



學大明陽立國

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本校推動「璞玉計畫」 增加弱勢學生就讀機會

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朱唯勤教授研發之iMET Device醫療器材，獲美國上市許可
本校獲選為「105年度辦理兵役業務績優學校」

朱唯勤教授研發之iMET Device醫療器材，獲美國上市許可



朱唯勤教授（中）以此項研發成果獲「2014生醫暨生農產業選秀大賽」生醫組潛力新秀獎

本校生物醫學工程系（所）朱唯勤教授實驗室研發的「交鎖式髓腔內鋼釘定位裝置」（Intra-Medullary Endo-Transilluminating (iMET) Device) 醫療器材，於2月17日獲得美國FDA 510(k)上市許可證。

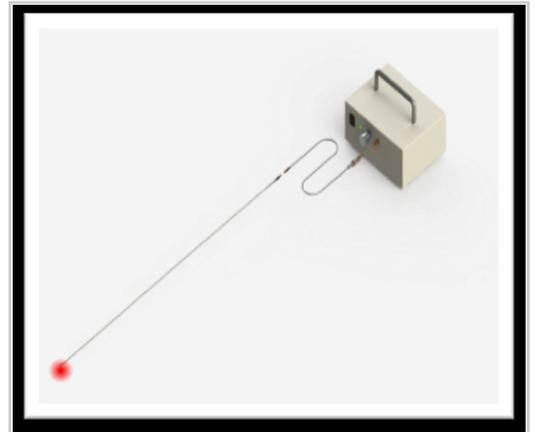
由朱唯勤教授主持的影像處理實驗室，於2010年起進行「交鎖式髓腔內鋼釘定位裝置」醫療器材研發，2010~2013年爭取到「臺灣生技起飛、鑽石行動」國家型計畫補助，並於2014年獲得科技部「產業前瞻技術」計畫補助；在「台灣生技整合育成中心」（Si2C）與本校相關單位大力支持與輔導下，於2015年中旬完成iMET Device產品雛形設計與試量產，同時也陸續申請到七國：台、美、歐盟（英、德、法）、中國、日本的發明專利（註：以上專利所有權人為陽明大學）。

iMET Device能準確、快速並在無需使用體外定位裝置或X-ray螢光檢查儀（fluoroscope）的情形下，進行「交鎖式髓腔內鋼釘」（interlocking nailing procedure）手術螺釘定位。由於沒有額外輻射劑量吸收，iMET Device可提供病人以及執行手術的醫療人員更安全、有效的醫療環境與品質。

根據統計，國內平均每分鐘就有一人因意外事故而骨折就醫，其中因長骨骨折而須以一般稱為髓內鋼釘的裝置來固定的病患，每年約有三萬人，而美國約30萬人，全球則有約150萬/年髓內釘手術。經市場調研與專利風險分析，本產品具有市場潛力，因此於2015年中旬在Si2C的輔導下，成立「唯醫生科技股份有限公司」(WeMed Biotech)，同時進駐竹北生物醫學園區。

iMET Device研發至今已獲得多項榮譽獎項，包括：時代基金會「2014生醫農產業選秀大賽」潛力新秀獎；「2014台灣生技整合育成中心Si2C Three-in-Five Competition」金質獎；工業技術研究院科技新創俱樂部舉辦之「2014科技新創資本加速計畫秋季場科技新創聯合發表會」第一名。

iMET產品已通過各項安全性檢驗，並於2016年下旬備案申請美國FDA 510(k)第二類(Class II)醫療器材上市許可證；該申請案已於今年(2017年)2月17日獲得FDA 510(k)上市許可(許可證號：K163037)。目前正積極與國內外廠商或創投機構洽談合作事宜，做產品量產與上市準備，以期開拓國產高階醫療器材自製自有的契機。



交鎖式髓腔內鋼釘定位裝置 (iMET) 示意圖

Intra-Medullary Endo-Transilluminating (iMET) Device for Interlocking Nailing Procedures
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1. Background
 Intra-medullary (IM) nailing is the most common method in treating lower limb fractures. During operation, a crucial but tedious step is to perform the distal locking. As this procedure is normally performed under fluoroscopic guidance, excessive radiation exposure to the patients and to the physicians can be encountered.¹⁻³ In order to avoid such undesired radiation exposure, custom-designed large-opening devices (TADs) have been used. Unfortunately, the applicability of these TADs is usually impaired due to the unavoidable deformation of the nail when inserted into a bone cavity. Trial and error processes are often inevitable rendering this approach a time-consuming and prone to error. In this study, we propose to use a visible light source to detect the distal interlocking screw holes. By inserting a light source inside the bone cavity near a lagged screw hole, a portion of the light is able to penetrate through the hole and the outer bone surface. The hole can then be detected in situ and in real time by an external observer with naked eyes. This compensates for the subsequent drilling and locking to be performed in a straightforward manner. Operational error and time are thus significantly reduced.

2. Methods
 Figure 1 is a schematic diagram of an iMET. A small and biocompatible light-emitting diode (LED) is attached to the distal end of a catheter. We have tested our iMET on six femur bones, on articulated human tibia and femur bones and on 19 in-vivo human tibiae from patients (11 males and 8 females). Institutional review board approval was obtained for this study.

3. Results
 Figure 2 shows the light spot originated from iMET that penetrated through the screw hole of an inserted interlocking nail and the on bone. Figure 3(a-c) is a set of photographs revealing the steps (from top to bottom) of inserting the iMET-interlocking nail set into an articulated leg, b) cutting the outer flesh of the leg, and c) revealing the light spot emitted from the iMET that designates the position of the screw hole to be drilled and locked. Note, all these photos were taken under normal lighting conditions.

4. Interpretation
 Over the years, there have been continuous efforts towards reducing radiation exposure and improving distal lock accuracy in interlocking nailing procedures.⁴⁻¹¹ Radiation exposure among orthopedic surgical team members during fluoroscopy screening is a great concern and has been extensively studied.¹²⁻¹⁴ With the use of the iMET, it was calculated that as high as 0.37*0.52 mSv/operation may absorption to a relatively inexperienced surgeon could be avoided. In terms of accuracy in distal lock, among the 19 tested subjects, the failure rate, defined as the number of repeated drilling attempts and/or reinsertion of screws, divided by the number of cases was 0% (0/19).¹⁵ Compared to the TAD method, a reported failure rate was 30% (3 out of 10 trials)¹⁶ in conjunction with a high percentage of moderate distal-lock contacts (54 out of 30 trials).¹⁷

In our current iMET design, the intensity of the LED is strong enough so that the diffused out light can be observed under normal ambient lighting conditions. In addition, the dimension of the LED is small that it can be fitted in a 2.4 mm ID stainless steel catheter. This size allows it to suit almost all interlocking nails on the market. All necessary tests required for the iMET to be used as a class II medical device were completed. The "self-illuminating guide wire" serves the purposes of a conventional guide wire and a fluoroscopic line and to distal lock. There is no additional procedures need to be added to the present-day interlocking nailing operations.

References
 1. Wimmer BA, et al. *Orthopedics*. 2005; 28(12):1511-1517.
 2. Wimmer BA, et al. *Orthopedics*. 2005; 28(12):1511-1517.
 3. Wimmer BA, et al. *Orthopedics*. 2005; 28(12):1511-1517.
 4. Wimmer BA, et al. *Orthopedics*. 2005; 28(12):1511-1517.
 5. Wimmer BA, et al. *Orthopedics*. 2005; 28(12):1511-1517.
 6. Wimmer BA, et al. *Orthopedics*. 2005; 28(12):1511-1517.
 7. Wimmer BA, et al. *Orthopedics*. 2005; 28(12):1511-1517.
 8. Wimmer BA, et al. *Orthopedics*. 2005; 28(12):1511-1517.
 9. Wimmer BA, et al. *Orthopedics*. 2005; 28(12):1511-1517.
 10. Wimmer BA, et al. *Orthopedics*. 2005; 28(12):1511-1517.
 11. Wimmer BA, et al. *Orthopedics*. 2005; 28(12):1511-1517.
 12. Wimmer BA, et al. *Orthopedics*. 2005; 28(12):1511-1517.
 13. Wimmer BA, et al. *Orthopedics*. 2005; 28(12):1511-1517.
 14. Wimmer BA, et al. *Orthopedics*. 2005; 28(12):1511-1517.
 15. Wimmer BA, et al. *Orthopedics*. 2005; 28(12):1511-1517.
 16. Wimmer BA, et al. *Orthopedics*. 2005; 28(12):1511-1517.
 17. Wimmer BA, et al. *Orthopedics*. 2005; 28(12):1511-1517.

Figure 1. A schematic diagram of an iMET.

Figure 2. By inserting the iMET into an interlocking nail and place them into an articulated bone, the light from the iMET is projected onto the bone surface as a bright red spot indicating the location of the screw hole.

Figure 3. By inserting the iMET-interlocking nail set into an articulated leg and turned on the light source, a vague light spot can be seen on the surface of the leg (left).

Figure 3a. The surgeon is cutting incision to reveal the light spot that indicates the location of the screw hole.

Figure 3b. The bright spot (top) emitted from the iMET indicates the position of the screw hole to be drilled and locked.

Figure 3c. The bright spot (bottom) emitted from the iMET indicates the position of the screw hole to be drilled and locked.

Among the 19 tibiae fracture interlocking nailing operations, no fluoroscopic guidance was required for the distal lock. No repetitive drilling or reinsertion of the screws was needed. The average time to finish one distal lock was 4.12±1.8 min. Compare to the TAD method, ranging from 16.7 to 19.1 min,¹⁶ a significant time was saved.

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