



## Perfusion pressure of a new cannulating fenestrated pedicle screw during cement augmentation



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### ABSTRACT

**Background:** Cannulating fenestrated pedicle screws are effective for fixating osteoporotic vertebrae. However, a major limitation is the excessive pressure required to inject a sufficient amount of cement into the vertebral body through the narrow hole of a pedicle screw. We have recently proposed a new cannulating fenestrated pedicle screw with a large hole diameter and a matched inner pin for screw-strength maintenance. Our purpose was to determine whether the new screw can significantly reduce bone-cement perfusion pressure during cement augmentation.

**Methods:** Two different methods were used to examine perfusion pressure. Hagen–Poiseuille's flow model in a tube was used to calculate pressure drop in the bone-cement channel. Experimentally, both Newtonian silicone oil and bone-cement (polymethyl methacrylate) were tested using a cement pusher through the cannulating screw at a constant rate of 2 ml/min.

**Findings:** The internal hollow portion of the screw was the bottleneck of the perfusion, and the new design significantly reduced the perfusion pressure. Specifically, perfusion pressure dropped by 59% ( $P < 0.05$ ) when diameter size was doubled.

**Interpretation:** The new design effectively improved the application of bone-cement augmentation with the ease of bone-cement perfusion, thereby enhancing operational safety.

### 1. Introduction

The fixation of pedicle screws is extensively used to treat osteoporotic spine disorders, such as spondylolisthesis, herniated disc, spinal stenosis and bursting fracture of vertebral body (Shea et al., 2014). However, many potential complications such as screw loosening, displacement and extraction occur when applying osteoporotic sclerotin because bone mineral density decreases (Chen et al., 2005). Enhancing the fixation strength of pedicle screws for osteoporosis patients remains challenging for spine surgeons (Halvorson et al., 1994; Patel et al., 2003).

Using cannulating fenestrated pedicle screws in bone-cement augmentation to perform spinal perfusion is an emerging technology for treating osteoporotic spine disorders (Dai et al., 2015; Lubansu et al., 2012a). During surgery, pressure injection of bone cement into cancellous bone of lumbar spine and bone-cement polymerization dispersed around pedicle screw enhance weakened bone and reinforced stability of screw through hollow and fenestrated parts (Becker et al.,

2008; Chao et al., 2013; Chen et al., 2015a; Choma et al., 2012; Costa et al., 2016a; Kueny et al., 2014; Pare et al., 2011; Tai et al., 2015a).

One of the main restrictions of applying bone-cement injection to enhance cannulating fenestrated pedicle screw is injection of thick bone cement into vertebral body through narrow cannulating part of pedicle screw needing excess pressure. Excess pressure results in early finish of perfusion operation; thus, bone-cement perfusion around the screw is not sufficient and even leading to perfusion failure (Kueny et al., 2014). Injection is implemented when bone cement is thin to reduce pressure. However, this method increases leakage risk (Liu et al., 2016a; Lubansu et al., 2012a; Lubansu et al., 2012b), and bone-cement leakage results in pulmonary embolism (Jang et al., 2002), paraplegia (Lee et al., 2002) and even death (Jr, 2003).

Thus, a method of changing the current situation and decreasing bone-cement injection pressure for the convenience of perfusion is needed. Research indicates that injection pressure exhibits functional relationship with inner diameter of pipeline, and decomposed calculation can be adopted (Baroud et al., 2004; Baroud and Steffen, 2005a;

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Bohner et al., 2003). We have studied perfusion pressure inside extra-pyramidal bone-cement pipe consisting of perfusion tube and pedicle screw and found that perfusion pressure can be decomposed into two parts, namely, pressure at perfusion tube segment and pressure at screw segment; moreover, pressure at each segment is related to its inner diameter (Baroud and Steffen, 2005a). We adopted existing mature and commercial bone-cement perfusion tube and push rod to constitute pressure at perfusion tube segment with stable geometric construction. This method can ensure that pressure at the perfusion tube segment remains unchanged, and that total perfusion pressure can be lowered only by changing pressure at the screw segment (Paré et al., 2011). Thus, in the present work, we proposed a new cannulating fenestrated pedicle screw with large inner diameter pattern to decrease bone-cement perfusion pressure for the convenience of perfusion. Meanwhile, this screw was matched with inner pin to maintain screw strength.

Increased inner screw diameter reduces screw strength. We solved this problem by using matching inner pin. At present, commonly used size of external screw diameter was limited by anatomical structure of vertebral pedicle within 6.0–7.0 mm. Hollow inner diameter was in inverse relation with the mechanical strength of screw. A greater hollow inner diameter means a smaller strength, so an inner screw diameter cannot be infinitely expanded (Shea et al., 2014). Seeking optimal balance between hollow inner diameter and mechanical strength was a key point of cannulating fenestrated screw design. At present, the inner diameter of a screw is generally within 1.5–2.2 mm (Charles et al., 2015; Chen et al., 2015b; Goost et al., 2014; Kueny et al., 2014; Paré et al., 2011; Tan et al., 2016). Referring to the design of expansive pedicle screws (Tai et al., 2015b), we increased the hollow inner diameter of screw to 3.0 mm and matched an inner pin. This method can maintain the strength of the expansion screw in principle.

The present study aimed to biomechanically test the perfusion pressure and verify our hypothesis through analytical modelling and experimental study. We assumed that bottleneck pressure of pipe consisting of perfusion tube and original cannulating fenestrated screw was located in hollow portion of pedicle screw. Whereas, large inner diameter design of new screw can overcome bottleneck pressure and significantly decrease perfusion pressure.

## 2. Methods

### 2.1. Screw design

Screw is a columnar design with screw pitch of 2.5 mm. The outer diameter and length of screws exhibit various specifications (Fig. 1a and b). The hollow inner diameter was 3.0 mm. Accurate thread was designed at tail end of hollow portion. The thread can be connected to connector thread to ensure airtight property. The screw body at 1/3 segment was designed with 10 side holes, which were under cross arrangement for five rows from near end to far end. Two holes composed each row which were gradually enlarged to 1.5, 1.75, 2.0, 2.25, and 2.5 mm. Exit of side holes was designed as transverse-row exit.

Tail end of matched inner pin (Fig. 1f) had threads that coincide with threads at tail end of hollow screw portion. A dedicated inner pin driver was used to inner pin after completion of bone-cement perfusion. Thus, solid screw pattern is restored and screw strength is maintained.

This study adopted specification clinically commonly used at present—U-type fastening screw of 6.5 mm × 45 mm (Liu et al., 2016b).

### 2.2. Screw grouping

Screws were divided into three groups as follows: inner diameter 1.5 mm group; inner diameter 2.25 mm group; and inner diameter 3.0 mm group. Other parameters remained unchanged. Whereby, the 1.5 and 2.25 mm groups were the two control groups. The inner 3.0 mm group was the new screw group.



Fig. 1. Combined fenestrated pedicle screw and perfusion system: a. compounding state; b. screw feature; c. bone-cement pusher; d. bone-cement perfusion tube; e. The cementing adapter; f inner pin.

### 2.3. Perfusion system

Bone-cement perfusion tube and pusher adopted existing commercially finished instrument (Trauson Medical Instrument, Jiangsu, China) (Fig. 1c, d). The length of tube was 200 mm. Inner diameter was 2.75 mm. Outer diameter was 3.4 mm and single-tube bone-cement volume was approximately 1.2 ml.

A cementing adapter (Trauson Medical Instrument, Jiangsu, China) (Fig. 1e) with an inner diameter of 3.4 mm was a hollow structure. This adapter can allow insertion of perfusion tube. This adapter consisted of two parts. The front end was designed with external threads that can match inner threads in hollow portion at screw tail end. Near-end portion was long and expanded that can stably hold perfusion tube.

## 3. Experimental method

### 3.1. Analytical model

According to specification and dimension of screw and perfusion tube, existing conditions had defined geometric structure of bone-cement perfusion channel (Fig. 2). Thus, the perfusion pressure  $\Delta P_{per}$  that refers to the pressure of pushing fluids can be estimated with Hagen–Poiseuille's law (Bohner et al., 2003)

$$\Delta P_{per} = Q \frac{8\eta L}{\pi a^4} \quad (1)$$

where  $a$  is the radius of tube,  $L$  is the length of tube,  $\eta$  is the viscosity of fluid, and  $Q$  is the flow quantity of fluids.

Among the three groups of screw systems, total perfusion pressure  $\Delta P_{per}$  in each group can be decomposed into two parts—perfusion pressure  $\Delta P_{tube}$  at perfusion tube segment and perfusion pressure  $\Delta P_{screw}$  at screw segment. This relation can be expressed as follows (Baroud and Steffen, 2005a):

$$\Delta P_{per} = \Delta P_{tube} + \Delta P_{screw} \quad (2)$$

After decomposed calculation, pressure pressures at perfusion tube segment and screw segment can be estimated according to formula (1).

Perfusion pressure  $\Delta P_{tube}$  at perfusion tube segment remained consistent in the three groups of tubes.  $\Delta P_{tube}$  was deemed to be unrelated to lowering perfusion pressure. In the three groups of tubes, only the inner screw diameter changed. Perfusion pressure  $\Delta P_{screw}$  at screw segment was the only correlational variable of lowering total perfusion pressure.

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