Development of Smart Low-cost Ball-tip Feeler for Automatic Breach Detection in Pedicle Screw Placement

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INTRODUCTION

Pedicle screw placement (PSP) is crucial for managing symptomatic spinal disorders, but its success hinges on accurate placement to avoid pedicle breaches and nerve damage. These breaches can occur in a concerning range of 1.1% to 29.0% of procedures [1]. The ball-tip technique is initially introduced by using a ball-shaped metal tip with a metal semi-flexible shaft. The use of a ball-tip feeler at various checkpoints could assist the surgeon in confirming pedicle wall integrity and re-planing the screw trajectory. While the smart ball-tip feeler improves surgical time and accuracy, it remains heavily reliant on surgeon experience.

To tackle this problem, recent studies have explored various sensors to automatically detect the breach during the drilling procedure, such as drilling force or electrical impedance [2]. Preliminary results show promising potential but are limited by cost and complexity. An affordable, user-friendly, and highly accurate breach detection solution would be preferential. Inertial measurement units (IMUs) and load cells are cost-effective options. However, traditional data processing methods can be unreliable. Deep learning, with its ability to identify patterns in complex data, presents a promising alternative for robust breach detection in PSP.

This paper proposes a low-cost, deep learning-based technique using the ball-tip feeler to provide breach alerts via audible beeps. The developed system evaluated its performance on synthetic phantoms.

MATERIALS AND METHODS

The prototype is comprised of a handle, a load cell, a IMU (MPU-9250, InvenSense) and a steel rod, as seen in Fig.1 A. The diameter of the ball-tip adheres to the standard at 2.3 mm, and the length of the shaft measures 100 mm. The load cell is capable of handling a normal capacity range of 500g and is connected to Sparkfun HX711, which features a built-in Wheatstone bridge. The IMU provides 6 measurements including 3-axis accelerates (Acc) from the accelerometer and 3-axis angular velocities from the gyroscope (Gyr). The IMU and load cell communicate through an Arduino UNO via I2C protocol around 90 Hz.

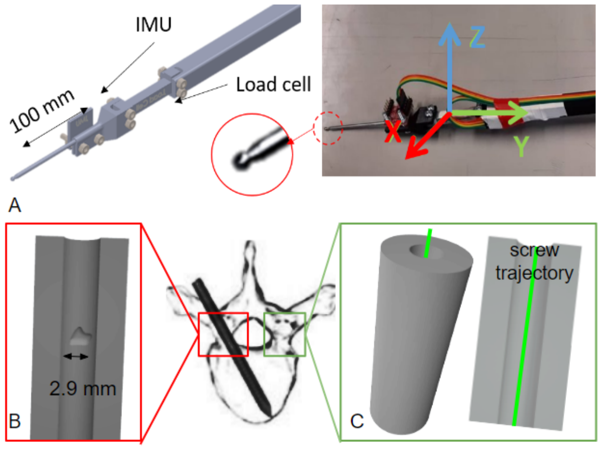

Fig. 1 (A) The CAD model and prototype of the customer-designed ball-tip feeler. The synthetic phantom with (B) a 2.9mm medial breach and (C) a desired pedicle screw trajectory (green) without breach.

The 3D-printed phantoms are designed to mimic the actual vertebrae pedicle, consisting of breached and non-breached pedicle models. For training, one phantom is fully closed with a desired screw trajectory as shown in Fig.1 C, while two breached phantoms are half open with 1.5 mm and 2.0 mm holes. For validation, three phantoms are designed with breaches of 2.0 mm, 2.5 mm, and 2.9 mm, respectively.

The measurements from IMU and load cell are synchronized during recording. Trial ID and timestamp are automatically assigned to each data pair. The data is then normalized and segmented into windows of 180 samples. For breach detection, a neural network has been implemented to identify patterns and correlations between the data and detect breaches. The proposed approach utilizes a combination of a 1D Convolutional Neural Network (CNN) and a Long Short-Term Memory (LSTM) Neural Network. The LSTM follows the original architecture with a forget gate, an output gate and an input gate [3]. The values of these gates control the flow of information to determine how much information is retained from the current input and output. The convolution layers possess feature mapping capabilities that enhance the performance of this network for our application.

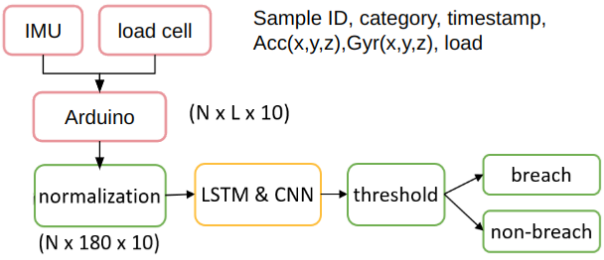

Fig. 2 The block diagram of proposed framework.

The network utilizes a max-pooling layer to output the maximum value in a moving window. Additionally, a time-distributed layer is employed to enable the same layer to be applied to different time slices of input. The input sample first gets cut up into several slices and fed into a CNN layer. The program defines a breach when the breach probability exceeds the target threshold at 0.8. Upon detecting a breach, the program generates a beep to alert the surgeon. This allows the surgeon to adjust the screw placement and prevent potential spinal cord injury.
The training data were collected from a breached and a non-breached phantom. The data were recorded by the operator palpating the inner wall of the pedicle on all tracks simultaneously. Then, all the data were manually labelled as 'breach' or 'non-breach' by two experienced users. In total, around 100 trials of samples were acquired in the training dataset. The recorded data was organized as a ten-dimensional array, including sample ID, category, timestamp, and six measurements from the IMU and load measurement. Zeros were padded at the beginning of the input sequence. Then, the network was trained with 30 epochs. Finally, experimental validation was conducted on the 3D-printed spine phantoms. This categorization of the testing data was compared with the manually labelled data. Prediction accuracy ACC was calculated as the correctly detected trials over testing datasets.

RESULTS

In total, the test datasets contain 36 trials manually collected from various phantoms. The results are demonstrated in Table I. The accuracy of the proposed program is 86.11%. For breach trials, 21 out of 24 trials are detected successfully. For non-breach trials, there are 10 trials are validated correctly while 2 trials are failed.

TABLE I The results on synthetic phantoms

model	total	predicted breach	predicted non-breach	ACC
breach	24	21	3	87.50%
non-breach	12	2	10	83.33%

DISCUSSION

This work proposes a smart low-cost ball-tip feeler. An automatic approach for detecting pedicle breaches based on deep learning was developed. The total material cost of the prototype is approximately 90 euros.
An accuracy of 93% was achieved on the training dataset while it dropped to 86% with the testing dataset. These results are comparable to a study where surgeons using a standard flexible ball-tip feeler achieved 80% accuracy while only reporting 2% false negatives [4]. These preliminary results suggest the proposed approach complements current breach detection approach. This implementation also holds promise for application in surgical training, enabling surgeons to identify and prevent breaches during future procedures.
However, the system still produced 3 false negatives and 2 false positives out of 36 trials. These mis-predictions, particularly false negatives, could result in spinal cord injury. Therefore, it is crucial to note that accuracy was obtained on a simplified setup, highlighting the need for further validation under more realistic conditions. The measurements from load cell change significantly precede the prediction of a breach. Additionally, gyroscope readings could introduce false positives due to sideways movement of the ball-tip feeler. Future research will also investigate using only accelerometer data.
Despite its promise, the proposed work has limitations. It is crucial to compare the system accuracy against the state-of-the-art approaches such as drill force and electrical impedance measurements. The experiment utilized a limited dataset derived only from synthetic phantoms. Further validation is necessary through a pre-clinical user study with surgeons on clinical datasets.

CONCLUSION

In conclusion, this study describes a smart low-cost ball-tip feeler for breach detection. This proof-of-concept design utilizes a combined load cell and IMU, along with an LSTM-CNN framework, to achieve high accuracy in breach classification. This system demonstrates promising potential for future clinical applications as a cost-effective and user-friendly surgical assistant.

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