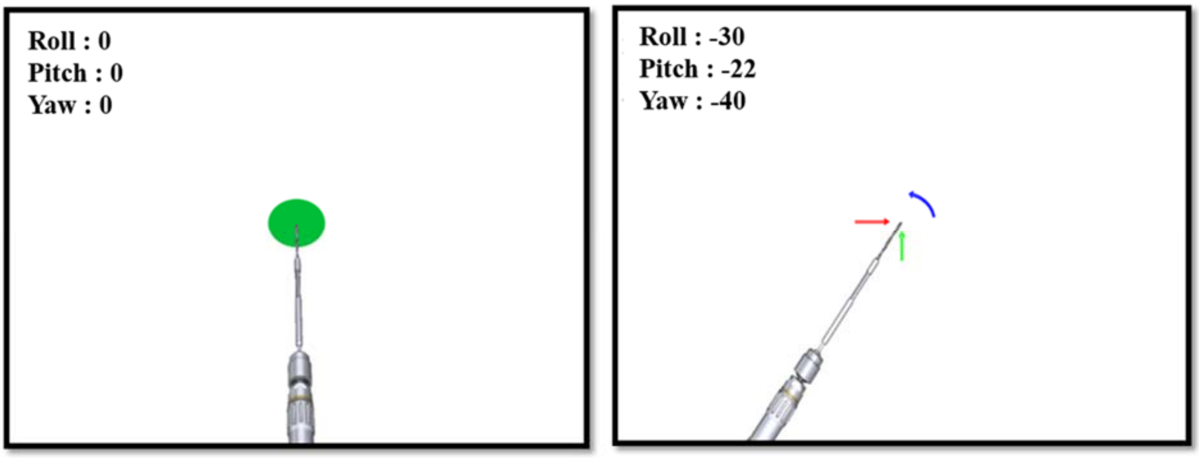

Figure 16. Real-time visual feedback on the drill's path

measured error in the form of Euler angles (yaw, pitch, and roll rotations) is visually fed back to the surgeon, along with the information on the correct drilling path. When the drilling orientation is correctly aligned with the direction toward the distal nail hole, a green circle is displayed at the tip of the drill bit. If the drilling orientation is not correct, the measured real-time error value is displayed together with the arrows indicating the direction of required adjustment.

3.3.3 Drill vibration effect consideration

Due to the vibration of a drill, sensing the real-time tilting angle of the drilling is distorted while the drill bit is being inserted. The drilling noise is determined based on the location of motor and gear. Especially the gear driving part in the drill accounts for up to 60% of overall vibration. Thus, the noise that is caused by the drilling vibration should be accounted for. We positioned the angle measurement module apart from the drill-involved motor and gear, which structurally are the most intensive vibrating parts. Hence, the effect of the drill’s vibration noise was alleviated.

3.4 Orientation estimation using complimentary filter

Using inertial and magnetic sensor units, for accurately estimation of 3-dimensional orientations of a drill bit and the distal nail hole, we employed an orientation algorithm based on the gradient descent method proposed by Madgwick et al [14]. It has advantages such as a low computational load and a low sampling frequency, compared with conventional 3-dimensional orientation estimation algorithms [15], [16]. In the estimation of the orientation of target objects (handle and drill) using a magnetic sensor, magnetic distortion inevitably occurs, owing to the effects of hard and soft irons. To mitigate this magnetic distortion, a reference direction for the magnetic field of Earth was predefined in previously proposed methods [17], [18]. In contrast, Madgwick’s algorithm does not require to predefine the reference direction, since it can compensate magnetic distortions [14]. Figure 17 illustrates the 3-dimensional orientation estimation method based on Madgwick’s algorithm for real-time tracking of orientations of a drilling and the distal nail hole. Here, we used an inertial sensor unit, MPU-9250 (Invensense, USA), which is composed of a 3-axis accelerometer, a 3-axis gyroscope, and a 3-axis magnetometer for 3-dimensional orientation estimation of a drilling and the distal nail hole. Using the sensor unit, the acceleration and angular rates of a moving target objects and the magnetic

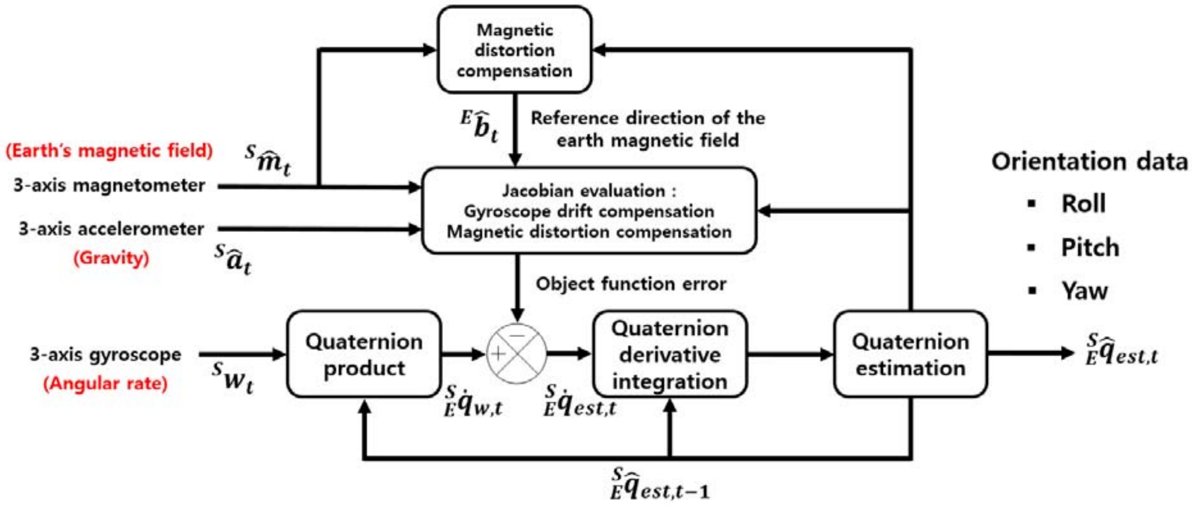

Figure 17. Block diagram of the 3-D orientation estimation method based on Madgwick's algorithm

field of Earth are simultaneously measured. Based on this information, the attitude and the heading direction of the drill bit and the distal nail hole with respect to the direction of gravity and the magnetic field of Earth can be estimated. In the algorithm, after calculating the quaternion derivatives of the measured 3-axis angular rate values, the derivatives are integrated to obtain the orientation of the sensor frame with respect to the reference frame of the Earth. The gyroscope bias drift error that occurs in the quaternion derivative integration stage over time, temperature, and motion, is compensated by orientation filters based on the integral feedback of the error with an appropriate gain. The filter gain, which is expressed by the magnitude of a quaternion derivative of an estimated rate of the gyroscope bias drift, determines the rate of convergence for removing the drift errors.

Chapter 4

EXPERIMENT RESULTS

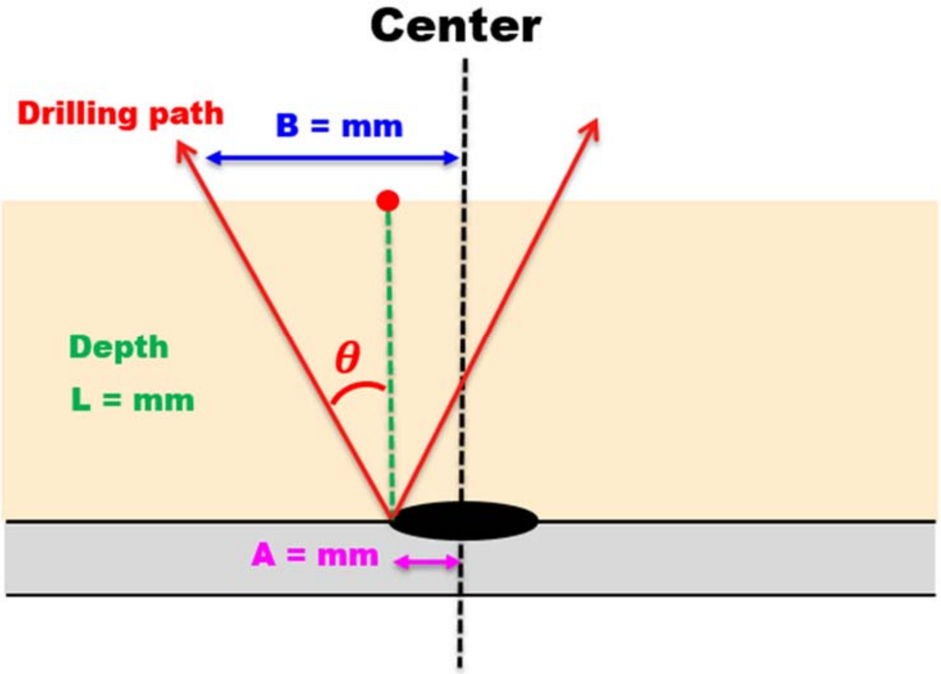

Figure 18. The black dotted line in the center represents the desired insertion path. The red arrow line represents an incorrect path of the drill bit

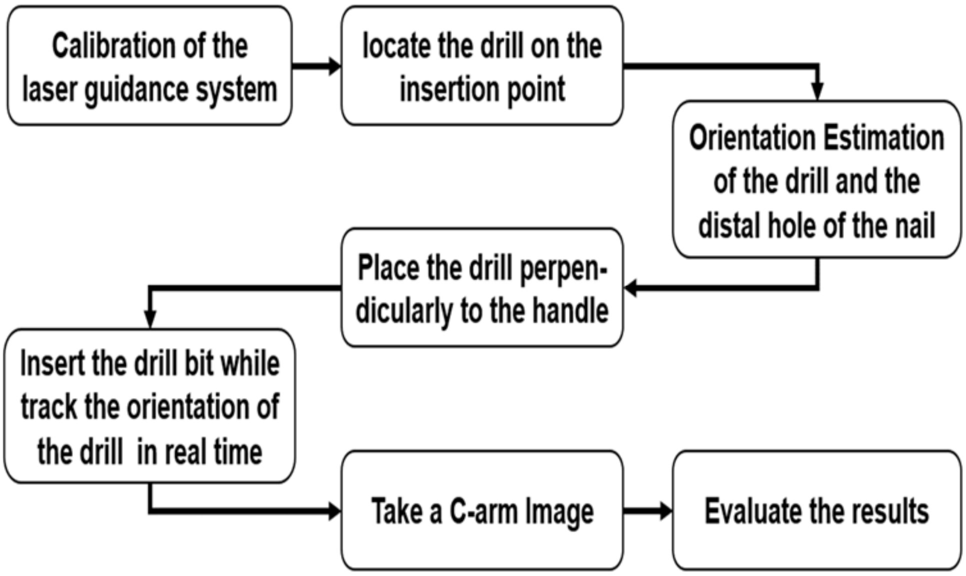

Figure 19. Experimental procedures for validating the developed system

Figure 18 illustrates the distal nail hole in the lateral view. L is the depth of the distal nail hole. Performance of the smart navigation system for intramedullary nailing in an orthopedic operation was evaluated by measuring the following parameters: (1) the incidence angle (θ) of a drill bit; (2) the distance between the center line of the distal nail hole and the insertion point of the drill bit (A); (3) the distance between the center line of the distal nail hole and the exit point of the drill bit (B).

The incidence angle (θ) of a drill bit represents the accuracy of the drill and the distal nail hole, obtained using the 3-dimensional orientation measurement method. The parameter A which means the distance between the center line and the insertion point represents the error of screw insertion point localization, indicating the extent to which the screw insertion point is perpendicular to the center point of the distal nail hole. The parameter B which means the distance between the center line and the exit point indicates the accuracy in the tracking the drill orientation in real-time. Figure 19 depicts the experimental procedures for validating our developed system: 1) the laser guidance system is calibrated manually for indicating the drill bit insertion point perpendicular to the distal nail hole before nail insertion; 2) the tip of the drill bit is located at the insertion point indicated by intersected line of two line lasers; 3) the orientations of the drill bit and the distal nail hole are estimated simultaneously and the orientation values are displayed on a display panel using an Android application. Therefore, an operator can monitor the orientations of the drill bit with respect to the distal nail hole in real- time; 4) the drill bit is then placed perpendicularly to the distal nail hole using the orientation information; 5) the drill bit is inserted while the orientation of the drill bit is tracked in real- time; 6) a C-arm image is acquired to evaluate whether the drill bit is properly inserted into the distal nail hole. A phantom experiment with femur sawbones was conducted to evaluate the performance of the proposed system. A total of 30 trials were conducted by two novices and two experts, respectively. Figure 20 illustrates a photograph of the phantom experiment. The intersection point of the two line laser beams indicates the insertion point of a drill bit. At the same time, the orientation information of the drill bit with respect to a distal nail hole is displayed on the screen in real-time. In the phantom experiment, to verify whether the drill bit was successfully inserted into the distal nail hole, a C-arm image was acquired at every trial. Figure 21 shows that, using our system, the drill bit was inserted precisely into the distal nail hole.

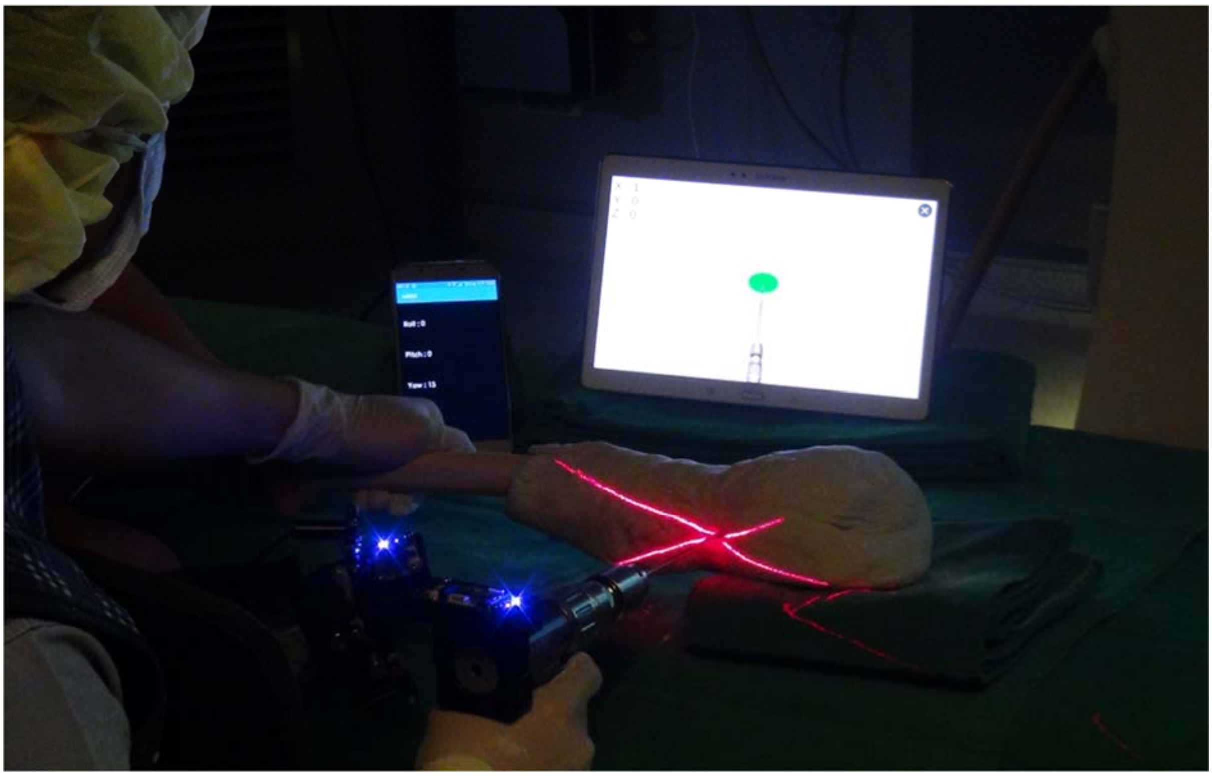

Figure 20. A phantom experiment using the laser guidance system with the orientation estimation system integrated in the drill and the handle

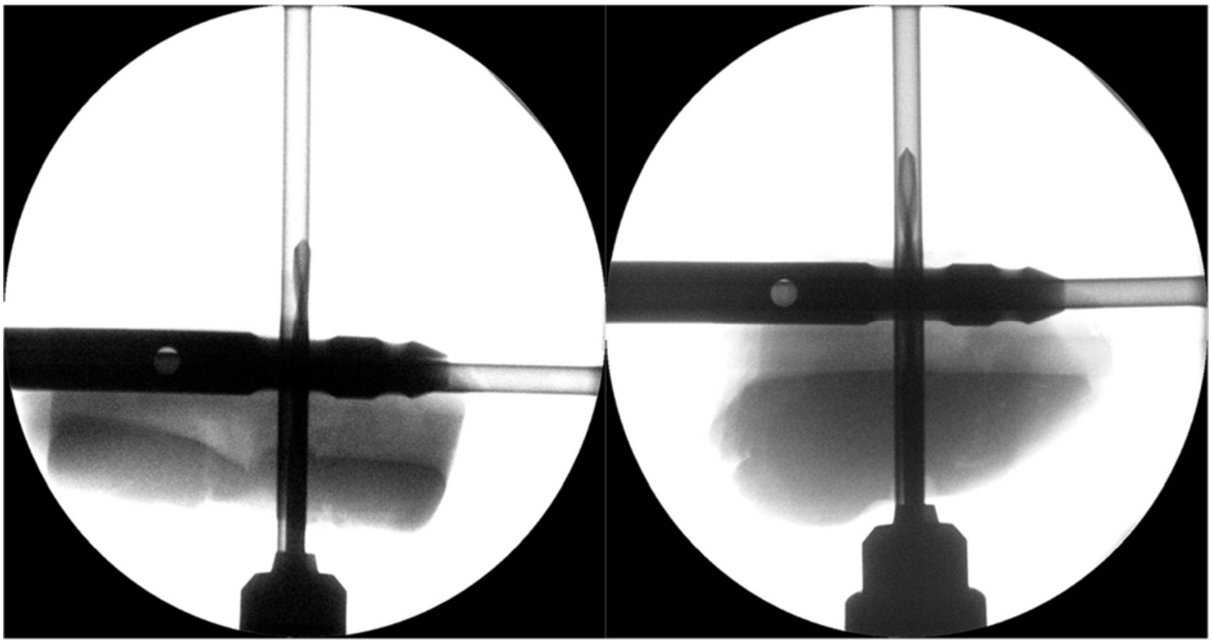

Figure 21. The C-arm images for evaluating the accuracy of the developed system

Among 120 trials for intramedullary nailing that were performed using this system, not a single case of failure was registered, thus demonstrating the potential of our system for intramedullary nailing. For quantitative evaluation of performance of the system for intramedullary nailing, the incidence angle (θ)

Novice group	**Mean**		**SD**		**Reliability**
	Novice 1	Novice 2	Novice 1	Novice 2	
AV of the incidence angle (θ) (degrees)	2.47	2.02	1.47	1.52	***r*=0.076, *p*=0.691**
AV of the A (mm)	1.84	2.47	1.57	1.69	***r*=0.196, *p*=0.298**
AV of the B (mm)	2.22	2.75	1.72	1.80	**r=0.200, *p*=0.290**
AV of the B-A (mm)	0.48	0.38	0.28	0.29	***r*=0.061, *p*=0.748**

Expert group	**Mean**		**SD**		**Reliability**
	Expert 1	Expert 2	Expert 1	Expert 2	
AV of the incidence angle (θ) (degrees)	3.35	2.48	2.19	2.11	***r*=0.190, *p*=0.314**
AV of the A (mm)	1.99	1.86	1.65	1.61	***r*=0.001, *p*=0.996**
AV of the B (mm)	2.42	2.16	1.84	1.65	**r=0.117, *p*=0.539**
AV of the B-A (mm)	0.64	0.48	0.42	0.40	***r*=0.186, *p*=0.324**

Novices vs Experts	**Mean**		**SD**		**Reliability**
	Novices	Experts	Novices	Experts	
AV of the incidence angle (θ) (degrees)	2.25	2.92	1.10	1.66	***r*=0.131, *p*=0.489**
AV of the A (mm)	2.16	1.92	1.26	1.15	***r*=0.193 *p*=0.308**
AV of the B (mm)	2.49	2.29	1.37	1.22	**r=0.172, *p*=0.363**
AV of the B-A (mm)	0.43	0.56	0.21	0.32	***r*=0.120, *p*=0.526**

* R: CORRELATION COEFFICIENT, AV: ABSOLUTE VALUE, SD: STANDARD DEVIATION

Table 1. Results of the experiments for evaluating the developed system

of the drill bit, the distance between the center line and the insertion point of the drill bit (A), and the distance between the center line and the exit point of the drill bit (B) were measured from the C-arm image. Table I lists the results of this quantitative analysis of the system performance. Comparing across Novice 1 and Novice 2, no significant differences were observed between the values of θ, between the values of |A|, between the values of |B|, and between the values of |B – A| (p-values = 0.691, 0.298, 0.290, and 0.740 > 0.05). In addition, the absolute angle of incidence for Expert 1 was not significantly different from that for Expert 2. The mean absolute angle of incidence for Expert 1 was 3.35° (SD: ±2.19°), whereas that for Expert 2 was 2.48° (SD: ±2.11°). In addition, no significant differences were observed between the mean values of |A|, |B|, and |B – A| for Expert 1 and Expert 2, respectively. The mean values of the θ, |A|, |B|, and |B – A| values for Expert 1 were 3.35° (SD: ±2.19°), 1.99 mm (SD: ±1.65 mm), 2.42 mm (SD: ±1.84), and 0.64 mm (SD: ±0.42 mm), whereas those for Expert 2 were 2.48° (SD: ±2.11°), 1.86 mm (SD: ±1.61 mm), 2.16 mm (SD: ±1.65 mm), and 0.48 mm (SD: ±0.40 mm), respectively. On comparison between the novice and expert groups, no significant differences between the θ values, the |A| values, the |B| values, and the |B – A| values were observed for the two groups. The mean values of θ, |A|, |B|, and |B – A| for the novice group were 2.25° (SD: ±1.10°), 2.16 mm (SD: ±1.26 mm), 2.49 mm (SD: ±1.37), and 0.43 mm (SD: ±0.21 mm), whereas those for the expert group were 2.92° (SD: ±1.66°), 1.92 mm (SD: ±1.15 mm), 2.29 mm (SD: ±1.22 mm), and 0.56 mm (SD: ±0.32 mm), respectively. These results demonstrate that, using the developed system, both the novice group and the expert group successfully performed precise intramedullary nailing with a high rate of success. This demonstrates the high potential of our system for intramedullary nailing.

Chapter 5

CONCLUSION AND DISCUSSION

5.1 Conclusion

In this study, we developed a novel surgical navigation system by implementing handle-integrated line-laser markers and drilling orientation measurement units for obtaining high-accuracy, low-cost and no need of radiography. Using the proposed system, an insertion point for locking screw was marked on skin, perpendicular to the center of the distal nail hole, allowing the locking screw to be inserted precisely into the distal nail hole. No failures were observed when nailing procedure was performed either by experts or novices. Although the developed system needs to be calibrated for different types and lengths of nails before operation, it is important to note that this navigation system allows orthopedic surgeons to achieve intramedullary nailing in a precise and time-saving way, with few fluoroscopic image acquisitions.

5.2 Discussion

One aspect of challenges in intramedullary nailing that haven't yet been addressed in this work is the compensation of the nail deformation induced during the nail insertion process [19]–[22]. Even though the effect of deformation is insignificant, for developing a more complete and robust guidance solution, a proper compensation technique such as that presented in [20] has to be introduced and implemented as a part of the system. Such an approach may involve fluoroscopic imaging steps, but the number of required images can be strictly limited (e.g. two images used in [20].) Most importantly, the proposed system is simpler and cheaper compared with existing devices [3]–[7], [9], [12]–[13]. The results of this study suggest that our developed system has great potential to serve as a novel tool for intramedullary nailing.

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요 약 문

수내못고정술의 원거리 결합을 위한 방사선을 사용하지 않는 고정밀 네비게이션 시스템

수내못고정술은 골절환자를 치료하기 위한 정형외과의 대표적인 수술로써, 골절부위에 nail이라 불리는 쇠막대를 삽입한 후 피부 외부에서 삽입된 나사와 nail의 구멍을 결합함으로써 골절부위를 고정한다. 기존의 수내못고정술은 nail의 구멍과 나사의 실시간 변위를 확인하기 위하여 C-arm 을 이용한 방사선 촬영에 의존하여 수술을 진행하였다. 하지만 방사선 촬영에 의존한 수술법은 골 내부에 위치한 수술장비의 실시간 변위를 파악하기 위하여 의료진과 환자 모두 지속적으로 방사선에 노출되어야 하며 방사선 이미지의 2-차원 특성으로 인해 수술시간의 지연 및 낮은 정밀도를 갖는다. 본 논문은 이러한 기존의 수내못고정술의 한계점을 개선하기 위해 새로운 수술용 스마트 네비게이션 시스템을 제시한다.

본 시스템은 직선 출력을 갖는 선형레이저의 출력특성을 이용한 레이저 가이드 모듈을 제시함으로써, 체내에 삽입되어 보이지 않는 nail의 구멍의 위치를 환자의 피부 위에 정밀하게 가리킬 수 있다. 선형레이저의 출력특성으로 본 레이저 가이드 모듈은 피부 두께에 따라 발생하는 기존 레이저 시스템의 가이드 위치 오차문제를 해결한다. 또한 본 논문에서 제시한 레이저 가이드 모듈은 기존 레이저 시스템과는 다르게 방사선 촬영이 필요하지 않으며, 수술 장비와의 결합 메커니즘을 통해 외부의 충격으로 발생하는 레이저 출력의 각도 오류를 자체적으로 보정하는 이점을 갖고 있다. 본 시스템은 레이저 가이드 모듈뿐만 아니라 실시간 드릴링 각도 측정 모듈을 제시함으로써, 골절 부 고정을 위해 체 외에서 삽입되는 드릴 날 및 나사의 실시간 변위를, 방사선촬영을 사용하지 않고도 의료진에게 시각적으로 전달한다. 레이저 가이드 모듈 및 드릴링 각도 측정 모듈을 통합한 본 시스템은 방사선 촬영의 의존성을 완전히 제거하였으며, 수내못고정술의 한계점을 해결하기 위해 제시되었던 기존의 시스템에 비해 높은 가격경쟁력 및 정밀도를 갖기 때문에 수내못고정술을 위한 새로운 네비게이션 시스템이라 할 수 있다.

핵심어 : 수내못고정술, 무방사선, 고정밀도, 레이저 가이드, 실시간 드릴링 각도 측정