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Pull out strength calculator for pedicle screws using a surrogate ensemble approach

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ABSTRACT

Background and objective: Pedicle screw instrumentation is widely used in the treatment of spinal disorders and deformities. Currently, the surgeon decides the holding power of instrumentation based on the perioperative feeling which is subjective in nature. The objective of the paper is to develop a surrogate model which will predict the pullout strength of pedicle screw based on density, insertion angle, insertion depth and reinsertion.
Methods: A Taguchi's orthogonal array was used to design an experiment to find the factors effecting pullout strength of pedicle screw. The pullout studies were carried using polyaxial pedicle screw on rigid polyurethane foam block according to American society for testing of materials (ASTM F543). Analysis of variance (ANOVA) and Tukey's honestly significant difference multiple comparison tests were done to find factor effect. Based on the experimental results, surrogate models based on Krigging, polynomial response surface and radial basis function were developed for predicting the pullout strength for different combination of factors. An ensemble of these surrogates based on weighted average surrogate model was also evaluated for prediction.
Results: Density, insertion depth, insertion angle and reinsertion have a significant effect ($p < 0.05$) on pullout strength of pedicle screw. Weighted average surrogate performed the best in predicting the pull out strength amongst the surrogate models considered in this study and acted as insurance against bad prediction.
Conclusions: A predictive model for pullout strength of pedicle screw was developed using experimental values and surrogate models. This can be used in pre-surgical planning and decision support system for spine surgeon.

1. Introduction

Pedicle screw instrumentation is the gold standard for treatment of spinal disorders and continues to gain popularity. Pedicle screws are used to increase the stability of fusion construct for achieving spinal fusion or fracture healing. They are inserted and connected with an instrumentation rod to achieve the reduction, decompression and fixation of the unstable vertebral segment at the same time [1]. Despite the advancements in the field of pedicle screw instrumentation, failures such as screw breakage or loosening due to fatigue

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loading and bending continue to be observed. Breakages are observed between 2.6% and 60%, whereas screw loosening incidences are reported between 0.6% and 11% [2,3]. These failures cause instability of fixations leading to high risk of implant failure, pseudarthrosis, spine curve progression and other complicated post-operation problems which need subsequent surgery [4]. Achieving optimal pedicle screw fixation is a major obstacle in surgical intervention for osteoporotic patients [5,6]. Spinal fixation failure due to osteoporosis or other metabolic bone diseases may require replacement of pedicle screws [7,8]. A study by Lipton et al. [9] identified a revision rate of 9% in 643 adult spinal deformity surgeries out of which 40% of revisions were related to non-union of fussion.

Presently, a surgeon decides the holding strength of pedicle screw based on the perioperative feeling of insertion torque during instrumentation of pedicle screw. This is a very subjective feeling which the surgeon gains based on training and experience [10]. Studies to date have found a conflicting relationship between insertion torque and pullout strength. Several experimental studies have reported a positive correlation between insertion torque and pull out strength in biomechanical tests [11–13] whereas some found no correlation [14–16]. Since insertion torque is measured during screw placement, this seldom alters screw selection in clinical practice [10].

The pullout strength of pedicle screws is an important index used by manufacturers and surgeons to know the holding strength of pedicle screw and objectively demonstrate their resistance to axial load [17,18]. Studies on pullout strength of pedicle screws are usually carried out on cadaver bones [19–22] or rigid polyurethane foam [23–25]. These tests are expensive, time consuming and requires maintenance of sterile hygienic conditions. An analytical formula for pullout strength prediction of cancellous and/or cortical screws inserted into the synthetic bone by Chapman et al. [7] found a close correlation between measured and predicted value [7,26]. However, pedicle screws have different thread geometry and screw profile than the cancellous and cortical screw. Tsai et al. [27] derived an analytical formula for pedicle screws as a function of material (shear strength of synthetic bone), screw parameters (diameter and pitch), and surgery (pilot hole) factors. These studies are based on thread geometry of pedicle screw and material properties of bone, whereas pullout strength is influenced by several factors, including screw length and insertion angle [28,29]. The effect of reinsertion on pull out studies has not yet been studied analytically and the current study tries to address these shortcomings.

Surgeons acquire their knowledge of holding power of pedicle screw based on their experience which is an intensive and time-consuming process. Clinically, information regarding the pedicle screw insertion path in manual hand guided insertion is based on experience of surgeon. With the advent of robot assisted surgery there is a need to develop a technique which will help in deciding on optimal pedicle screw insertion path, which will lead to maximum bone–screw engagement, prevent misplacement of instrumentation [30]. Therefore, developing a decision support system has received considerable attention from information systems researchers and practitioners [31]. Surrogate models are widely used to develop smooth analytic functions for estimation of system response [32] by replacing expensive and time-consuming experimental process. Selection of surrogate depends on the data and application since their performance is case dependent [33]. Most researchers observed that no single surrogate can act efficiently for all the problems. Therefore, as an alternative to using a single metamodel, several researchers combined multiple metamodels in the form of an ensemble [32–34].

The current scope of the paper is to: (i) identify the factors that play a role in pull out strength; (ii) construct an ensemble of surrogate and use them to predict pull out strength for a new combination of input variables thus avoiding the need for expensive experiments. The assumptions made to address the scope of study are: pedicle region which contributes about 60% of holding power [35,36] was considered to be of uniform density in osteoporotic and normal bone and hence its effect was assumed to be a uniform across the bone types. Complexity of vertebral geometry is not considered and only angle of pedicle is used in the study since complexity influences the loading pattern and not pull out strength. Since the study involved understanding the initial hold, cyclic loading was not carried out.

2. Materials and methods

2.1. Rigid polyurethane foam

Experiments with cadaveric bones are expensive and they demonstrate high inter and intra-sample variation of material properties. These are addressed using polyurethane foam because they have consistent and homogeneous structural properties and are easily available. Studies with rigid polyurethane foam help in developing a biomechanical model of the vertebra to carry out pullout strength experiments [37]. As per the American Society of Testing Materials (ASTM F-1839) [38] the grades of foams representing osteoporotic to normal bone confining to the specifications were obtained from POLYONATE FOAM® (Banglore, India). The foams with their density and representation are as follows: Grade 5 (5 lbm/ft^3; 80.1 kg/m^3) represented extremely osteoporotic bone density, Grade 10 (10lbm/ft^3; 160.2 kg/m^3) represented osteoporotic, Grade 15 (15 lbm/ft^3; 240.3 kg/m^3) represented normal bone density and Grade 20 (20 lbm/ft^3; 300 kg/m^3) represented more than normal bone density. A block with dimensions 120 mm × 60 mm × 40 mm was sawn from blank for each test as shown in Fig. 1.

2.2. Pedicle screw and instrumentation

Two CE approved polyaxial pedicle screws (GESCO®, General Surgical Company, Chennai, India) with dimensions 6 × 40 mm and 7 × 40 mm of medical grade titanium alloy shown in Fig. 2 were used in the study. The thread parameter dimensions of screw are shown in Table 1. A 5.5 mm diameter tensile steel rod was fixed to the pedicle screw using a set screw mimicking the actual configuration of the pedicle screw as shown in Fig. 3a. This was mounted on a test jig with a variable axis frame which is used to align the pullout axis as shown in Fig. 3b. Pull-out tests on the foam with inserted screws were done using a BiSS Nano-25™ universal testing machine having a specification of 15 kN force actuator operating at 50 Hz data acquisition. A