The Effect of Tourniquet Use and Sterile CO_2 Gas Bone Preparation on Cement Penetration in Primary Total Knee Arthroplasty

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Abstract

Introduction: Tourniquetless total knee arthroplasty (TKA) is experiencing resurgence in popularity due to potential pain control benefits. Further, optimal cement technique and implant fixation remain paramount to long-term cemented TKA success, as aseptic loosening continues to be a leading cause of revision. The purpose of this study was to determine how tourniquet use and/or novel bone preparation using sterile, compressed carbon dioxide (CO_2) gas affected cement penetration in TKA.

Methods: A retrospective review was performed on 303 consecutive primary TKAs with the same implant in three groups: (1) a tourniquet without sterile CO_2 compressed gas used for bone preparation, (2) no tourniquet with CO_2 gas, and (3) tourniquet use and CO_2 gas bone preparation. Cement penetration was measured on radiographs by two independent, blinded raters across seven zones defined by the Knee Society Radiographic Evaluation System.

Results: The three groups did not differ on age, BMI, or sex ($p \geq 0.1$). Cement penetration was greater in six of seven zones with significantly greater cement penetration in three zones (Tibial AP Zone 2, Femoral Lateral Zones 3A and 3P) in groups that utilized CO_2 gas bone preparation compared to the tourniquet only group ($p \leq 0.039$).

Conclusion: Bone prepared with CO_2 gas showed significantly more cement penetration in three zones with greater cancellous bone. The results suggest use of CO_2 gas bone preparation may achieve greater cement penetration than using a tourniquet with lavage only.

Keywords: total knee arthroplasty; cement penetration; bone preparation; tourniquet; Radiographic Evaluation System

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Introduction

While cemented total knee arthroplasty (TKA) is a widely successful procedure to treat many forms of arthritis, aseptic loosening remains one of the primary causes for early and late revisions. [1-5] Studies and 2017 national registries report up to 28.7% of all revisions are due to aseptic loosening. [3, 6-8] The projected economic burden of these revisions makes the prevention of TKA failures imperative. [9-11] An evaluation of TKA failures estimated that 40% of early revisions could be avoided, in part, with optimal cement fixation. [12] Increasing the amount of cement into the tibial and femoral bone (cement penetration) has been shown to provide a stronger bone-cement interface which leads to increased stability and long-term survivorship of the implants. [13-15]

Traditionally, a tourniquet is used during TKA to optimize cement fixation via minimizing the blood within the cancellous bone to allow more cement penetration and subsequent interdigitation. Studies with and without tourniquet use have reported conflicting results with respect to optimizing cement penetration; however, no difference in implant migration has been reported out to two years. [16-19] Further, there are potential clinical drawbacks reported in the literature with using a tourniquet such as increased postoperative blood loss and pain scores with slower recovery, and decreased quadriceps strength which make tourniquetless TKA appealing. [16-18, 20-22]

Recently, a novel bone preparation method of sterile pressurized carbon dioxide (CO_2) gas has been used for its ability to clean out more fluids, fat and other lipid soluble debris than a pulsatile lavage alone. [23, 24] This technique theoretically offers an even cleaner bone surface for greater bone cement penetration and can be used during TKA to minimize the potential deleterious effect of blood within the cancellous bone during cementation. Recently, the technique of sterile CO_2 compressed gas was utilized in completely tourniquetless TKA, which resulted in less pain and narcotic use in females compared to those utilizing a tourniquet. [22] However, a paucity of published literature exist showing the effect on cement penetration of CO_2 gas as a bone preparation technique. Therefore, the purpose of this study was to evaluate cement penetration in three groups: (1) tourniquet only group with no CO_2 gas bone preparation, (2) tourniquet group utilizing CO_2 gas bone preparation and (3) completely tourniquetless surgery utilizing CO_2 gas used as bone preparation prior to bone cement application in a consecutive series of primary TKAs.

Materials and Methods

With institutional review board approval, a retrospective review of 303 consecutive primary TKAs performed between January 2016 and September 2017 was conducted. All procedures were performed by a single surgeon at one designated hip and knee center. The same perioperative pain and rehabilitation protocols were used for all cases. Of the 303 TKAs, 32 were excluded due to a variety of confounding factors: tibial screw usage (1), prior ACL surgery (1), patient death within two months of surgery unrelated to TKA (2), unable to identify the bone cement used (1), and suboptimal or a lack of a one-month or one-year radiographs (27) resulting in a sample size of 271 cases.

Radiographic Cement Penetration

All radiographs were accessed in the institution's digital radiographic repository (Synapse, PACS, Fujifilm, USA). Radiographs were obtained by a trained radiologist with a standardized protocol for all cases. Cement penetration was measured according to the zones described by the Knee Society Radiographic Evaluation System (Figure 1). [25] Tibial AP

Zones 1 and 2 (Figures 1 and 2A) represent the medial and lateral inferior surfaces of the tibial baseplate, respectively. Tibial Lateral Zones 1 and 2 (Figures 1 and 2B) represent the anterior and posterior distal surfaces of the tibial baseplate, respectively. Femoral Lateral Zones 3A, 3 and 3P (Figures 1 and 2B) represent anterior, distal and posterior proximal surfaces of the femoral component, respectively. For zones 1 and 2 in both the AP and lateral tibial views, cement penetration was measured at the one-third and two-third marks (Figure 2). For the lateral femoral view, cement penetration in zone 3A was measured at the one-third and two-third mark while cement penetration in zones 3 and 3P was measured at the one-half mark due to the smaller relative size of these zones to the other zones (Figure 2B).

Only radiographs with implant views collinear to the x-ray beam were measured to allow the most accurate measurement of cement penetration. Cement penetration measurements were made on one-month radiographs for all patients unless suboptimal views of the implants were identified. If suboptimal views were found, then the next available postoperative radiograph was used (i.e. one-year, two-year, etc.). Measurements were collected on digital radiographs with a digital ruler calibrated to the thickness of each tibial baseplate (7.42 mm) which was identical for all sizes of this particular implant. Once each radiograph was calibrated and each zone was measured horizontally and divided into the appropriate number of sections, the vertical linear distance of cement penetration was measured from the distal-most part of the implant to the distal-most part of the cement mantle (Figure 2). The cement penetration measurements collected at the one- and two-thirds partition of each zone were averaged for an overall cement penetration value for that particular zone.

Measurements were made by two independent raters, blinded to the three study groups (tourniquet only, CO_2 only, and tourniquet with CO_2). Discrepancies between raters greater than

1.0mm were resolved by each rater independently re-visiting measurements until measurements agreed within 1.0mm. After discrepancies were resolved, measurements between raters were averaged to calculate an average cement penetration value for each radiographic zone.

Surgical Technique

A median parapatellar approach was used for all procedures. The fat pad was completely excised during all procedures and the patella was subluxed into the lateral gutter without patella eversion in all cases. In addition, a right angle retractor was placed lateral to the tibia retracting the patella clear of the lateral proximal tibia and a retractor placed posteriorly behind the tibia exposing the entire proximal tibial plateau. Standard coronal plane tibial and femoral bone cuts were made with computer-aided navigation (Stryker Navigation, Kalamazoo, MI). One knee arthroplasty system (DJO EMPOWR 3D®, DJO Surgical, Austin, TX) was used in all patients and intravenous tranexamic acid was used in all patients. The surgeon routinely utilized a cruciate-retaining (CR) implant with a conforming polyethylene insert in all patients with or without preservation of the posterior-cruciate ligament. All sclerotic surfaces were prepared with small drill holes to facilitate bone cement interdigitation and were cleaned thoroughly with a pulsatile lavage in all three study groups. Medium-viscosity polymethylmethacrylate (PMMA) bone cement was mixed with low-dose antibiotics and the components were securely cemented with manual hand pressurization (i.e. finger packing) in a standardized manner during the working phase of the bone cement in all cases. The cement was allowed to cure with the knee held in extension and visual confirmation of secured component fixation was obtained. Upon drying, all extraneous cement was removed from all aspects of the knee. Finally, the knee was vigorously irrigated again with a pulsatile lavage to remove any cement particles and the final polyethylene insert was inserted and impacted into a locked position. The only alterations to this protocol were when compressed CO_2 gas (CarboJet®, Kinamed, Inc., Camarillo, CA) was used for bone preparation prior to applying the bone cement or a tourniquet was not used. When a tourniquet was not utilized, it is important to clarify that the tourniquet was not applied to the operative leg and therefore not utilized at any point during the procedure, not even during cementation.

The "tourniquet only" group utilized a tourniquet without compressed CO_2 gas for bone preparation. The "CO_2 only" group did not use a tourniquet and used compressed CO_2 gas for bone preparation. The "tourniquet with CO_2" group utilized both a tourniquet and CO_2 gas for bone preparation. All three groups received pulsatile lavage regardless of CO_2 gas bone preparation or tourniquet use. All other events for the surgical protocol were unchanged for all cases.

Statistical analysis

Minitab® 17 (State College, PA) was used for statistical analyses. Outliers were assessed with a form of Dixon's outlier test dependent on the sample size. Data were evaluated for normality using Anderson-Darling (AD) tests. Tibial AP Zone 1, Tibial AP Zone 2, Tibial Lateral Zone 1, Tibial Lateral Zone 2 and the overall cement penetration across all seven zones were normally distributed ($p \geq 0.456$). Consequently, cement penetration measurements for these five variables were evaluated with an Analysis of Variance (F) while the cement penetration measurements of the other three zones were non-normally distributed ($p \leq 0.043$) and therefore required a Kruskal-Wallis (H) test adjusted for ties. Pearson's Chi-Square (X^2) test was used to test independence among categorical variables, with Fishers Exact test p values reported for 2 x 2 contingency tables. A significance level of 0.05 was used for all statistical analyses.

Results

Demographics

Two hundred seventy-one TKAs were available for analysis. Overall, mean age was 67.8 years (SD 8.7) and median body mass index (BMI) was 33.0 kg/m^2. Seventy-two percent (n=194) of the study population was female. TKAs were then grouped by intraoperative tourniquet use and bone preparation method. Thirty-seven percent of the cohort used a tourniquet only with no CO_2 bone preparation (n=101), 34% used a tourniquet and CO_2 bone preparation (n=91) and 29% used CO_2 bone preparation with no tourniquet (n=79). No difference in age, BMI, or proportion of females to males was detected in the three groups (Table 1, $p \geq 0.1$).

Cement Penetration

The depth of cement penetration was compared in each radiographic zone among the three groups. No differences in cement penetration were found for Tibial AP Zone 1, Tibial Lateral Zone 1, Tibial Lateral Zone 2 or Femoral Lateral Zone 3 (Table 2, $p \geq 0.173$). However, Tibial AP Zone 2, Femoral Lateral Zone 3A and Femoral Lateral Zone 3P showed significantly more cement penetration for groups using the compressed CO_2 gas for bone preparation (Table 2, $p \leq 0.039$). In fact, one of the two groups that utilized the compressed CO_2 gas almost always showed equivalent or greater cement penetration compared to the tourniquet only group (except for Tibial Lateral Zone 2) although some zones did not achieve statistical significance (Figure 3). The average cement penetration across all seven zones also showed no difference ($F = 1.12$, $p = 0.326$); however, the tourniquet with CO_2 gas had the greatest overall cement penetration

(2.23mm SD 0.41) followed by the CO_2 only group (2.18mm SD 0.50) and then the tourniquet only group (2.13mm SD 0.48, Figure 3).

Discussion

Previous reports have advocated for tourniquet use to enhance cement fixation strength so that blood does not interfere with the bone-cement interface and therefore provides an increased shear strength for the interface. [16, 26] However, the use of a tourniquet has been reported to be correlated with potential clinical drawbacks such as higher *postoperative* pain and blood loss, and slower recovery. [16, 20, 22] Due to these findings, tourniquetless TKAs have experienced a resurgence with similar clinical results compared to tourniquet TKAs. [19, 27] In addition, alternative techniques (i.e. compressed, sterile CO_2 gas) are being pursued to increase cement penetration and provide increased initial stability and hopefully better long-term survivorship for cemented TKAs.

Cement penetration appears to be a pertinent measure of implant fixation both in the short-term, but also in the longer term as a predictor of TKA longevity. Miller and colleagues conducted a postmortem retrieval study of 14 TKAs implanted from zero to 20 years and documented decreasing depth of interdigitation and cement interlock correlated with time in situ. [14] In a subsequent analysis, the authors further loaded retrieved implants in mechanical compression to assess micromotion. [28] The authors demonstrated that TKA tibial implants with less initial interdigitation between cement and bone and more time in service had less current cement-bone interdigitation (r^2=0.86, p=0.0002) and tibial implants with greater initial interdigitation also had less micromotion after in vivo service (r^2=0.36, p=0.0062). [28] This provides direct evidence that greater initial interlock between cement and bone in tibial components of TKA results in more stable constructs with less micromotion with in vivo service and validates utilizing cement penetration as a surrogate for implant fixation and longevity.

Three radiographic zones (Tibial AP Zone 2, Femoral Lateral Zone 3A and Femoral Lateral Zone 3P) showed significantly more cement penetration for one of two groups that utilized the CO_2 gas for bone preparation compared to tourniquet alone. These three zones tend to have less bone density and greater porosity of cancellous bone, as opposed to the frequently sclerotic medial tibial plateau in osteoarthritic varus knees, and therefore by using the CO_2 gas as a bone preparation technique, cleared out more fat and debris to allow for enhanced cement penetration. Our data corroborate the few studies evaluating the efficacy of CO_2 gas as an effective alternative to other irrigation and lavage techniques. [23, 24, 29, 30] In a cadaver study conducted by Boontanapibul et al., cement penetration was measured with calipers and shown to be greater in areas of cancellous bone on the proximal tibia for the group that used the pressurized CO_2 gas for bone preparation compared to pulsatile lavage alone (1.90mm vs. 1.21mm, p=0.04). [29] Similarly, we report significantly greater cement penetration on the proximal tibia with the use of CO_2 gas used for bone preparation compared to pulsatile lavage alone (Figure 3, 2.08mm vs. 2.43mm, $p = 0.007$). In another cadaveric study, Ravenscroft et al. [30] investigated the push out strength of bone cement plugs between bone preparation techniques of CO_2 compressed gas and standard syringed saline. The authors reported the required force to remove a bone cement plug was significantly higher when CO_2 gas was used for bone preparation compared to standard saline alone (median force 580.6N vs 366.6N, $p = 0.009$) suggesting the pressurized CO_2 gas provided enhanced bone cement interdigitation and a stronger bone-cement interface. [30] In two other studies, investigating the efficacy of compressed CO_2 gas and osteochondral allografts, both studies found that the use of compressed

CO_2 gas more effectively cleared out bone marrow elements than using saline solution only. [23, 24]

Cement penetration differences were only seen in one of the two CO_2 gas groups (with and without a tourniquet) compared to tourniquet with lavage alone. However, considering the potential drawbacks of tourniquet use reported in the literature, [16, 20-22, 31] this *may* obviate the need for a tourniquet clinically. Therefore, based on the cement penetration data presented here, the use of CO_2 gas without a tourniquet for bone preparation *may* achieve equivalent cement penetration without the potential drawbacks of tourniquet use. [16, 20-22, 31]

This study had limitations. One limitation was the amount of missing data due to suboptimal radiograph quality with implants not being collinear to the radiograph machine collimator for accurate cement penetration measurements. This strict inclusion criterion also can be a strength to the study as only the most accurate measurements of cement penetration were collected, avoiding erroneous data points. Another limitation was the lack of bone density data, as this metric was not able to be measured with the available tools at our institution, nor is it practical or within the scope of this clinical study. Studies have shown that patients with lower bone density can achieve greater cement penetration and therefore improved initial implant stability. [15, 32] Although we did not have access to bone density data for each patient, we do not believe it was responsible for the difference in cement penetration between the groups. The three groups did not differ in the proportion of females to males in any group ($p \geq 0.1$) or the overall cement penetration between females and males (mean Female = 2.16mm (SD 0.46) and Male = 2.21mm (SD 0.48); $t = 0.78$, $p = 0.436$). Lastly, a limitation to this study was the slight increase in cost associated with using this device ($130 USD per case); however, the benefit to using this device could help reduce aseptic loosening rates in TKA and therefore reduce cost in the long-term by minimizing costly revisions.

To the authors' knowledge, this is one of the first studies to evaluate in vivo differences in cement penetration using this novel bone preparation method of sterile pressurized CO_2 gas. These results suggest that a movement toward CO_2 gas bone preparation in cemented TKA could achieve improved implant fixation via greater cement penetration than using a tourniquet with lavage only. The improved cement penetration when using CO_2 gas for bone preparation may lead to less implant loosening and therefore better patient outcomes. Longer follow-up of these cases is recommended to evaluate any differences with implant survivorship related to aseptic loosening.

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Figure Legend

Figure 1. Radiographic zones defined by the Knee Society Radiographic Evaluation System.

Figure 2. A – Cement penetration (AP view). Each AP zone was divided into thirds and cement penetration was measured. B – Cement penetration (Lateral views). Each lateral zone was divided into thirds and measured except for Femoral Zones 3 and 3P which were divided in half due to the smaller size of these zones.

Figure 3. Cement penetration for all radiographic zones. CO_2 only or tourniquet with CO_2 groups had equivalent or greater penetration compared to tourniquet only in each zone except for Tibial Lateral Zone 2.

Table 1. Study Group Demographics.

	Tourniquet Only	CO_2 Only	Tourniquet with CO_2	Test Statistic	*p*
N (%)	101 (37%)	79 (29%)	91 (34%)	-	-
Mean Age (Years)	68.9 (SD 8.5)	66.9 (SD 7.9)	67.4 (SD 9.7)	F = 1.35	0.261
Median BMI (kg/m^2)	31.0	35.0	33.6	H = 2.56	0.279
Female (%)	79%	67%	67%	$X^2 = 4.598$	0.100

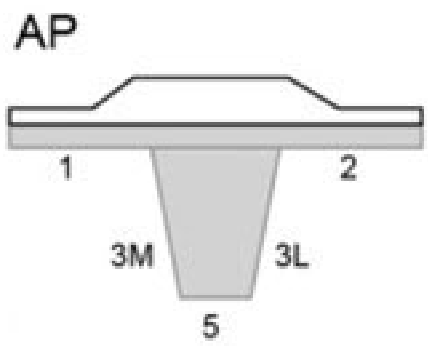
N, sample size
SD, standard deviation
F, ANOVA test statistic
H, Kruskal-Wallis test statistic
X^2, Pearson's chi-square
BMI, body mass index

Table 2. Cement Penetration (in mm) by Radiographic Zone.								
	Tourniquet Only		**CO_2 Only**		**Tourniquet with CO_2**		**Test Statistic**	***p***
Overall	n = 101		n = 79		n = 90[+]			
Average Across 7 Zones	2.13		2.18		2.23		F = 1.12	0.326
Range (min, max)	1.18	3.68	1.02	3.44	1.20	3.45		
AP Tibia	n = 69		n = 45		n = 48			
Zone 1	1.79		1.72		1.93		F = 1.01	0.367
Range (min, max)	0.26	3.32	0.35	3.00	0.54	4.14		
Zone 2	2.08[A]		2.34[AB]		2.43[B]		F = 5.15	**0.007**
Range (min, max)	0.44	3.52	1.03	3.82	1.39	3.98		
Lateral Tibia	n = 81		n = 57		n = 64			
Zone 1	2.64		2.72		2.81		F = 0.89	0.412
Range (min, max)	1.16	4.35	0.50	4.60	1.08	5.46		
Zone 2	2.61		2.60		2.38		H = 3.50	0.173
Range (min, max)	1.12	4.08	1.50	4.54	0.85	4.99		
Lateral Femur	n = 75		n = 58		n = 67			
Zone 3A	2.16[A]		2.48[B]		2.38[AB]		H = 6.77	**0.034**
Range (min, max)	0.00	3.44	1.26	3.65	1.10	3.57		
Zone 3	1.71		1.76		1.79		H = 0.38	0.829
Range (min, max)	0.00	3.19	0.67	3.89	1.02	2.47		

Zone 3P	1.64^{A}		1.90^{AB}		1.87^{B}		H = 6.50	**0.039**
Range (min, max)	0.00	2.90	0.00	3.54	0.00	2.93	-	-

n, sample size
SD, standard deviation
H, Kruskal-Wallis test statistic
F, ANOVA test statistic
Means or medians that do not share a letter are statistically different

[+] One significant outlier was removed from the overall cement penetration average (value = 5.22mm, r22 = 0.54, $p < 0.001$)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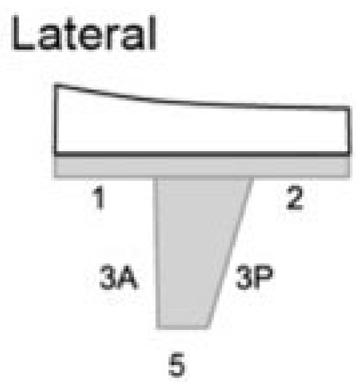
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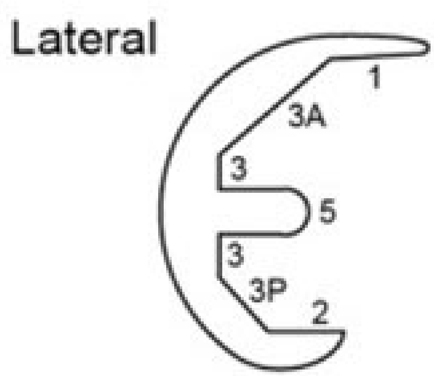
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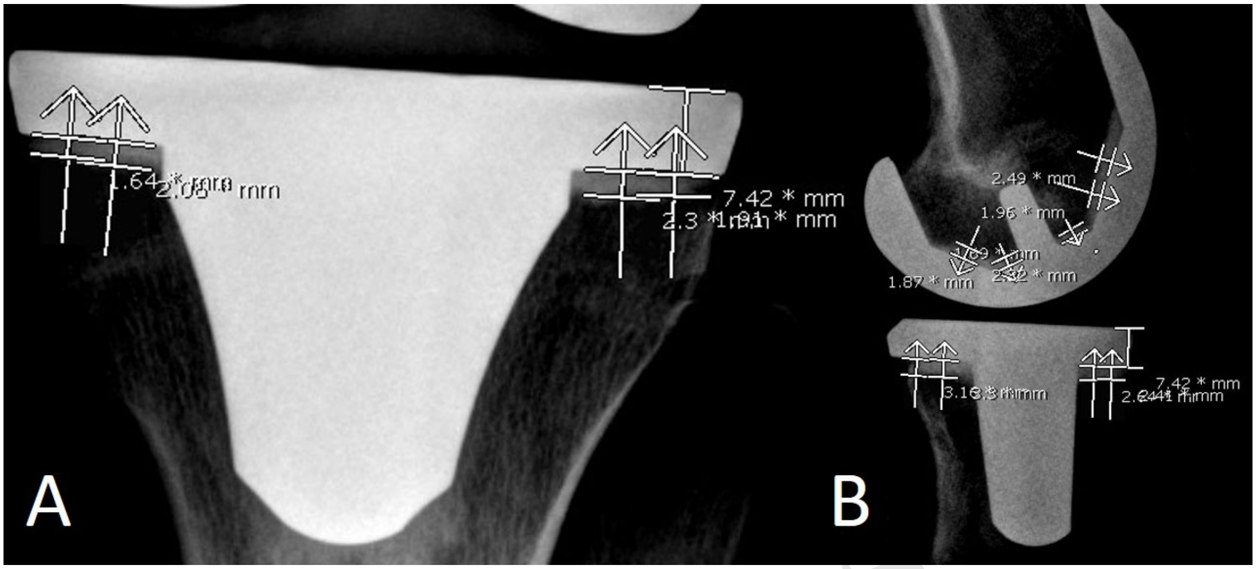
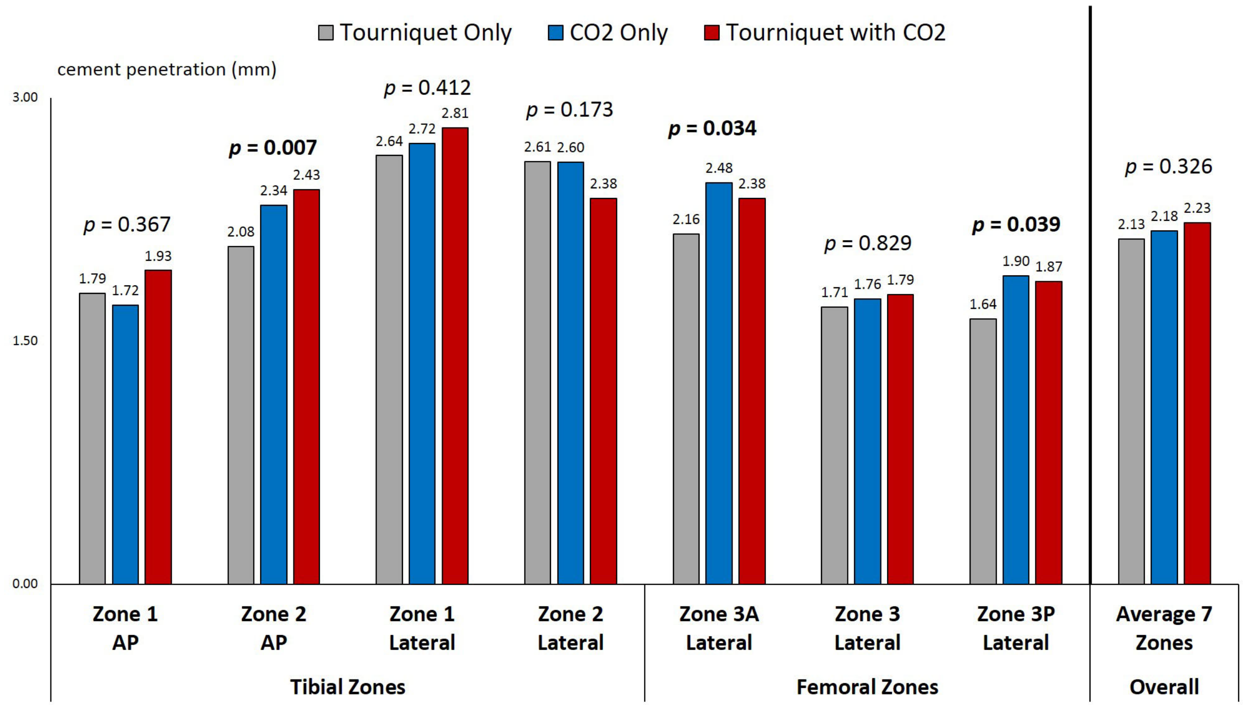
3P
2


A
B
7.42 * mm
2.49 * mm
1.96 * mm
1.87 * mm
7.42 * mm


Tourniquet Only
CO2 Only
Tourniquet with CO2
cement penetration (mm)
3.00
1.50
0.00
p = 0.367
p = 0.007
p = 0.412
p = 0.173
p = 0.034
p = 0.829
p = 0.039
p = 0.326
1.79 1.72 1.93
2.08 2.34 2.43
2.64 2.72 2.81
2.61 2.60 2.38
2.16 2.48 2.38
1.71 1.76 1.79
1.64 1.90 1.87
2.13 2.18 2.23
Zone 1 AP
Zone 2 AP
Zone 1 Lateral
Zone 2 Lateral
Zone 3A Lateral
Zone 3 Lateral
Zone 3P Lateral
Average 7 Zones
Tibial Zones
Femoral Zones
Overall

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