·新技术新方法·

脊柱手术中基于视觉追踪导板的增强现实导航系统的模型构建与验证

张培海 孙振兴 张恺 郭毅 陈刚 杨学军

【摘要】 **目的** 构建椎弓根置钉过程中基于视觉追踪导板的增强现实导航模型，并评价该导航系统的应用价值。**方法** 设计并制作可用于脊柱手术导航的视觉追踪导板，并采用视觉追踪导板和增强现实设备完成增强现实图像与真实物体之间的图像配准和实时追踪。增强现实导航系统辅助下，先后由两位操作者以克氏针模拟椎弓根置钉操作，并按照克氏针置入点与视觉追踪导板的距离分为邻近组（< 100 mm）和远离组（100 ~ 200 mm），对比分析不同操作者以及邻近组与远离组置入点误差值和角度误差值以评估增强现实导航系统的精度。**结果** 两位操作者均顺利完成模型置钉，共获得100例置入点误差值和角度误差值。两位操作者置入点误差值（$t = 0.835$，$P = 0.406$）和角度误差值（$t = 0.220$，$P = 0.826$）差异均无统计学意义。远离组置入点误差值大于邻近组（$t = 3.221$，$P = 0.002$），进一步将其分解为x值和y值，远离组置入点误差x值（$t = 4.980$，$P = 0.000$）和y值（$t = 2.416$，$P = 0.018$）均大于邻近组；而角度误差值组间差异无统计学意义（$t = 1.786$，$P = 0.077$）。**结论** 初步构建基于视觉追踪导板的增强现实导航模型，并完成导航系统精度评估，随着置入点与视觉追踪导板距离的增加，置入点定位能力下降，但角度指向性较为稳定。

【关键词】 脊柱疾病； 神经外科手术； 增强现实； 视觉，眼； 手术导航系统； 椎弓根钉

Construction and validation of augmented reality navigation system based on visual tracking guide template in spinal surgery

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【**Abstract**】 **Objective** To construct an augmented reality (AR) navigation system model based on visual tracking guide template during pedicle screw placement, and to evaluate the application value of the model. **Methods** A visual tracking guide template was designed and fabricated for spinal surgery navigation. The visual tracking guide template and AR equipment were used to complete image registration and real-time tracking between AR images and real objects. With the assistance of AR navigation technology, 2 operators performed screw insertion with Kirschner wire respectively. According to the distance between the insertion point of Kirschner wire and the visual tracking guide template, the model was divided into adjacent group (< 100 mm) and distant group (100-200 mm). The accuracy of the AR navigation system was evaluated by comparing and analyzing the insertion point error value and angle error value of different operators and the adjacent group and the distant group. **Results** The 2 operators successfully completed the screw placement, and a total of 100 cases of insertion point error value and angle error values were obtained. There was no significant difference in the insertion point error ($t = 0.835$,

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P = 0.406) and angle error value (t = 0.220, P = 0.826) between the 2 operators. The error value of the insertion point in the distant group was higher than that in the adjacent group (t = 3.221, P = 0.002), while there was no significant difference in the angle error value between the 2 groups (t = 1.786, P = 0.077). Further, the insertion point error value is decomposed into x vaue and y value. There were significant differences in x value (t = 4.980, P = 0.000) and y value (t = 2.416, P = 0.018) between the adjacent group and the distant group. **Conclusions** The AR navigation system model based on visual tracking guide template is preliminarily constructed, and the navigation accuracy is evaluated. As the distance between the insertion point and the visual tracking guide template increases, the positioning ability of the insertion point decreases, but the angle directivity is stable.

【**Key words**】 Spinal diseases; Neurosurgical procedures; Augmented reality; Vision, ocular; Surgical navigation systems; Pedicle screws

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椎弓根置钉作为脊柱手术的关键操作之一，因毗邻脊髓、脊神经根和血管等重要结构，存在严重医源性损伤风险[1-6]。传统导航需外科医师视线离开术区，通过远处屏幕获取信息后再操作，增加认知负荷和操作失误概率[7-9]。X线透视、计算机辅助导航系统（CANS）及手术机器人可以提高手术精准性和安全性[6,10-17]，但价格昂贵，且增加照射剂量、手术时间和住院费用。增强现实（AR）技术可将虚拟图像实时叠加在真实环境中[18]，使术者同时获得虚拟图像和真实视野，并按照图像引导完成操作，克服传统导航需将注意力转移至远处屏幕的问题[7-9]。近年来，增强现实技术已较多应用于脊柱手术[19-27]，甚至达CANS标准[21,25,27]，但这些研究均需术中CT进行增强现实图像配准和实时追踪，虽然导航精度较高但成本和照射剂量增加。清华大学附属北京清华长庚医院通过生物医学工程方法设计并生产一种视觉追踪导板，基于此构建可用于脊柱手术的增强现实导航模型，该项技术无需外接定位设备，通过增强现实设备内置相机即可完成图像注册和实时追踪，将包含手术信息的虚拟图像叠加在视野中，实现高精度原位增强现实导航手术。本研究基于构建的增强现实导航模型进行椎弓根置钉操作，评估增强现实导航系统的精度，以为脊柱椎弓根内固定提供新型导航技术。

材料与方法

一、实验材料

1.视觉追踪导板　视觉追踪导板主要采用3D Slicer软件（https://www.slicer.org）和SolidWorks软件（https://www.solidworks.com）进行计算机辅助设计，再经高韧性光敏树脂3D打印而成（山东新速度科技发展有限公司），包括两部分组件，第一部分是与脊柱棘突连接的基座，基座设计有螺钉孔，可安装于棘突上；第二部分是固定架，其上可安装4枚由3M 7610高增益红外反光胶带制作的红外反光标志物（直径10 mm、厚度0.50 mm的圆形贴片，图1）。

2.增强现实设备　HoloLens 2平台为美国Microsoft公司产品，分辨率为2560×1440，可同时追踪头动和眼动，并利用环境传感器自动扫描周围环境，确认设备自身与周围场景的空间坐标关系，是目前临床应用最广泛的增强现实设备。HoloLens 2平台内置的AHAT相机在主动亮度图像模式下，可直接检测到红外反光标志物，经增强现实导航平台运算，实现视觉追踪导板的动态识别和空间定位（图2）。视觉追踪导板基座安装于棘突上，可实现视觉追踪导板与目标椎体物理结构的互补，并通过HoloLens 2平台确认其与脊柱的位置关系，完成增强现实图像与真实目标的空间配准。

3.模型制备　制作可进行克氏针置入的模型（图3a）。模型盒体由高韧性光敏树脂3D打印而成，底部安装6枚直径10 mm的钢珠，用于后续图像配准的注册；模型内部填充石蜡以便于置入克氏针；模型头部设计3D打印的椎体、椎板和棘突，安装视觉追踪导板，增强现实设备可追踪定位模型，以评估基于视觉追踪导板的增强现实导航系统精度（即置入点定位和角度定位精度）。

二、研究方法

1.模型置钉　采用uCT760 CT扫描仪（上海联影医疗科技股份有限公司）行CT扫描，原始CT图像以DICOM格式表示，导入3D Slicer软件，按照置入

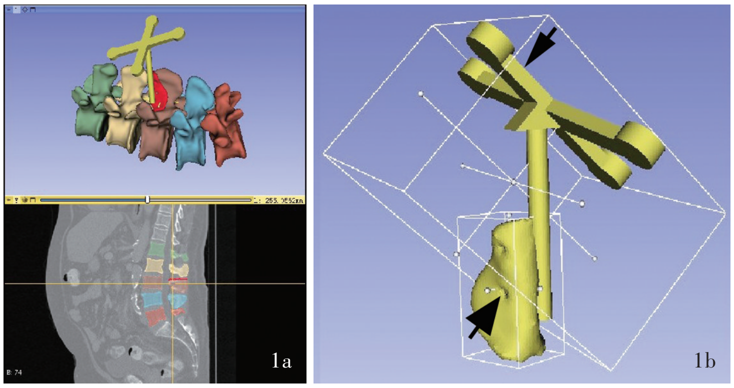

图1 采用3D Slicer软件设计的视觉追踪导板 1a 基于脊柱CT图像（下图）进行计算机辅助设计（上图） 1b 视觉追踪导板基座（粗箭头所示）和固定架（细箭头所示）

Figure 1 3D Slicer software was used to design the visual tracking guide template. Aided design assisted by spinal CT images (Panel 1a). The base (thick arrow indicates) and the fixation frame (thin arrow indicates) of the visual tracking guide template (Panel 1b).

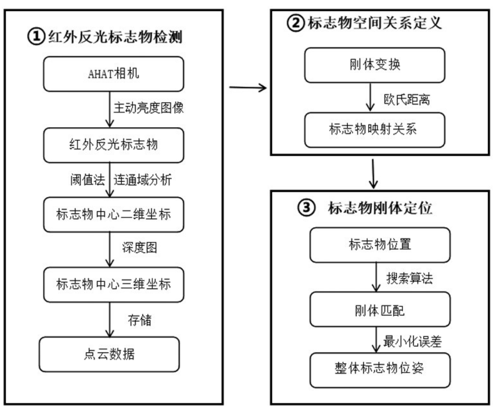

图2 视觉追踪导板的识别与追踪流程

Figure 2 Recognition and tracking process of the visual tracking guide template.

点与视觉追踪导板的距离，在模型表面规划10×5（行×列）的克氏针置入点并设计克氏针置入计划（包括置入点和置入路径），共设计50例（图3b）。导航精度受置入点与视觉追踪导板的距离影响，据此将50例分为10组（L1～L10，共10行），每组各5例（共5列），各组置入点与视觉追踪导板的距离逐渐增加，L1组～L5组的距离＜100 mm，定义为邻近组（25例）；L6组～L10组的距离100～200 mm，定义为远离组（25例，图4a）。由两位操作者先后佩戴HoloLens 2平台，根据观察到的导航引导信息确定克氏针置入点和角度，再采用手术导引器（美国Johnson & Johnson公司）固定其置入角度，以确保手术导引器轴线与虚拟导航置入路径相一致，分别将50枚克氏针置入模型内部后行CT扫描，通过模型底部钢珠将操作前后的CT图像配准（图4b）。

2.增强现实导航系统精度评估　包括置入点定位和角度定位精度。（1）置入点误差：将导航计划置入点与实际置入点投影至同一二维平面，相应两点之间距离即为置入点误差值。将置入点误差值进一步分解为x值和y值，x值定义为内外方向（靠近模型中心为内侧，反之为外侧）的误差值，偏内侧为正值、偏外侧为负值；y值定义为头尾方向（靠近模型头部为头侧，反方向为尾侧）的误差值，偏头侧为正值、偏尾侧为负值。（2）角度误差：分别沿导航计划的置入路径和实际克氏针长轴作直线，测量2条直线之间夹角，即为角度误差值。

3.统计分析方法　采用SPSS 26.0和GraphPad 8.0.2统计软件进行数据处理与分析。正态性检验采用Shapiro-Wilk检验，呈正态分布的计量资料以均数±标准差（$\bar{x} \pm s$）表示，采用两独立样本的t检验。以$P \leqslant 0.05$为差异具有统计学意义。

结　果

两位操作者均顺利完成模型置钉，共计获得100例置入点误差值和角度误差值，置入点误差值为0.10～5.20 mm，平均为（1.91±0.82）mm；角度误差值为0.13°～7.14°，平均为（2.39±1.17）°。两位操作者置入点误差值和角度误差值比较，差异无统计学意义（均$P > 0.05$，表1），表明增强现实导航系统稳定性较高。根据置入点与视觉追踪导板的距离分组，远离组置入点误差值大于邻近组（$P = 0.002$），而角度误差值组间差异无统计学意义（$P = 0.077$，表2）。将置入点误差值进一步分解为x值和y值，x值为-4.77～2.54 mm、平均（-0.11±1.60）mm，y值为-2.44～2.35 mm、平均（-0.07±1.33）mm，远离组置入点误差x值（$P = 0.000$）和y值（$P = 0.018$）均大于邻近组（表3），表明邻近组与远离组置入点在内外方向和头尾方向均存在差异。

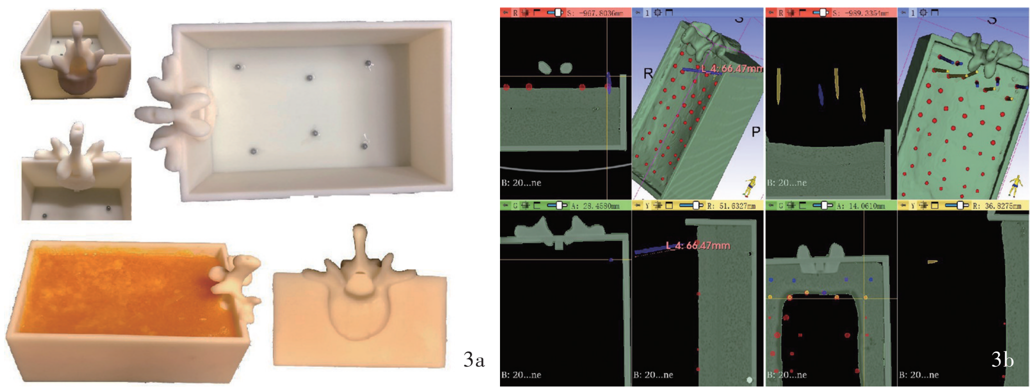

图3　模型和克氏针置入计划　3a　模型的3D打印盒体及内部灌入石蜡后外观，盒底可见用于CT影像注册的金属钢球　3b　基于模型CT数据设计的克氏针置入计划（红点为设计的克氏针置入点，蓝线为设计的克氏针置入路径）

Figure 3　The experimental model and Kirschner wire insertion plans　The body and internal appearance of the 3D printing box of the experimental model after being filled with paraffin, and the metal steel ball for CT image registration could be seen at the bottom of the box (Panel 3a). The designed Kirschner wire insertion plan based on the CT data of the experimental model (red points indicate the designed Kirschner wire insertion points, and blue lines indicate the designed Kirschner wire insertion paths; Panel 3b).

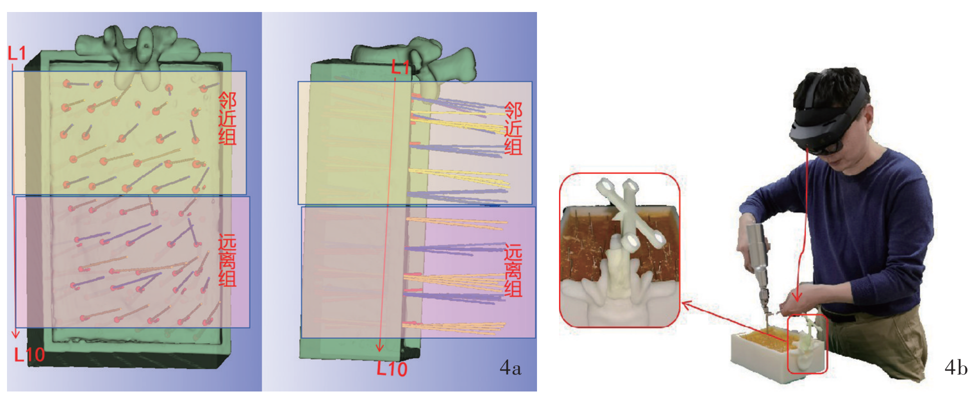

图4　克氏针置入计划分组与操作场景　4a　邻近组与远离组的位置（左图为上面观、右图为侧面观）　4b　操作者佩戴HoloLens 2平台在模型上进行克氏针置入操作

Figure 4　Grouping of the Kirschner wire insertion plans and operational scenarios　The positions of the adjacent group and the distant group (left picture is the upper view, and right picture is the lateral view; Panel 4a). The specific operation scene in which the operator wore HoloLens 2 to insert the Kirschner wire of the model (Panel 4b).

讨　论

增强现实技术是一种新兴的椎弓根置钉辅助方法，术者穿戴增强现实设备后可根据虚拟导航引导精准完成置钉操作，但目前其实施过程仍面临一些挑战。Liebmann等[20]尝试应用增强现实设备的内置相机，通过视觉追踪方法采集试验表面的点云数据，进行增强现实图像的注册，指导克氏针的模拟置入，但该项研究缺少用于实时追踪和校准导航漂移的人工标志物，一旦出现研究目标漂移，无法及时更新引导信息，必要时需重新注册，而且实际手术中难以实现类似试验中脊柱模型的骨骼化显露程度，与临床实际手术场景不一致。Molina等[25]通过增强现实导航技术对5例尸体标本进行T_6～L_5椎体双侧椎弓根置钉，术中应用固定于棘突的人工标志物，胸椎椎弓根置钉的准确率为98.25%（56/57），胸腰椎准确率为89.4%～100%，然而该项研究的图像注册和追踪流程并未较传统脊柱导航和手术机器人简化，需术中CT获取即时影像信息、红外定位装置实现虚拟与真实数据的三维坐标统一，并制定手术计划，对手术团队整体硬件设备和技术素养的要求较高，不利于临床推广和应用。

基于增强现实的导航技术用于椎弓根置钉过程中，最重要的技术环节是图像注册和追踪。现有解决方案存在操作流程复杂、需定制器械、需行术中CT及红外定位等问题，不仅延长手术时间，而且增加医疗费用和照射剂量[21,25,27]。本研究创新性提出一种基于视觉追踪导板的增强现实导航系统，简

表1 两位操作者置入点误差值和角度误差值的比较($\bar{x} \pm s$)

Table 1. Comparison of insertion point error and angle error between 2 operators ($\bar{x} \pm s$)

组别	例数	置入点误差值(mm)	角度误差值(°)
操作者1	50	1.84 ± 0.92	2.36 ± 1.09
操作者2	50	1.98 ± 0.71	2.41 ± 1.24
*t*值		0.835	0.220
*P*值		0.406	0.826

表2 远离组与邻近组置入点误差值和角度误差值的比较($\bar{x} \pm s$)

Table 2. Comparison of insertion point error and angle error between distant group and adjacent group ($\bar{x} \pm s$)

组别	例数	置入点误差值(mm)	角度误差值(°)
邻近组	50	1.66 ± 0.74	2.18 ± 1.04
远离组	50	2.17 ± 0.83	2.59 ± 1.27
*t*值		3.221	1.786
*P*值		0.002	0.077

表3 远离组与邻近组置入点误差x值和y值的比较($\bar{x} \pm s$,mm)

Table 3. Comparison of x value and y value of insertion point error between distant group and adjacent group ($\bar{x} \pm s$, mm)

组别	例数	置入点误差	
		x值	y值
邻近组	50	0.61 ± 1.11	0.25 ± 1.27
远离组	50	- 0.83 ± 1.69	- 0.39 ± 1.32
*t*值		4.980	2.416
*P*值		0.000	0.018

化增强现实技术在椎弓根置钉过程中的应用流程,保证注册精度的同时,避免额外的定位操作和设备,降低医疗成本,减少照射剂量,为术者提供更便捷、精准的新型手术辅助手段。模型试验过程中,所有操作者均可迅速完成视觉追踪导板的安装,并利用其刚性结构的几何特性估算空间姿态,追踪和重建每一帧图像中视觉追踪导板的三维形态,完成视觉追踪导板定位和姿态估计、红外反光标志物与研究目标的空间关系定义和转换,通过视觉追踪导板基座与脊柱棘突嵌合的物理位置关系,根据提前标定的相机内部成像相关空间定位参数将增强现实影像投影到AHAT相机单位平面,实现原位增强现实导航。

为排除实际任务对增强现实导航系统精度的影响,本研究构建基于视觉追踪导板的增强现实模型,并通过克氏针置入计划评估置入点定位和角度定位精度,从三维层面进行增强现实导航系统精度的系统评估,结果显示,置入点误差方面,误差值波动在0.10 ~ 5.20 mm之间,平均为(1.91 ± 0.82) mm,不同操作者之间置入点误差值无明显差异,表明模型稳定性较好、可重复性较强,但随着克氏针置入点与视觉追踪导板距离的增加,增强现实导航系统精度下降,远离组置入点误差平均值已超过2 mm,但是仍低于3 mm,且邻近组和远离组在内外方向和头尾方向均存在差异。此外,与邻近组相比,远离组x值和y值中负值更多,表明增强现实导航系统的置入点定位能力随距离的增加出现偏外侧和偏尾侧的倾向;角度误差方面,两位操作者之间无明显差异,邻近组和远离组均获得较好的平均角度误差值(< 3°)且无明显差异,角度误差值整体分布较均匀且密集,个别离群值考虑可能是人为误差所致,表明增强现实导航系统的角度指向性和稳定性均较为可靠。

综上所述,针对增强现实技术在椎弓根置钉手术中的挑战,本研究成功构建基于视觉追踪导板的增强现实导航模型,无需外接定位设备或硬件改造,即可将手术信息以增强现实图像的形式呈现在视野中。通过模型试验评估增强现实导航系统的置入点定位和角度定位精度,证实了该导航系统的指向性和稳定性,尤其是其可靠的角度指向性,符合临床导航的实际要求,具有进一步临床转化的潜力,亦为后续开展真实的椎弓根置钉临床研究奠定基础。然而,本研究尚存在一定的局限性,以脊柱仿真模型为研究对象,未考虑脊柱变形等实际临床问题,此外,该导航系统涉及众多生物医学工程相关软件,需相关技术人员进行编程与开发,临床医师需与其紧密协作,未来仍需在真实应用场景中验证该导航系统的稳定性和可靠性。

利益冲突 无

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