Effectiveness Testing of Combined Innovative Pressurized Carbon Dioxide Lavage and Pulsatile Normal Saline Irrigation to Enhance Bone Cement Penetration in Total Knee Replacement: A Cadaveric Study

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Background: *The cementing technique in total knee arthroplasty (TKA) is essential for a successful outcome. Previous studies have shown that deeper cement penetration results in greater tensile and shear strength between the bony part and the prosthetic parts.*
Objective: *To investigate the effectiveness of combined innovative pressurized carbon dioxide lavage and pulsatile normal saline irrigation for enhancing cement penetration into cancellous bone, as compared with standard pulsatile normal irrigation alone.*
Material and Method: *An intra-individual comparative cadaveric study was conducted at the Department of Orthopaedic Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University in April 2015. Ten fresh cadavers underwent TKA via the medial parapatellar approach. The proximal tibia was cut perpendicular to its anatomical axis at a point nine millimeters inferior to the lateral plateau. After randomization of knees, the proximal tibia of one side was prepared with pulsatile normal saline irrigation followed by innovative pressurized carbon dioxide lavage. The contralateral side was then prepared using standard pulsatile normal saline irrigation alone. After completing bilateral cemented TKA, the tibial prostheses were removed from both knees. The proximal tibia was then cut on three planes. The posterior coronal plane cut, the medial sagittal oblique plane cut, and the lateral sagittal oblique plane cut facilitated visualization and measurement of the depth of cement penetration into the posterior, middle, and lateral columns, respectively. A bone sample from each column was measured by digital vernier caliper to evaluate bone cement penetration.*
Results: *Combined innovative pressurized carbon dioxide lavage and pulsatile normal saline irrigation produced significantly deeper cement penetration into cancellous bone, as compared with pulsatile normal irrigation alone (1.90±0.39 mm vs. 1.21±0.21 mm, p = 0.04).*
Conclusion: *Combined innovative pressurized carbon dioxide lavage and pulsatile normal saline irrigation produced significantly deeper bone cement penetration than pulsatile normal saline irrigation alone.*

Keywords: *Carbon dioxide, Therapeutic irrigation, Arthroplasty, Replacement, Knee, Prostheses and implants, Lavage, Cemented, Knee arthroplasty, Prostheses*

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Total knee arthroplasty (TKA) is an established, effective, and widely used procedure in patients who suffer from degenerative disorders of the knee. TKA decreases pain, modifies or corrects deformity, and increases range of motion; all of which improve patient quality of life[1]. The cementing technique in which cement is used to conjoin cancellous bone and the prosthetic joint is essential for a successful outcome. Inappropriate or inferior cementing technique results in spaces between cement-bone interfaces. These spaces are demonstrated radiographically as radiolucent lines that indicate or foretell aseptic loosening of the periprosthetic joint. These patients suffer from severe pain and require surgical fixation[2-5].

Previous studies have shown that deeper cement penetration results in greater tensile and shear strength between the bony part and the prosthetic parts[6-8]. A depth of as much as three millimeters has

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been shown to provide long-term stability and prolonged anticipated working life of prosthetic joints[9]. In contrast, a depth of one millimeter has resulted in micromotion of the prosthetic joints, because adhesion between cement and transverse trabeculae of cancellous bone of at least one level was compromised[3]. This micromotion results in later instability and loosening of prosthetic joints.

Innovative pressurized carbon dioxide lavage that is used to prepare bones prior to cement penetration has already passed phase I study. Sterility of the equipment after standard sterilization has also been validated[10]. The aim of this phase II study was to investigate and describe the effectiveness of combined innovative pressurized carbon dioxide lavage and pulsatile normal saline irrigation for enhancing cement penetration into cancellous bone, as compared with standard pulsatile normal irrigation alone.

Material and Method

This phase II intra-individual comparative study was designed and conducted to evaluate the effectiveness of combined innovative pressurized carbon dioxide lavage and pulsatile normal saline irrigation for improving cement penetration into cancellous bone in TKA. This procedure was compared with pulsatile normal saline irrigation alone, which is the current standard bone preparation method in TKA. This study was conducted at the Department of Orthopaedic Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University in April 2015. The protocol for this study was approved by the Siriraj Institutional Review Board (SIRB).

Ten fresh cadavers were used instead of artificial bone to best imitate the anatomical environment. One side of the proximal tibia was prepared using standard pulsatile normal saline irrigation alone. This was defined as the control group. The other side was prepared with combined innovative pressurized carbon dioxide lavage and pulsatile normal saline irrigation[10]. This was defined as the treatment group. This intra-individual comparative method was intended to circumvent problems associated with anatomical variations of proximal tibia among cadaveric subjects. Intra-individual knee randomization was performed by randomization software from www.randomization.com.

All 10 fresh cadavers underwent TKA via medial parapatellar approach. The anterior and posterior cruciate ligaments were cut to subluxate the tibia anteriorly apart from the femur until the entire articular surface of tibia was visible. The proximal tibia cut was performed at a point 9 mm inferior to the lateral plateau at a plane perpendicular to its anatomical axis according to the extramedullary guide. The size of prosthetic tibial part or tibial tray (Zimmer® NexGen® High-Flex; Zimmer Inc., Warsaw, IN, USA) was measured individually in each cadaver with the same size used bilaterally to ensure equal surface contact and load distribution between bilateral tibias and tibial trays. Tibial broaching was then performed for tibial component placement. After randomization, each proximal tibia underwent its allocated method of preparation. High viscosity cement (Zimmer® Osteobond®; Zimmer Inc., Warsaw, IN, USA) at the doughy phase was pasted along the proximal tibial surface before planting the tibial tray and being hammered with the surgical hammer 10 times. One specialized surgeon conducted all of the processes in all cadavers. The tibial tray was pressed along the anatomical axis of tibia for 15 minutes. Twenty minutes after the polymerization phase of the cementing process, the tibial component was removed by sharp saw and osteotomy.

Data collection

The proximal tibia was cut on three planes. The posterior coronal plane cut, the medial sagittal oblique plane cut, and the lateral sagittal oblique plane cut facilitated visualization and measurement of the depth of cement penetration into the posterior, middle, and lateral columns, respectively. The posterior coronal plane cut was made first using a sharp saw that is specifically used for TKA at a point five millimeters posterior to the tibial fin. The medial sagittal oblique and lateral sagittal oblique cuts were then performed at a 45-degree angle to the posterior coronal cut at five millimeters medially and 5 millimeters laterally from the tibial fin, respectively (Fig. 1). Only the tibial plate was examined. A point away from the tibial fin was therefore chosen to minimize the deferred depth, which may have been caused by tibial tray removal. The deepest cement penetration into the cancellous bone of each column was measured by digital vernier caliper (precision 0.00 mm). Inter-rater reliability was analyzed using measurement from photograph and compared to measurement by digital vernier caliper.

Data analysis

Depth of cement penetration is described as mean ± standard deviation and findings are summarized by treatment arm. The first arm received combined

innovative pressurized carbon dioxide lavage and pulsatile normal saline irrigation. The other treatment arm received standard pulsatile normal irrigation alone. Group Stats software (open source) was used to compare means between groups. A *p*-value of less than 0.05 was considered statistically significant.

Results

Depth of cement penetration of the proximal tibia using combined innovative pressurized carbon dioxide lavage and pulsatile normal saline irrigation was significantly deeper than the penetration achieved by pulsatile normal saline irrigation alone (1.90±0.39 mm vs. 1.27±0.21 mm, respectively; $p = 0.04$).

Discussion

Previous research has proven that the tensile strength of the cement-bone interface depends on the amount of bone interdigitated with cement[11]. Several authors have thus researched various methods and devices to improve the penetration of the cement of femoral and tibial prostheses during TKA including impactor devices[12], negative pressure intrusion technique[13], irrigation and suction technique[14,15], pressurization pulsed lavage[16]. In 2007, an innovative device named CarboJet (Kinamed, Camarillo, CA, USA) was evaluated, which was proven to improve the cement mantle thickness[17].

The present study intended to evaluate the efficacy of innovative pressurized carbon dioxide lavage which uses locally made, low cost and reusable equipment. Innovative pressurized carbon dioxide lavage facilitated the removal of water, fat, and bony fragments from the proximal tibial end before TKA. This process eliminated the space between the cement and the cancellous bone contact surfaces down to a depth of 1.90 mm. The effect of this method facilitated deeper cement penetration and delivered a more stable mechanical bone-cement interfaces.

There were some limitations in our study. First, the measurement of the depth of cement penetration was defined as the deepest part of each column rather than the accurate volume of integrated cement from computed tomography reconstruction. Second, quality of cementation requires better biochemical testing to evaluate tensile and shear strength between cement-bone interfaces, which we did not perform in this study.

In the future, we intend to perform further studies to modify and adapt this novel cement penetration technique for practical use in real life clinical settings.

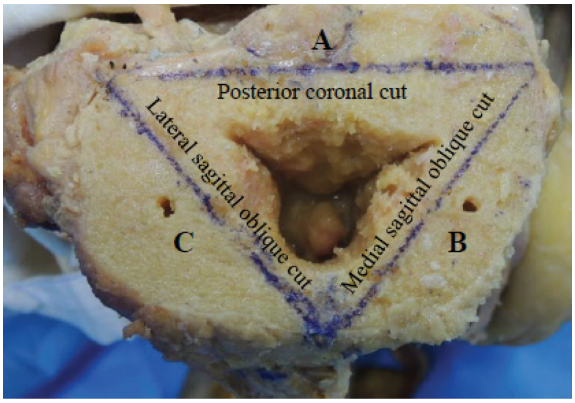

Fig. 1 Illustration of the posterior coronal, medial sagittal oblique, and lateral sagittal oblique cuts, with A, B, and C representing the depth of cement penetration into the posterior, middle, and lateral columns, respectively.

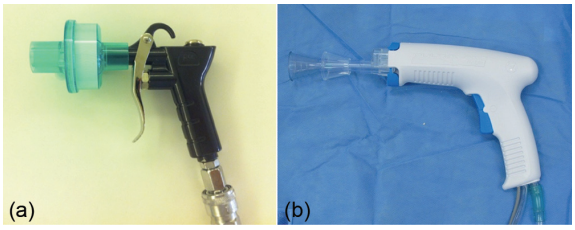

Fig. 2 (a) Innovative pressurized carbon dioxide lavage device. (b) Pulsatile normal saline irrigation device.

Conclusion

Combined innovative pressurized carbon dioxide lavage and pulsatile normal saline irrigation produced significantly deeper bone cement penetration than pulsatile normal saline irrigation alone. This innovative method may have positive cost and patient quality of life implications by reducing the likelihood of periprosthetic joint loosening and extending the functional life of the implant.

What is already known this topic?

The innovative pressurized carbon dioxide lavage is locally made, has a low cost, and is a reusable equipment used to prepare cementation for the cancellous bone contact surfaces.

What this study adds?

The effectiveness of combined innovative pressurization carbon dioxide lavage and pulsatile normal saline irrigation produced significantly deeper

bone cement penetration than pulsatile normal saline irrigation alone.

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Potential conflicts of interest

None.

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การตรวจสอบประสิทธิภาพของนวัตกรรมเครื่องอัดก๊าซคาร์บอนไดออกไซด์ในการแทรกซึมของซีเมนต์เข้าในเนื้อกระดูกสำหรับการผ่าตัดเปลี่ยนข้อเข่าเทียม

กฤต บุญธนาพิบูลย์, ภาคภูมิ เรืองสมบูรณ์, จตุรงค์ พรรัตนมณีวงศ์, กีรติ เจริญชลวานิช

ภูมิหลัง: *การแทรกซึมของซีเมนต์ระหว่างพื้นผิวกระดูกกับข้อเข่าเทียมเป็นสิ่งสำคัญ ในการผ่าตัดเปลี่ยนข้อเข่าเทียม มีการศึกษาว่าการแทรกซึมที่ลึกขึ้นของซีเมนต์ทำให้บริเวณพื้นสัมผัสระหว่างกระดูกโปร่งและข้อเข่าเทียมมีความต้านทานแรงดึงและแรงเฉือนที่เพิ่มขึ้น*

วัตถุประสงค์: *เพื่อตรวจสอบประสิทธิภาพของเครื่องมือถึงความลึกในการแทรกซึมของซีเมนต์เข้าไปในเนื้อกระดูกโปร่งภายหลังการเตรียมผิวข้อเข่าด้วยนวัตกรรมเครื่องอัดก๊าซคาร์บอนไดออกไซด์ ร่วมกับการล้างด้วยน้ำเกลือในร่างอาจารย์ใหญ่*

วัสดุและวิธีการ: *เข่าจากร่างอาจารย์ใหญ่ 10 ร่าง ได้รับการผ่าตัดแบบ medial parapatella approach และตัดผิวข้อของกระดูกทิเบียส่วนต้นตั้งฉากแนวแกนทางกายภาพ ออกจากผิวข้อด้านข้าง 9 มิลลิเมตร ผิวข้อของกระดูกทิเบียส่วนต้นข้างหนึ่งจะได้รับการเตรียมผิวข้อด้วยการล้างด้วยน้ำเกลือและตามด้วยนวัตกรรมเครื่องอัดก๊าซคาร์บอนไดออกไซด์ ส่วนอีกข้างหนึ่งจะได้รับการเตรียมผิวข้อด้วยการล้างด้วยน้ำเกลือเพียงอย่างเดียวตามวิธีมาตรฐาน จากนั้นเข่าทั้ง 2 ข้าง จะถูกนำข้อเทียมออกและตัดตาม posterior coronal cut, medial sagittal oblique cut และ lateral sagittal oblique cut เพื่อเป็นตัวแทนของ cement penetration depth ของ posterior, middle และ lateral column ตามลำดับ กระดูกที่ถูกตัดออกมาในแต่ละ column จะนำมาประเมินความลึกของการแทรกซึมของซีเมนต์ที่เข้าสู่เนื้อกระดูกโปร่ง และจะได้รับการวัดด้วย digital vernier caliper ตามลำดับ*

ผลการศึกษา: *พบว่าการแทรกซึมของซีเมนต์เข้าไปในเนื้อกระดูกโปร่งภายหลังการเตรียมผิวข้อเข่าด้วยนวัตกรรมเครื่องอัดก๊าซคาร์บอนไดออกไซด์ ร่วมกับการล้างด้วยน้ำเกลือ มีความลึกมากกว่ากลุ่มที่เตรียมผิวข้อด้วยการล้างด้วยน้ำเกลือเพียงอย่างเดียวอย่างมีนัยสำคัญทางสถิติ (1.90±0.39 มม. vs. 1.21±0.21 มม., p = 0.04)*

สรุป: *นวัตกรรมเครื่องอัดก๊าซคาร์บอนไดออกไซด์สามารถเพิ่มความลึกในการแทรกซึมของซีเมนต์ เข้าไปในเนื้อกระดูกโปร่งได้ดีกว่าเทคนิคการใช้การล้างด้วยน้ำเกลืออย่างเดียว*