Reducing radiation exposure in intra-medullary nailing procedures: Intra-medullary endo-transilluminating (iMET)

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ABSTRACT

The purpose of the study was to reduce the level of radiation exposure during intra-medullary nailing procedures. A visible light source was inserted into the medullary bone cavity in order to detect the distal interlocking screw holes. The light penetrates out of the bone surface, revealing the position of the screw hole, and this allows the subsequent drilling and placing of the interlocking screw to be free of fluoroscopy. Among the 19 consecutive tibia-fracture patients recruited for this study, no repetition of the drilling procedure or insertion of a transverse interlocking screw was needed. The average time to finish the insertion of one distal interlocking screw was 4.1 ± 1.8 min. It was extrapolated that 13–41% of previous radiation exposure levels could be saved. The non-fluoroscopic approach thus decreases the health hazards that the patients are experiencing as well as those of the surgical team who need to perform such intra-medullary nailing operations on a routine basis.

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For decades, intra-medullary nailing has been the most commonly used technique when treating patients with lower limbs fractures.  During the operation, a crucial but tedious step is to locate the distal interlocking screw holes. This is because the nail is embedded in the medullary cavity and therefore positioning the screw holes cannot be done with the naked eye. To date, this procedure has been performed either using fluoroscopy (the so-called free-hand method) or with the aid of a specially designed target-aiming device (TAD). The main problem with the fluoroscopic approach, besides its relatively higher operation cost, is the radiation exposure to the patients and to the surgical team. As the risk of injury exists for fluoroscopic-guided interventional procedures, various TADs have been designed in order to lessen such risk.

The TAD approach is a time-consuming process that involves trial and error. Without the aid of fluoroscopy, the surgeon often has to 'guess' the insertion position and angle of screw holes to be drilled. The diameter of these screw holes is only a few millimetres and even a slight mismatch in choosing either the insertion position or the angle stops the subsequent placing of the interlocking screw. Applicability of TADs is further impaired by the fact that nail deformation is commonly encountered during insertion. When such a situation occurs, new guesses and repeated drillings have to be made until a precise match is obtained. It has been observed that this procedure may take an average of 15–20 min, with a high percentage of moderate drill-nail contacts (16 out of 30 drillings) and a failure rate of 10% (3 out of 30 screws). Moreover, the bony structure may be fragmented due to the repeated drillings. Thus, the fluoroscopic method remains the most popular approach to date.

The purpose of this study was to develop a fluoroscopy-free technique that would aid the positioning of intra-medullary interlocking screws. Biological tissues are translucent to light over the wavelength range from 700 to 1000 nm; based on this unique feature we developed an intra-medullary endo-transilluminating (iMET) device that was able to aid distal interlocking. By directing a light source inside the bone cavity near a targeted screw hole, a portion of the light is able to penetrate through the hole and the outer bone surface. It can then be detected in situ and in real time by an external observer with naked eyes.

Material and methods

Subjects

Institutional review board approval was obtained for this study. A total of 19 (11 males and 8 females) consecutive tibia-fracture patients were recruited for the study. All fractures were stabilised...
with intra-medullary nails (Osteo, Selzach, Switzerland). The average age of the patients was 26.5 ± 6.2 years. The diameter of the implants ranged from 9 to 12 mm. In all cases, evaluation was carried out based on the failure rate and operation times. Failure rate is defined as the number of repeated drilling attempts divided by number of cases. In addition, the time required to place the distal interlocking screw and to complete the iMET-based intra-medullary nailing procedure were separately documented.

MET design and its specifications

Depending on the light source and the method used to guide it to the desired location, various iMET designs can be realised. One such design uses a small light-emitting diode (LED), as shown in fig. 1. The device consists of a 3-mm diameter LED light source, a catheter, a pair of conduction lines and an external power supply. The LED is fixed at the distal end of a catheter, which has an outer diameter smaller than the inner diameter of the intra-medullary nail.

MET operation procedures

Before the operation, the iMET device is sterilised following the same protocol used for sterilising the 'guide-wire' in the intramedullary nailing operation. Upon detecting the interlocking screw hole, the iMET is inserted into the cavity of the intramedullary nail. After it has been properly positioned in the bone cavity near the targeted screw hole, the depth of insertion is adjusted until the light emitted from the iMET penetrates through the screw hole and bone, such that it can be detected by an external observer. The ambient light is usually reduced for better observation. Once the light is detected, minor adjustments are made to the depth of insertion until a maximum light intensity, which marks the position of the screw hole, is determined. At this point, the observed light should have a circular shape with its centre indicating the centre of the screw hole.

Results

Fig. 2 shows the endo-transilluminating device together with a fractured tibia and the inserted interlocking nail. Fig. 3 is a photograph taken during a tibial fracture intra-medullary nailing operation under reduced ambient lighting. The light originating from the iMET device and diffusing out of the bone surface can be easily seen. An offline image enhancement procedure is shown in the lower-right corner of Fig. 3, and this reveals the in situ interlocking screw hole.

No fluoroscopy was required for placing the distal interlocking screw and no repetitive drilling or insertion of the transverse

Fig. 2. The illustration shows an iMET together with the structure of the fractured tibia and the inserted interlocking nail.

interlocking nail was needed. Thus the failure rate was 0% (0/19). The average time to finish inserting one distal interlocking screw was 4.1 ± 1.8 min. The mean total operation time was 49.1 ± 11.7 min.

Discussion

There have been continuous efforts towards developing techniques/devices that aid distal interlocking that reduce or eliminate the use of fluoroscopy. The purpose of this study is to provide physicians with a less-invasive and more-accurate technique that can easily be carried out as part of the existing intra-medullary interlocking nailing procedures. The idea behind this technique is endo-transilluminatation. Human tissues are translucent over the wavelength range from 650 to
Therefore, such light sources are suitable for intra-body illumination. However, there are two problems in using them to illuminate human tissue: (1) reflection from the tissue surface is much stronger than the light that penetrates into and then diffuses out of the tissue; and (2) the wavelength range of 650–850 nm is within the scale length of microscopic tissue–density variations and therefore suffers from strong scattering.

Fortunately, in many surgical applications, there is little demand for a high degree of spatial resolution. As a result, scattering is not a serious problem if tissue thickness is less than a few centimetres. Surface reflection is the major factor that prohibits the use of external visible light sources in this particular area. To solve this problem, we used light generated inside the body and then detected the light from outside. The diffusing light reveals the tissue/organ structure near the light source. Although scattering from such tissues still limits spatial resolution, it also increases the homogeneity of the illumination. The deep-red spectral components of the partially diffused light, although weak, can be observed with the naked eye under reduced ambient illumination. If the light source contains near-infrared spectral components, then many charge-coupled device (CCD) cameras can also be used to detect the light.

Illumination from inside of the tissue increases the efficiency of the illumination and, at the same time, removes interference caused by surface reflection. As the observed light pinpoints the exact location of the targeted interlocking screw hole, positioning accuracy should not be affected by nail deformation, which is commonly encountered during nail insertion into the medullary canal. This nail deformation can vary from mild to severe and may cause drill–nail contacts. This problem can result in the failure of the TAD approach in severe cases.

Radiation exposure among orthopaedic surgical team members during fluoroscopy screening has caused great concern and has been extensively studied. Müller et al. measured the radiation exposure to the hands of the surgeon during 41 procedures of peri-medullary nailing of femoral and tibial fractures. The average dose to the surgeon was 1.27 mSv. Madan and Blakeway reported that the mean nail nailing fluoroscopy time for consultants and for middle-grade surgeons were 0.56 and 1.28 min, respectively. According to the measured hand/skin exposure of 0.29 mSv min⁻¹ to the surgeon during fluoroscopically assisted orthopaedic procedures, the subsequent mean radiation dose for placing the interlocking screw is thus between 0.16 and 0.37 mSv. As no fluoroscopy time is required when the IMET method is used, a calculated 13% (0.16/1.27) to 29% (0.37/1.27) of the fluoroscopy–related radiation dose would be saved. A recent study reported the use on average of 108 s of fluoroscopic time for the insertion of 'one' distal interlocking screw. Under these circumstances, using IMET, 41% of the radiation dose would be saved.

With IMET, the average time required to achieve the positioning of one distal interlocking screw was 4.1 ± 1.8 min, a comparatively shorter time than what has been reported (ranging from 16.7 to 19.1 min) when using other types of TADs. Some extra time is required to insert the light source and this may be remedied by attaching the light source to the guide-wire so that the 'self-illuminating guide-wire' would be able to serve both purposes in one device. Extra care should be taken to ensure that the light source is removed before subsequent drilling procedures take place.

In conclusion, although safety procedures for minimising radiation exposure are always enforced when surgeons are routinely performing fluoroscopy-guided interventional procedures, the accumulated dose may still present a health concern. The proposed endo-transillumination method allows prompt, accurate and reduced radiation exposure during intra-operative nailing procedures.

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