Pullout evaluation of sawbone experiment in different types of pedicle screws combined with bone cement augmentation for severe osteoporotic spine

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Purpose: The conventional screw is unable to provide enough screw-bone interface strength for osteoporotic cencellous bone, and complications resulting from loosening or failure of the implants remain a significant clinical problem. Hence, the purpose of this study is to investigate pullout strength and energy in three types of the pedicle screws, including conventional solid pedicle screw, cannulated pedicle screw, and cannulated pedicle screw with a central pin, using osteoporotic sawbone test block with different bone cement volumes through pullout force testing. *Methods:* The control group ($n = 15$) of the osteoporotic sawbone test block includes groups A, B, and C to reflect three types of the pedicle screws without bone cement augmentation. The cemented group ($n = 45$) of the osteoporotic sawbone test block includes groups D1, D2, D3, E1, E2, E3, F1, F2, and F3 to reflect three types of the pedicle screws with PMMA bone cement of 2, 3, and 4 mL augmentation. *Results:* The results showed that the pullout strength and energy in the cemented group were significantly larger than that in the control group. Moreover, the best performances of the pullout strength and energy in the cemented group were evidenced obviously in the case of cannulated pedicle screw with a central pin with 4 mL bone cement augmentation. *Conclusions:* This study concludes that cement argumentation in the cannulated pedicle screw with a central pin can increase a pullout strength of pedicle screw for severe osteoporotic patients while bone cement of injective volume is limited.

Key words: osteoporosis, bone cement augmentation, cannulated pedicle screw, sawbone, pullout strength

1. Introduction

The spine is the main support of the body axis and transmits the weight of the trunk to the lower limbs. With the advent of medical technology, the dramatic increase of aging population and associated osteoporosis has led to increased amount of patients with spinal trauma and related spinal disorder [2]. The majority of osteoporotic spinal fractures are stable ones with a small risk of associated neurological injury. In patients with acute neurological symptoms or instability, early surgery may be necessary. In 2002, American National Osteoporosis Foundation reported that there are over 500,000 vertebral compression fractures annually, and more than one fourth of American women above 65 years of age suffer from vertebral compression fractures [13], [17]. In 2006, Taiwan Department of Health reported that 12.5% of aged male and 20% of aged female suffer from vertebral compression fracture due to osteoporosis.

Osteoporosis plays a significant role in progression of adult spinal instability and deformity. It has become a growing concern among the medical community as both a primary cause of musculoskeletal dysfunction and a comorbidity among patients required orthopedic care. In fact, it is a challenge for surgeons to perform an instrumentation on an osteoporotic spine [3]. Currently pedicle screw instrumentation has been frequently used for spinal restoration, fixation, correction and coupling decompression in spinal trauma and related spinal disorder surgery [23].

However, the conventional screw is unable to provide enough screw-bone interface strength for osteoporotic cancellous bone, and complications resulted from loosening or failure of the implants remain a significant clinical issue [7], [14]. Moreover, loosening or pullout of the pedicle screws occurs in cases of inadequate fixation strength of the screws or mechanical overloading of the construct, especially in patients with osteoporosis [4], [18]. Surgical remedies currently in practice include modifying the morphology or structure of the pedicle screw, increasing the diameter or length of the pedicle screw, or using various bone cements for augmentation of the pedicle screw [12]. Larger pedicle screws increase risks of pedicle fracture with resultant neural elements injury and longer pedicle screws have potential problems of anterior vertebral body penetration with ensuing vascular or visceral injury [19]. In severe osteoporotic spine, fixation of pedicle screws can be improved by filling the hole with Polymethylmethacrylate (PMMA) bone cement before inserting the pedicle screw [20]. The proper use of the PMMA has been proved to be a safe and reliable material for pedicle screw augmentation. However, conventional pedicle screw augmentation with the PMMA has still left some potential problems in clinical practices, such as elaborate surgical procedures and inability to adjust the position of cemented pedicle screw [24].

The development of surgical fixation techniques and pedicle screw designs were considered to play an important role to influence the screw pullout strength for causing fixation complications of osteoporotic spine [15]. Previous biomechanical studies have demonstrated that screw pullout strength in the osteoporotic spine could be reduced significantly by screw fixation techniques [1]. Hence, conventional pedicle screw must be designed and improved to enhance the screw pullout strength to decreases a risk of the screw pullout or displacement [21]. The pullout strength between pedicle screw and bone can be affected by surgical insertion technique, type of screw design, augmentation with bone cement and vertebral density [9]. Biomechanical testing provides quantitative methodology to determine strength, stiffness, fatigue, and other biomechanical parameters, and also enables to characterize biomechanical behavior for new spinal

implants, such as pedicle screws [5]. Examining the biomechanical effect of bone cement and the performance of bone cement anchoraged pedicle screw in a cadaveric spine is difficult. The material properties of human bone vary with age and species, which causes variability among all subjects and makes it unable to obtain reliable and comparable experimental results. To overcome this experimental limitation, a custom-made sawbone is used to exhibit morphologic and flow properties similar to osteoporotic vertebral bone. The sawbone is selected because of the well-connected and controlled porosity, which offers a uniform and consistent density that eliminates the variability encountered when testing with human cadaver bones. Hence, the purpose of this study is to investigate the pullout strength and energy of different pedicle screw designs combined with and without bone cement augmentation by the sawbone test block of in vitro mechanical testing.

2. Materials and methods

In present research three pedicle screw types including conventional solid pedicle screws (group A), cannulated pedicle screws (group B), and cannulated pedicle screws with a central pin (group C) were tested (Fig. 1). For investigating effect of bone cement augmentation, three types of the pedicle screws were also used to compare the biomechanical effect with bone cement augmentation (three types of the pedicle screws were assigned into group D, group E, and group F with cemented testing). Three injected volumes of the bone cement with 2 mL, 3 mL, and 4 mL were investigated in this study. A commercially available synthetic bone (#1522-507, Pacific Research Laboratory, Inc., Vashon Island, WA, USA) was used to simulate a human or cadaveric spinal bone with severe osteoporosis. The synthetic bone, made from open-cell rigid polyurethane foam with a density of 0.12 g/cm^3, provides a consistent and uniform material with properties in the range of human cancellous bone with severe osteoporosis. The sawbone test blocks in this experiment have a rectangular shape with dimensions of 78 × 70 × 42 mm^3. Additionally, an injected pressure of syringe is required

Fig. 1. Usage of the pedicle screws in this study including conventional solid pedicle screws (a),
cannulated pedicle screws (b), and cannulated pedicle screws with a central pin (c)

to push the bone cement to infiltrate the porous and permeable test blocks. The sawbone test blocks were prepared in three groups according to three kinds of the pedicle screws.

The commercial PMMA bone cement OSTEOBOND (Zimmer, Inc., Warsaw, IN, USA) was used with a liquid-to-powder ratio similar to the one used clini-

cal practice. A bone cement volume of 2, 3 and 4 mL was prepared to introduce through a spinal needle or the designed pedicle screw into the sawbone test block at a rate of 0.2, 0.3, and 0.4 mL per second in groups D, E, and F, respectively. In the process of sawbone test block preparation with cement groups, cement injection for the conventional solid pedicle screw
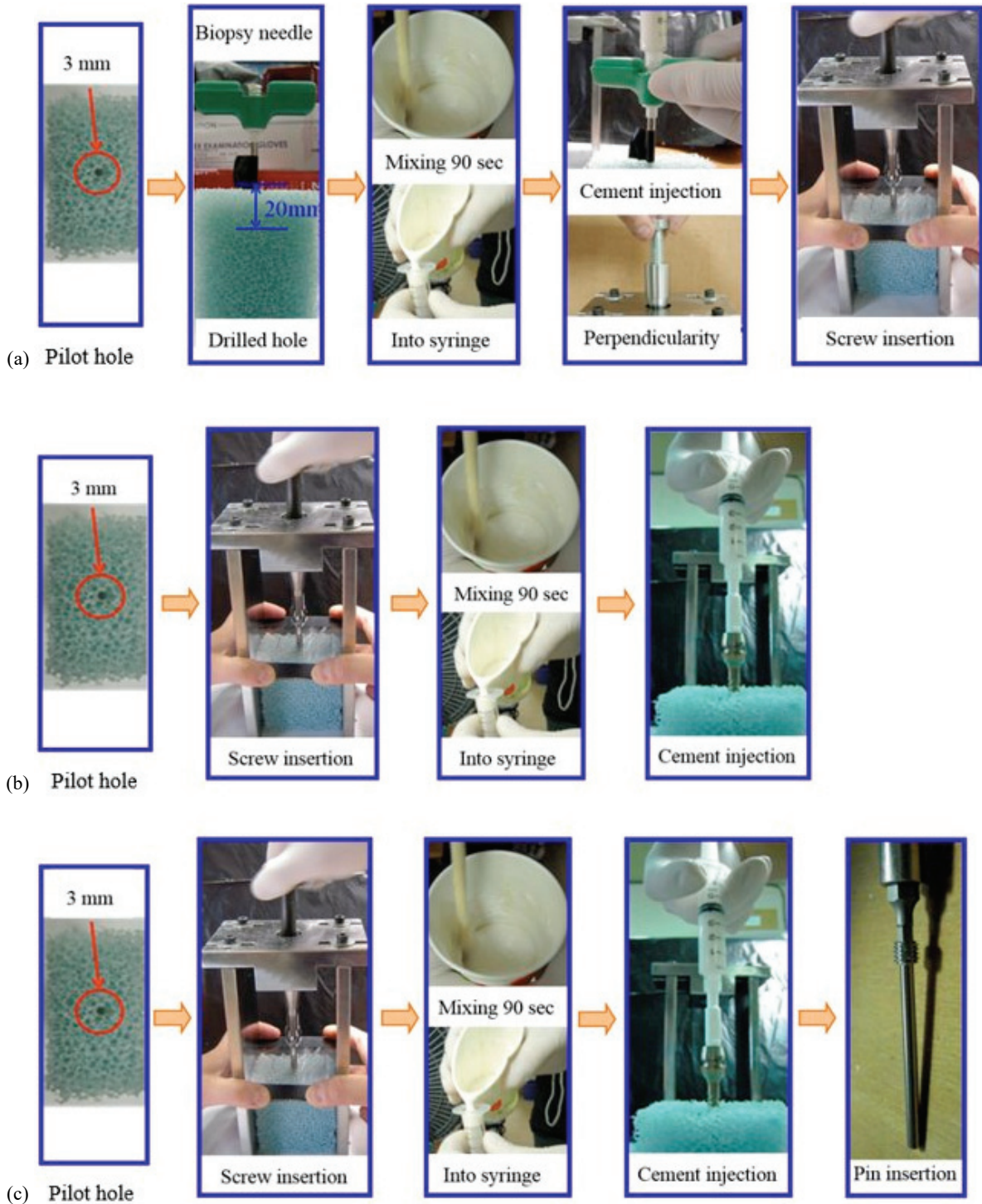

Fig. 2. The processes of sawbone test block preparation with cemented groups.
Group D: Preparation in the conventional solid pedicle screw (a). Group E: Preparation in the cannulated pedicle screw (b).
Group F: Preparation in the cannulated pedicle screw with a central pin (c)

showed that the sawbone a pilot hole with a diameter of 3 mm and a depth of 40 mm should be drilled, and then, the bone cement, of volumes of 2, 3, 4 mL, was then injected into the prepared drilled hole by syringe control, followed by conventional solid pedicle screw insertion. For group E of the cannulated pedicle screws, the pilot hole was prepared firstly in the sawbone, then the cannulated pedicle screw was inserted, followed by injecting bone cement through central hole and side-grooving into sawbones. For group F of the cannulated pedicle screws with a central pin, the processes basically were the same as in group E of the cannulated pedicle screw, but at the end matched central pin is inserted and locked to pressurize and push out the bone cement within the cannulated central hole to further distribute the surrounding sawbone. The control groups without bone cement had the same operations, but no cement was injected into sawbone test blocks. The five sawbone test models were prepared and tested in each of groups (Fig. 2), according to three types of the pedicle screws. The numbers of the sawbone test models in the control and cemented groups were 15 and 45, respectively.

The experimental method was used to measure the axial pullout strength and energy required to fail or remove pedicle screws from the sawbone test block. Each specimen was mounted onto a material testing system (HUNG TA 2402BP) with the use of a custom-made clamping device with 3D adjustment. The 3D adjustment enabled to compensate for the variation in the pedicle screw orientation among specimens quickly and easily, and to ensure that each pedicle screw was pulled purely along its long axis (Fig. 3). For all specimens, pilot holes were drilled into the sawbone test block using a 3 mm drill. A depth gauge was used to confirm a uniform depth of 40 mm of the pilot hole. Once the specimen was tightly secured, a 2 N extensive proload is applied at the rate of 1 mm/min for 10 seconds. After this preconditioning procedure, each pedicle screw was pulled at the rate 1 mm/min under displacement control until failure of the pedicle screw and the data of force and displacement were recorded in real-time. The pullout strength was obtained from the yield strength of the force-displacement curve of specimen testing. The pullout energy was calculated by integrating the force--displacement curve from zero displacement to yield point displacement. To evaluate the effect of different methods of the pedicle screw implantation on stability of the fixation, one-way analysis of variance (ANOVA) is applied to compare the pullout strength and energy for statistically significant difference with $P < 0.05$. Bonferroni test was to be further compared between groups if statistical difference of the ANOVA were proofed.
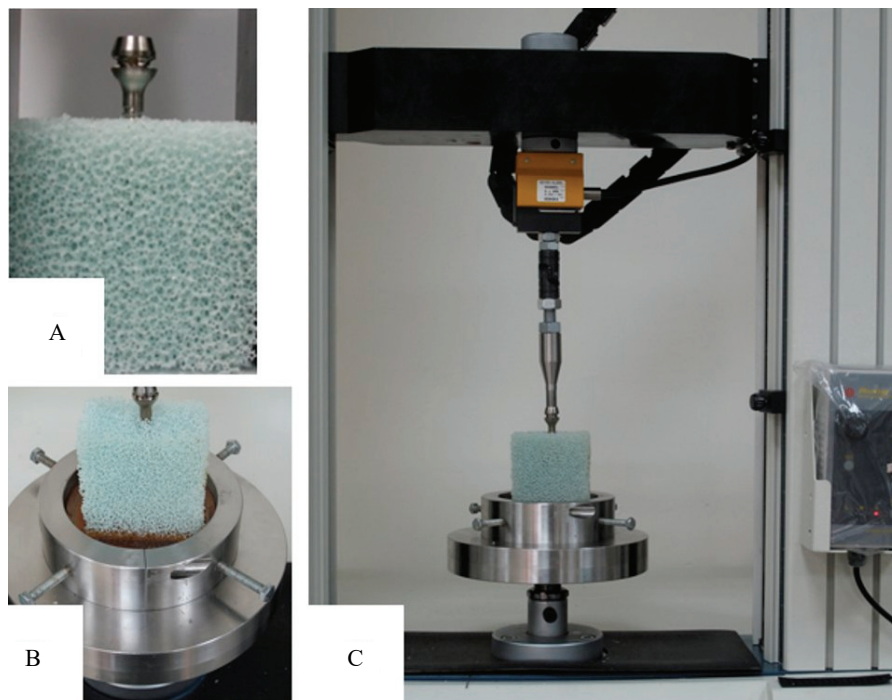

Fig. 3. Each specimen is mounted onto a material testing system (HUNG TA 2402BP)
with the use of a custom-made clamping device with 3D adjustment:
A – Sawbone test block with pedicle screws insertion, B – Sawbone test block embedded in the clamp,
C – Sawbone test block with pedicle screws insertion examined for pullout strength by material testing machine

3. Results

First, a total of nine groups with bone cement were checked to validate the feasibility and convenience of the bone cement anchoraged pedicle screw and examined the bone cement distribution pattern for three different pedicle screws inserted into sawbone test block with 2, 3, and 4 mL PMMA bone cement injection (Fig. 4). The occupied space of different bone cement distribution was also quantitatively characterized for length, diameter, and volume by using 3D scanning and measurement of reverse engineering.

The results of bone cement distribution pattern for the conventional solid pedicle screws show that (1) group D1 is presented as a semi-regular spherical cement cloud, (2) group D2 – as a rather regular spherical cement cloud, and (3) group D3 – as a dense and regular spherical cement cloud. The results of bone cement distribution pattern for the cannulated pedicle screws show that (4) group E1 is presented as a semi-regular elliptical cement cloud, (5) group E2 – as a rather regular elliptical cement cloud, and (6) group E3 – as a dense and regular elliptical cement cloud. The results of bone cement distribution pattern for the cannulated pedicle screws with a matched central pin insertion show that (7) group F1 is presented as a semi-regular elliptical cement cloud, (8) group F2 – as a rather regular elliptical cement cloud, and (9) group F3 – as a dense and regular elliptical cement cloud.

The bone cement distribution pattern can show similar morphology, either spherical or elliptic cement cloud. The spherical cement cloud of group D may be caused by the unique exiting bore of the spinal needle. The elliptic cement cloud of group E and F may be created by the side-grooves related to the capillary phenomenon. The measurements of bone cement cloud for nine groups with different cement-injected volumes were calculated in Table 1.

(1) Group D1   (2) Group D2   (3) Group D3

(4) Group E1   (5) Group E2   (6) Group E3

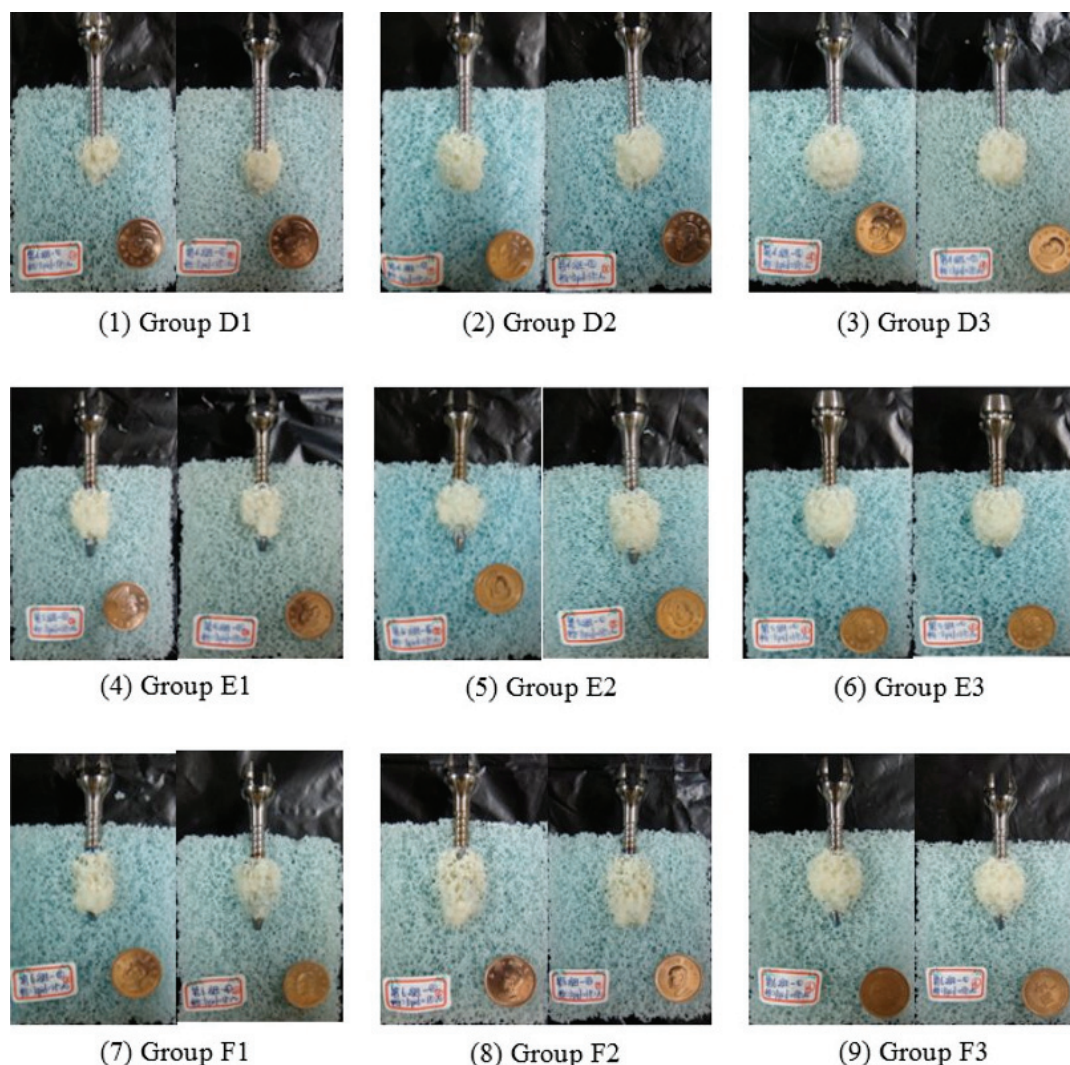(7) Group F1   (8) Group F2   (9) Group F3

Fig. 4. The bone cement distribution patterns of nine groups

Table 1. Measurements of average length, diameter,
and volume in the cement cloud

	Length [mm]	Diameter [mm]	Volume [mm³]
Group D1	16.67	16.97	2,197
Group D2	19.41	18.21	3,257
Group D3	22.44	20.98	4,320
Group E1	17.15	15.88	2,033
Group E2	19.95	17.54	3,068
Group E3	23.34	20.16	4,076
Group F1	19.70	15.64	2,289
Group F2	20.10	17.87	3,272
Group F3	23.40	20.55	4,286

Figures 5 to 8 show typical force-displacement curves resulting from each sample testing of group A, B, C, D1, D2, D3, E1, E2, E3, F1, F2, and F3. The testing results of pullout strength and energy are showed in the Table 2. Three different pedicle screws in control groups were easily pulled out from the sawbone test block. There was no significant difference in the pullout failure strength among all groups, but the pullout failure strength of the conventional pedicle screws (group A) was higher than that of the cannulated pedicle screws with a matched central pin insertion (group C), and the cannulated pedicle screws with a matched central pin insertion was
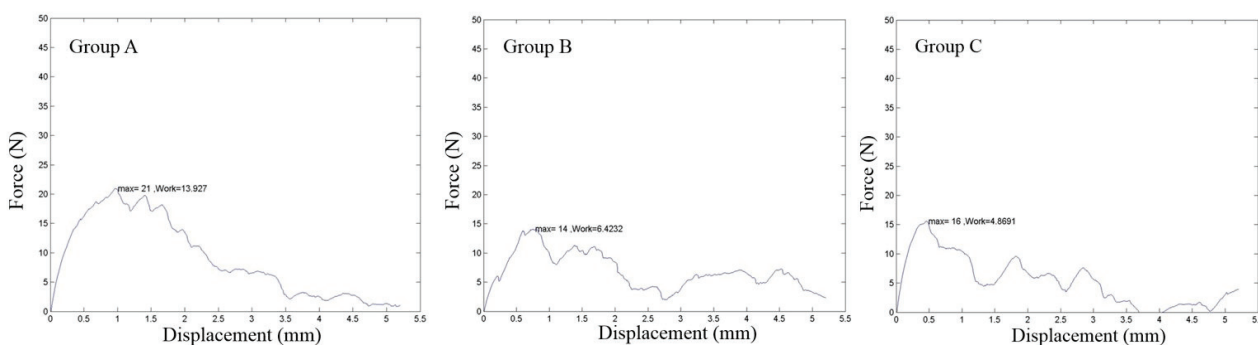
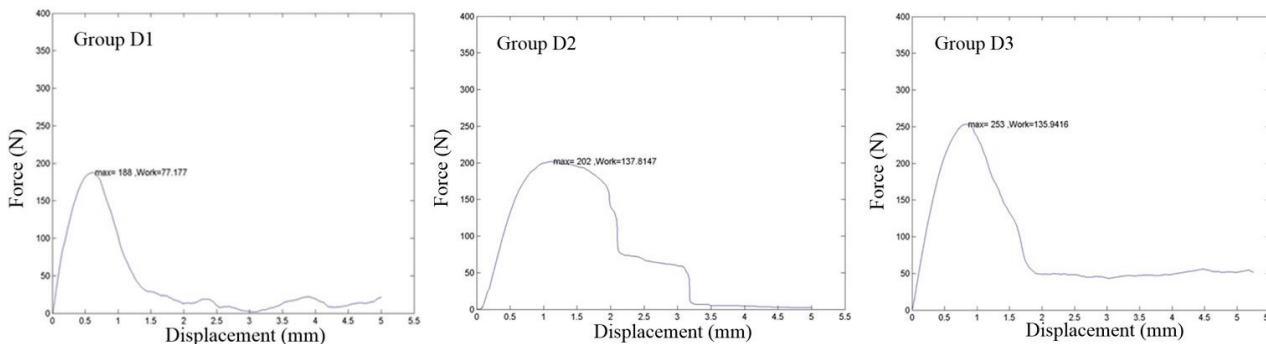Fig. 5. Force-displacement curves from each sample testing of groups A, B, and C

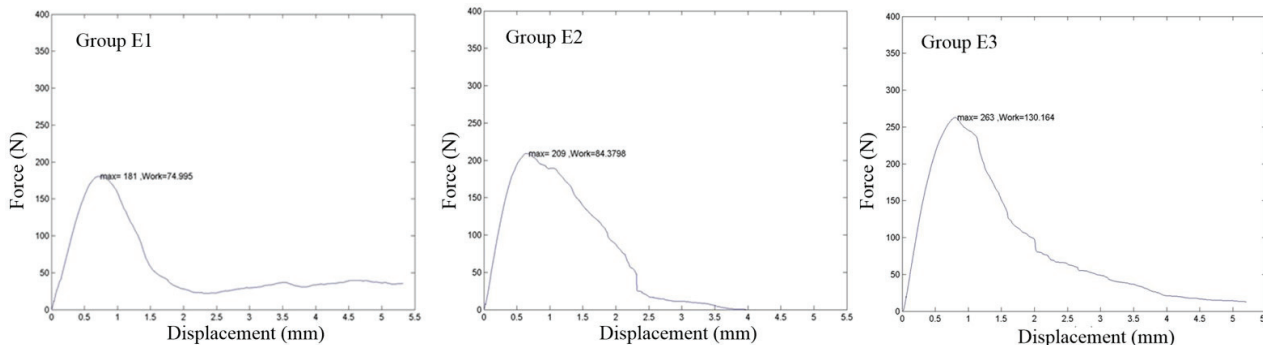Fig. 6. Force-displacement curves from each sample testing of groups D1, D2, and D3

Fig. 7. Force-displacement curves from each sample testing of groups E1, E2, and E3
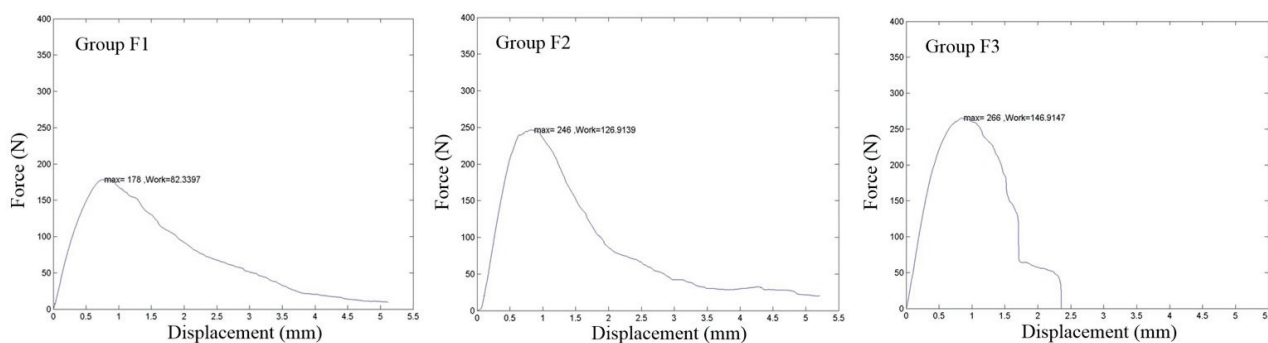
Fig. 8. Force-displacement curves from each sample testing of groups F1, F2, and F3

Table 2. The results of the pullout strength (force) and energy (work) in twelve groups ($N = 5$)

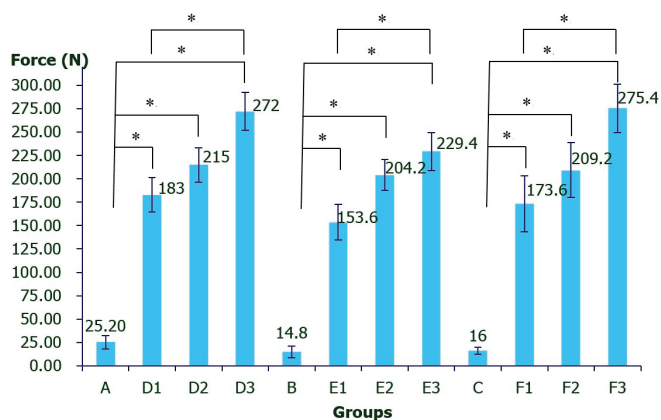|	Force [N]	Work [N-mm]	Force [N]	Work [N-mm]	Force [N]	Work [N-mm]
	Group A		Group B		Group C	
Mean ± SD	25.2 ± 7.2	13.55 ± 2.3	14.8 ± 6.3	5.94 ± 2.0	16 ± 3.7	7.75 ± 1.9
	Group D1		Group D2		Group D3	
Mean ± SD	183 ± 18.4	80.48 ± 13.5	215 ± 18.4	144.6 ± 17.4	272 ± 20.2	169 ± 37.8
	Group E1		Group E2		Group E3	
Mean ± SD	153.6 ± 19.2	65.4 ± 10.7	204.2 ± 16.6	109.2 ± 16.5	229.4 ± 20.3	134 ± 26.9
	Group F1		Group F2		Group F3	
Mean ± SD	173.6 ± 30.0	94.6 ± 24.4	209.2 ± 29.3	124 ± 11.6	275.4 ± 26.0	168.2 ± 18.5

Fig. 9. The comparisons of the pullout strength (force) in the control groups (A, B, and C) and the cemented groups (D, E, and F), each group was tested by using five samples of the sawbone testing blocks. (* $p < 0.05$)
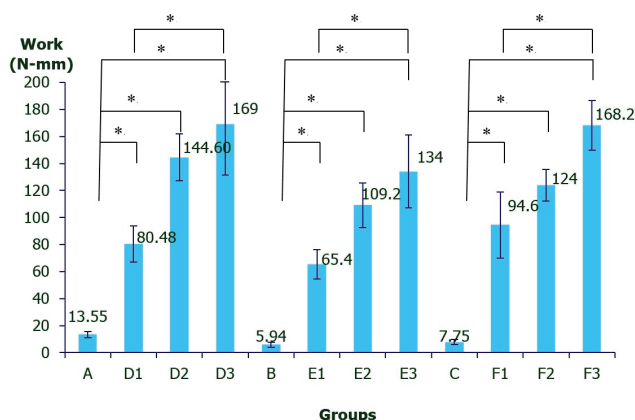

Fig. 10. The comparisons of the work in the control groups (A, B, and C) and the cemented groups (D, E, and F), each group was tested by using five samples of the sawbone testing blocks (* $p < 0.05$)

higher than that of the cannulated pedicle screws (group B).

Cemented samples belonged to groups D, E, and F. The conventional pedicle screws in cemented groups (group D) needed at least six times strength higher than control groups (cementless groups) to be pulled out from the sawbone test block. The cannulated pedicle screws with or without a matched central pin insertion in cemented groups (group E and group F)

needed at least fourteen times strength higher than control groups (cementless groups) to be pulled out from the sawbone test block. A significant increase in the pullout failure strength of pedicle screws with PMMA bone cement augmentation relative to pedicle screws without bone cement augmentation was observed among each group ($P < 0.05$) (Fig. 9). In further comparison of pullout strength of the cement augmentation between 2 mL and 4 mL cement vol-

umes, the significant difference of statistical result was also evidenced. Moreover, the comparisons of the work showed the same tendency of statistical results for evaluating with and without cement augmentations (Fig. 10). The cement/bone composite was well bonded to the screws until failure of the pullout testing, implying that the screw/composite interfacial strength was much higher than the composite/sawbone interfacial strength. The results demonstrate that using PMMA bone cement augmentation can effectively increase pedicle screw fixation in sawbone test block.

The pullout failure strength of using 4 mL bone cement augmentation was higher than that of using 3 mL bone cement augmentation in cemented groups. The pullout failure strength of using 3 mL bone cement augmentation was also higher than that of using 2 mL bone cement augmentation in cemented groups. The larger amount of bone cement augmentation, the more contact surface and interdigitalization with surrounding sawbone, thereby enhanced the pedicle screw fixation strength. There was no significant difference in the pullout strength and energy using the same volume of the PMMA bone cement augmentation among each cemented groups. Further comparing of pullout strength and energy in bone cement volume between 2 mL and 4mL in the significant differences of statistical test were confirmed ($P < 0.05$), but that between 2 mL and 3mL were not significant ($P > 0.05$). The PMMA bone cement which was introduced through the cannulated central hole and exuded from four quadrantal side-grooves provided function and efficacy similar to the traditional open vertebroplasty technique. However, the feasibility and convenience of the cannulated pedicle screw for clinical application in osteoporotic spinal surgeries are difficult to determine and need further investigation.

4. Discussion

A lot of biomechanical studies have attempted to determine the pullout strength for specific pedicle screw designs. The reported results vary greatly, raising concern about bone quality, screw orientation, depth of penetration, with or without bone cement augmentation, and measurement techniques. In the present study, commercially available artificial osteoporotic bones (sawbone test blocks) were used as a substitute for human osteoporotic vertebrae. The material properties of human bone vary with age and species, creating variability among all subjects and making it very difficult to obtain reliable and compa-

rable experimental results. The sawbone test blocks can offer a uniform and consistent density that eliminates the variability encountered for modeling in osteoporotic cancellous bone.

Numerous in-vitro investigations using synthetic cancellous bone as a substitute for cadaveric specimens have shown that synthetic cancellous bone is a good predictor of mechanical characteristics in real patients. Johnson and Keller investigated the comprehensive mechanical properties of synthetic vertebrae, and concluded that synthetic open-cell foam vertebrae offer researchers an alternative to human vertebral bone for static and dynamic biomechanical experiments, including studies examining the effects of bone cement injection [11]. Zdero and Schemitsch examined the effects of screw pullout rate on cancellous bone screw purchase strength in synthetic cancellous bone cubes [26]. Their results indicated that failure force, failure stress, and resistance force were highly linearly correlated with pullout rate. The use of synthetic cancellous bone simplifies the experimental set-up, limiting experimental error. It provided a consistent test platform (independent of bone variation) for comparing screw designs with different numbers of radial holes. Cancellous bone one generally reported to have a density in the range of 0.09–1.25 g/cm^3. The synthetic bone material used in this study had a density of 0.12 g/cm^3, and becasue of that it was chosen to model osteoporotic spinal vertebrae.

Recently, there is an increasing trend in applying PMMA bone cement on osteoporosis for spinal surgeries. PMMA bone cement is usually used to interdigitate with surrounding trabecular bone to stabilize the fractured vertebrae or increase fixation strength and firmly anchor the inserted pedicle screws. The most popular product OSTEOBOND (Zimmer, Inc., Warsaw, IN, USA) in Taiwan is used for this experimental investigation. The OSTEOBOND bone cement is an acrylic cement-like substance which permits seating and securing of a metal or plastic prosthesis or other fixation device into living bone in orthopedic surgeries. When polymerization is complete, the cement acts as a buffer for even distribution of mechanical stresses between prosthesis and bone.

Previous experimental studies demonstrated that various bone cement such as PMMA, hydroxyl apatite, calcium sulfate, and calcium phosphate are effective in augmentation of pedicle screw [10]. Among these cements, PMMA is the most available, cost effective, and has been used in many orthopedic applications for decades. Some studies comment that PMMA has stronger augmentation power than calcium sulfate and calcium phosphate in primary screw augmentation [12], [19], [22]. Other studies report that PMMA

could increase pullout strength up to 96% to 300% and transverse bending stiffness up to 153% [25]. Recently, many non-PMMA or biodegradable substitutes have been developed and proved to increase the pullout strength of 30 to 90%. However, those non-PMMA bone cement have to wait at least 4 to 24 hours to reach the appropriate strength and stiffness for screw augmentation. In clinical practice, quick setting of bone cement with maximal fixation strength is mandatory and necessary during assembling of the spinal construct, especially when compression and distraction force for correcting the spinal deformity is needed. If the pedicle screw fixation is not rigid enough, immediate loosening of the construct can occur, especially in patients with severe osteoporosis.

Several reports address the effect of pedicle screws with radial holes (side holes) designs on pullout strength. McKoy and An compared the ultimate pullout strength of cannulated screws with side ports injected with PMMA to solid screws with the same dimensions on cadaveric osteoporotic vertebrae [16]. Consecutive ports were made along the entire shaft of the screw by rotating the screw of approximately 30° for a total of eight ports. Their results revealed that the cannulated screw with cement augmentation (2956 ± 567 N) had by 278% greater pullout strength than the solid screw (781 ± 151 N) [8]. Also with use of cadaveric osteoporotic vertebrae, Becker et al. [6] compared the pullout forces of two different screw designs (solid and perforated screws) and four screw augmentation methods (solid screw with no augmentation, solid screw with vertebroplasty, solid screw with balloon kyphoplasty, and perforated screw with vertebroplasty) [6]. The perforated screws had a central canal without a distal opening and 2×2 holes at 20% and 40% of the thread length from the screw tip. Their results indicated that perforated screw with vertebroplasty group (mean 918.5 N) had a significantly higher pullout force than solid screw with no augmentation (control) group (mean 513 N).

Chen et al. tested six groups of cannulated conical screw designs, with or without radial holes [8]. The groups included Group S: solid screw without holes; Group C0: Central hole only; Group C2: Central hole with two radial holes; Group C4: Central hole with four radial holes; Group C6: Central hole with six radial holes, and Group C8: Central hole with eight radial holes. The holes were 2 mm in diameter and were located at 4 mm increments along the length of screw, starting at the screw tip. A uniform synthetic bone was used to provide a platform for each screw design. Specimens with inserted screws were tested for axial pullout failure. They reported all cannulated screws with

cement augmentation had significantly higher pullout strength than solid screw. The average pullout strength for cannulated screws with PMMA injection increased as the radial holes number increased.

The elliptic cement cloud of group E is a little smaller than group D and F because of about 0.2 mL bone cement retained inside the cannulated central hole. It means that about 10% cement volume will decrease in group E when 3 mL bone cement is used for augmentation. Because there were some air emboli accumulated within the cement cloud, the measured length or diameter and calculated volume was a little larger than the volume of PMMA bone cement injection. The optimal amount of bone cement augmentation for each pedicle screw is not known for different patients and different bone quality. However, both safety and strength of cement augmentation must be balanced. Theoretically, the higher strength of pedicle screw fixation can be obtained with the larger amount of injected bone cement, but this may have higher risk of cement leakage. Additionally, the larger amount of bone cement injection usually takes more time and requires higher pressure, which can influence the limited time available to insert pedicle screws correctly before bone cement hardening.

In clinical practice, the bone cement anchoraged pedicle screw design may have advantages of secure pedicle screw fixation which can decrease the instrumented and fusion segments, and shorten the wound incision and operative time. However, the efficiency and convenience of the bone cement anchoraged pedicle screw for clinical application in osteoporotic spinal surgeries need further investigation and experiment. The limitation of this study is the fact that the properties of the sawbone test block cannot reflect biomechanical effects to the real osteoporotic patients and lack of testing to compare with patients or human cadavers due to difficult source limitation. Moreover, effect and structure of cortical shell was not included for evaluation in this study. The only axial pullout force parallel to screw is applied to test pullout strength in the sawbone test block. The performances of different strength in relationship between pedicle screw and bone cement will not be provided.

5. Conclusion

Osteoporosis plays a significant role in the progression of adult spinal instability and deformity. It has become a growing concern among the medical community as both a primary cause of musculoskeletal dysfunction and a comorbidity among patients

requiring orthopedic care. The feasibility and performance of the pedicle screw prototype is proved by using sawbone test block of compromised quality empirically and analytically. The use of the bone cement anchoraged pedicle screw can enhance the fixation strength and stability in sawbone test block with compromised quality, particularly in biomechanical testing. Moreover, relationship between bone cement volume and pullout failure strength is evidenced to have a positive correlation, but more cement injection may induce leakage risk to cause damage under surgery. The cannulated pedicle screw with a central pin can pushout remaining cement into cancellous bone to increase holding power when pedicle screw is applied a tensile force or bending moment. This study concluded that the best cement argumentation in the cannulated pedicle screw with a central pin can be considered as a clinical option in instrumentation for severe osteoporosis patients while increasing usage of injective volume in bone cement is limited.

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