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Does Pressurized Carbon Dioxide Lavage Improve Bone Cleaning in Cemented Arthroplasty?

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Abstract: Cemented implant fixation in total joint arthroplasty has been proven to be safe and reliable with good long-term results. However, aseptic loosening is one of the main reasons for revision, potentially caused by poor cementation with low penetration depth in the cancellous bone. Aim of this prospective laboratory study was, to compare impact pressure and cleaning effects of pulsatile saline lavage to novel carbon dioxide lavage in a standardized carbon foam setup, to determine whether or not additional use of carbon dioxide lavage has any impact on cleaning volume or cleaning depth in cancellous bone. Carbon specimens simulating human cancellous bone were filled with industrial grease and then underwent a standardized cleaning procedure. Specimens underwent computed tomography pre- and post-cleaning. Regarding the impact pressure, isolated carbon dioxide lavage showed significant lower pressure compared to pulsatile saline lavage. Even though the combination of carbon dioxide lavage and pulsatile saline lavage had a positive cleaning effect compared to the isolated use of pulsatile saline lavage or carbon dioxide lavage, this was not significant in terms of cleaning volume or cleaning depth.

Keywords: carbon dioxide lavage; pulsatile lavage; joint arthroplasty; bone preparation; cement; total knee arthroplasty; total hip arthroplasty

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1. Introduction

Cemented implant fixation in total joint arthroplasty has demonstrated to be a reliable and safe procedure with excellent long-term results [1–4]. However, there are many regional differences if cemented or non-cemented fixation is performed. Regarding cemented fixation in total hip arthroplasty, those differences vary from 76% (Sweden) to 29% (Denmark) [5]. National registries demonstrate slight differences in the technique for total knee arthroplasty as well. In Germany, the Netherlands and New Zealand, 95% and more of total knee arthroplasties are performed using the cemented technique [6–8], whereas in Sweden it was only 92% in 2019 [9].

Despite regional differences in the choice of technique, the procedure for cemented arthroplasty is standardized. In total knee arthroplasty this includes to use high-pressure pulsatile saline lavage irrigation, drilling holes into the tibia, drying the bone and applying vacuum-mixed-cement to both, implant and bone [10]. In total hip arthroplasty third generation cementing technique is performed. This includes preparing bone bed properly by aggressive rasping, using high-pressure pulsatile saline lavage irrigation, using a distal cement restrictor, applying vacuum-mixed-cement in retrograde technique into the femur

via cement gun, pressurizing the cement and inserting the stem with a distal centralizer [11]. Despite improved technique of cementing, aseptic loosening is still the main reason for revision after cemented total knee and hip arthroplasty [6,12,13].

Implant stability can be increased by adequate cleaning of the bone bed prior to cement application. In addition, pulsatile lavage can have a protective effect on implant stability in case of reduced bone density [14]. This preparation requires removal of bone marrow containing residual bone material, blood and fat. Even the presence of blood between bone and cement can reduce integrity of bone-cement interface [15]. Bone cement interface and penetration depth of cement are directly related to prior cleaning. For stable anchorage, desired cement thickness is described as 2–5 mm [16,17]. With this cement penetration depth, implant failure rates are significantly lower compared to cement thickness below 2 mm [18]. In addition, harmful thermal effects of polymerizing cement are not observed, which are described for a cement thickness of more than 5 mm [19,20].

A reliable method for this crucial cleaning procedure of cancellous bone is using saline high-pressure pulsatile lavage and subsequent drying of bone bed with abdominal cloth and suction. However, after this procedure liquid and fatty material often remains and may prevent cement from penetrating in the desired depth into the cancellous bone. Many studies have shown, that cleaning cancellous bone using pulsatile lavage is more efficient than manual rinse cleaning by bladder syringe alone [21–25]. For the application of pulsatile lavage, different rinsing pressures are recommended in the literature depending on the area of application or tissue type, since pulsatile lavage is used to clean contaminated wounds as well. When comparing pressures of these procedures, it is important to distinguish whether the pressure specifications are "output pressure" or "impact pressure". The US Department of Health and Human Services recommends an impact pressure between 0.03 N/mm^2 (4 PSI) and 0.10 N/mm^2 (15 PSI) for cleaning wounds [26]. This recommendation is based on a number of studies that have shown a pressure of less than 0.03 N/mm^2 being inefficient in removing surface pathogens. Also, pressure of more than 0.10 N/mm^2 can potentially facilitate bacterial contamination in deeper tissue layers or cause traumatic soft tissue damage. Regarding the topic of this study, much higher pressures for cleaning cancellous bone have been reported in the literature. They reach from 0.48 N/mm^2 (70 PSI) to 0.59 N/mm^2 (85 PSI) [27,28].

A novel type of high-pressure carbon dioxide lavage, which is recommended for usage after standard saline lavage, is designed to advance cleaning and simultaneous drying of the bone [29]. A cadaveric study demonstrated that a combination of pressurized carbon dioxide and common pulsatile saline lavage produced a significantly deeper bone cement penetration than saline lavage alone [30]. Another study from 2019 showed that by using sterile compressed CO_2 in addition to the established pulsatile lavage, a significantly deeper cement penetration in three of seven defined zones (Knee Society Radiographic Evaluation System) could be achieved in 303 total knee endoprosthesis [31]. In addition bone cement interface was stronger in an experimental study using human radii [32]. However, cases of embolic events using carbon dioxide lavage in intramedullary cleaning during cemented hip arthroplasty have been reported [33,34].

Aim of this prospective laboratory study was to compare impact pressure and cleaning effects of pulsatile saline lavage to novel carbon dioxide lavage in a standardized carbon foam setup and to determine whether or not additional use of carbon dioxide lavage has any impact on cleaning volume or cleaning depth in cancellous bone.

2. Materials and Methods

First, we investigated impact pressure to the surface of two different devices. This was followed by measurements of cleaning volume and cleaning depth of the two devices and their combination in a standardized laboratory setting.

2.1. Devices and Investigated Carbon Specimens

2.1.1. Lavage and Cleaning Systems

In an in vitro study, we investigated the bone cleaning effect of carbon dioxide lavage compared to pulsatile lavage and in addition to pulsatile bone cleaning. We used the InterPulse (Stryker, Kalamazoo, MI, USA) for conventional bone cleaning with saline solution and the CarboJet (Kinamed, Camarillo, CA, USA) for carbon dioxide cleaning (Figure 1). The bone cleaning tip (REF 0210-010-00) for the InterPulse and the supplied Wide-Angle-Knee-Nozzle of the CarboJet were used for the experiments (Figure 1). To investigate the impaction pressure, the cleaning systems were divided into the InterPulse and CarboJet group. For the analysis of the cleaning effect, the two systems were investigated separately and in combination. This resulted in the groups InterPulse (A), CarboJet (B) and InterPulse + CarboJet (C).

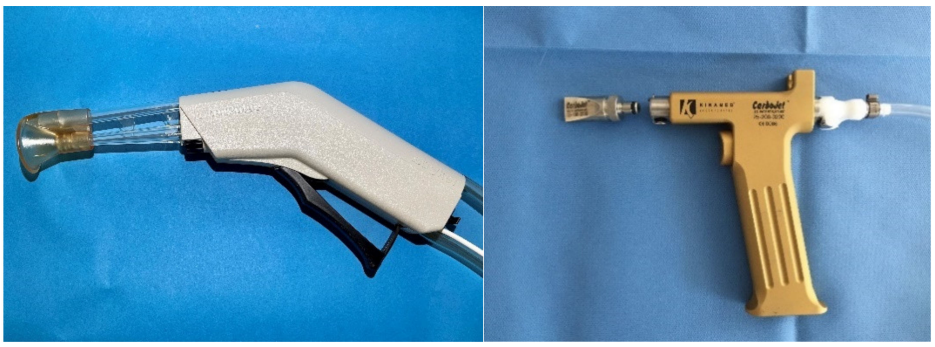


Figure 1. (**left**) Handpiece of InterPulse by Stryker. (**right**) Handpiece of CO_2 lavage CarboJet by KINAMED.

2.1.2. Determination Impact Pressure

The impact pressure of both investigated lavage systems was determined under standardized condition. Therefore, we used a custom-made setup with mounting platform for the lavage systems and a target with integrated force measuring plate (Figure 2). Each lavage system was firmly fixed on the movable mounting platform. This was necessary to place the tip with splash shield for the InterPulse and the nozzle for the CarboJet at a defined distance of 2 mm in front of the force measuring plate (Figure 2). A distance of 2 mm was maintained to avoid interference between the force plate and the tip due to the flushing liquid or carbon dioxide. The flushing medium was applied centrally onto the force plate. The distance of the tip of the saline lavage device to the force measuring plate was specified by the splash shield (Figure 1, left). For the InterPulse this was 17 mm (15 + 2 mm) and in case of the CarboJet, the distance was 2 mm because there was no splash shield.



Figure 2. Force measuring plate with 2 mm distance to the CO_2 nozzle.

The impact pressure was calculated by dividing the force and the area of the nozzle orifice (Figure 3). The nozzle openings of the two lavage systems investigated were

measured using a calibrated digital microscope (Digital Microscope VHX-500 by Keyence, Osaka, Japan). Both lavage systems were tested four times within the first minute of powering up. The force values were recorded at a sampling rate of 1000 Hz and the mean values were calculated.

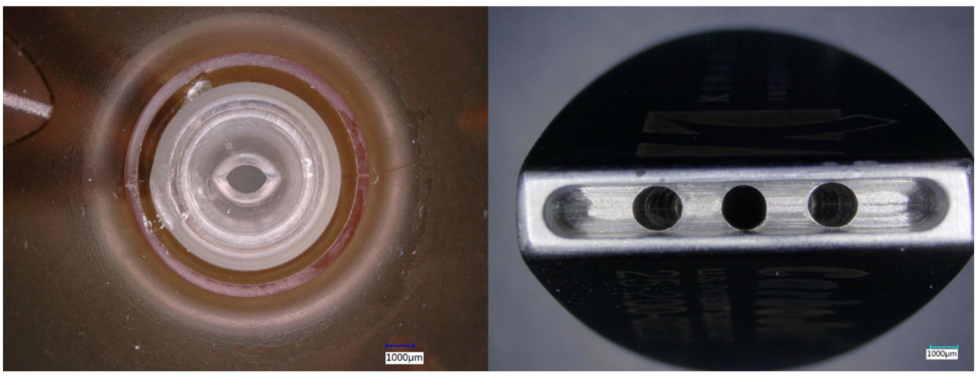


Figure 3. Top view of: (**left**) Stryker- InterPuls bone cleaning tip, (**right**) KINAMED—CarboJet Wide-Angle Knee—Nozzle.

2.1.3. Determination of the Cleaning Effect

The two lavage systems were divided into group InterPulse (A), CarboJet (B) and InterPulse + CarboJet (C) as described. A sample size of 10 specimens per group (30 in total) were used. In case of the InterPulse a saline irrigation volume of one liter per specimen was used. The cleaning distance was determined by the splash shield. Following the manufacturer's specifications, a cleaning duration of 30 s was used for the CarboJet.

The determination of the cleaning effect of the investigated lavage systems were performed using validated and standardized carbon foam specimens (RVC foam; ERG Materials and Aerospace, Oakland, CA, USA) as substitutes for human cancellous bone [35]. The carbon specimens showed a porosity of 30 PPI (pores per inch), which corresponds to 1.2 PPM (pores per millimeter). During the manufacturing process, the specimens were compressed twice, resulting in similar trabecular bone structure (Figure 4, right). The carbon foam specimens were filled with standardized technical fat (Bechem Rhus FA 37; Carl Bechem GmbH, Hagen, Germany), to simulate human bone marrow [36]. One ingredient of the fat was an aluminum-complex soap which we used as contrast medium for the radiological analysis. The fat-filled carbon specimens were coated with a shrink-on tube simulating the cortex (Figure 4, left).



Figure 4. (**Left**) Fat filled carbon specimen with shrink tube, (**right**) close up of Carbon foam.

The evaluation of cleaning effects was determined by using computer tomography scans (SOMATOM Emotion, Siemens Healthcare GmbH, Erlangen, Germany). For this

purpose, the fat-filled specimens were scanned before and after cleaning with a slice thickness of 0.75 mm. For volume determination, a reference volume was recorded for each scan. The segmentation and calculation of the cleaning volume was performed with the software itk-Snap [37]. The mean flushing depth was calculated using the volume and the geometric parameters. Exclusion criteria were air inclusions or if specimens would not have been fully filled with fat. One specimen in Group A had to be excluded due to air inclusions that would have biased the cleaning effect. Therefore, only 9 out of 10 samples could be analyzed for Group A. Beyond that, no other specimens had to be excluded.

2.2. Statistics

Using SPSS V.25 (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp., Armonk, NY, USA) a descriptively data analysis was performed. A Shapiro- Wilk test was used to test for normal distribution. A *t*-test was done to detect significances in impact pressure. Analysis of variance (ANOVA) was used to determine if there are significant differences regarding cleaning effects. $p < 0.05$ was set to be the significance level.

3. Results

3.1. Impact Pressure

The *t*-test revealed a statistically significant difference for the impact pressure between the InterPulse 0.76 ± 0.02 N/mm^2 and CarboJet 0.12 ± 0.01 N/mm^2 group, t(3.4) = 59.0, $p < 0.001$, (95% CI [0.61–0.68]). Whereas this was a mean difference increase of 0.64 N/mm^2 for the InterPulse system (Figure 5).

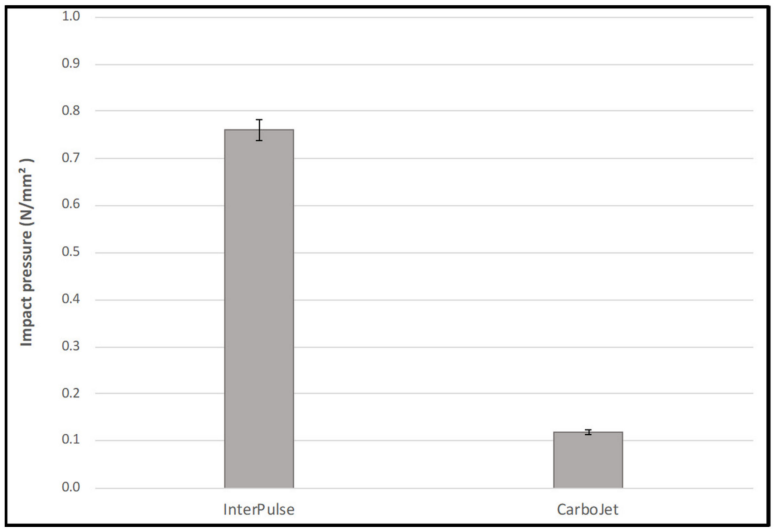


Figure 5. Impact pressure in N/mm^2.

3.2. Cleaning Effect

The ANOVA-test comparing cleaning volumes showed no statistically significant difference between the InterPulse, CarboJet and the combination of both, F(2,26) = 1.14, $p = 0.334$ (Table 1, Figure 6). Cleaning depth showed also no significant differences between the investigated groups, F(2,26) = 1.07, $p = 0.259$ (Table 1, Figure 7).

Table 1. Mean cleaning volume and cleaning depth in carbon foam specimens.

	Mean Cleaning Volume	Mean Cleaning Depth
InterPulse	2832.1 ± 1236.6 mm^3	2.1 ± 0.9 mm
CarboJet	2755.4 ± 906.3 mm^3	2.1 ± 0.7 mm
InterPulse + CarboJet	3428.4 ± 1100.0 mm^3	2.6 ± 0.8 mm

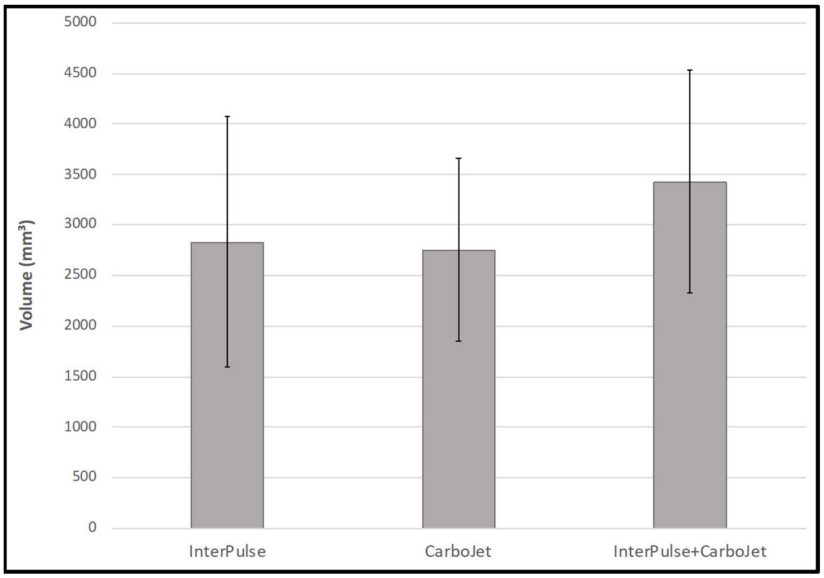


Figure 6. Volume of removed grease in standardized carbon foam specimens.

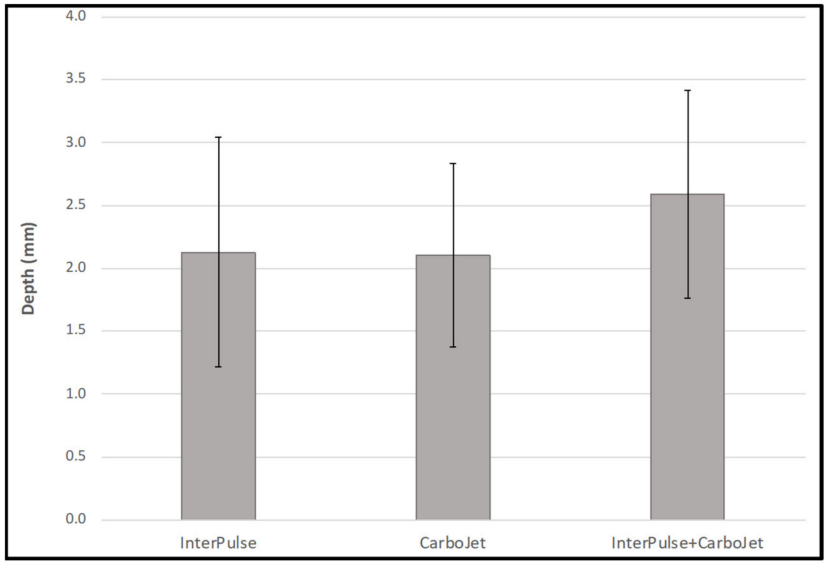


Figure 7. Cleaning depth in mm in standardized carbon foam specimens.

4. Discussion

The use of pulsatile lavage is known to enhance the fixation of cemented total knee arthroplasty [38]. Highly significant improvements of cement penetration into cancellous bone can be demonstrated in vitro comparing manual rinsing and pulsed saline lavage [25]. In addition, cleaning of cancellous bone leads to improved cement penetration and therefore to a stronger bone cement interface, which reduces the probability of aseptic loosening [18,39]. However, aseptic loosening is the main reason for revision in cemented total knee and hip arthroplasty [12,13]. Modern cementing technique requires pulsed saline lavage, drying bone by abdominal cloth and suction, drilling holes in the tibia and applying vacuum-mixed-cement either on both, metal and bone in total knee arthroplasty, or filling the femur in retrograde technique using a cement gun in total hip arthroplasty. Considering this, many factors besides the cancellous bone cleaning result can affect cementation. Bone density or sclerotic bone also can cause reasonable differences [40]. Cement storage temperature, humidity, cement viscosity or timing of cement application are other aspects that have to be considered [41,42].

In our experimental in vitro study, we compared a standard high-pressure pulsatile saline lavage to a novel lavage system using compressed carbon dioxide to enhance cleaning efficiency of cancellous bone under standardized conditions. Cancellous bone was simulated by standardized fat-filled carbon foam. In this experimental setup, impact pressure was applied to a force-measuring-plate. We detected significantly higher pressures in pulsatile saline lavage (InterPulse) than in pressurized carbon dioxide lavage (CarboJet). Although we showed higher cleaning volume and deeper penetration in carbon foam, when using carbon dioxide lavage additionally to high-pressure pulsatile saline lavage (Group C) these differences were not significant. Similar results were obtained for the single use of carbon dioxide lavage (Group B) in comparison to the single use of pulsatile saline lavage (Group A) (Figures 6 and 7).

So far, there is only limited data available about carbon dioxide lavage. A cadaveric study in 10 knees in 2016 demonstrated that a combination of pressurized carbon dioxide and common pulsatile saline lavage produced a significantly deeper bone cement penetration than saline lavage alone [30]. In addition, another study demonstrated that bone cement interface was stronger [32]. In 2019, Gapinski et al. revealed that using sterile compressed carbon dioxide in addition to the established pulsatile jet lavage, resulted in a deeper cement penetration in six of seven defined zones (Knee Society Radiographic Evaluation System) in 303 total knee endoprostheses. This difference was significant in three out of seven zones [31].

In this standardized laboratory setup, which was established in earlier studies [35,36], no significant difference between the three experimental groups was detected although higher cleaning volumes and cleaning depth using additional carbon dioxide lavage (Group C) was discovered. In this study the aspect of preparing bone bed prior to cementation was investigated. Other aspects such as pressure during cementing, viscosity of cement, remaining blood or fat in the interface or the timing of cement-application were excluded from the investigations. With this test setup, the ability of carbon dioxide lavage to clean cancellous bone was examined closely. Whether or not the slightly enhanced cleaning ability will result in deeper cement penetration remains uncertain. The use of additional carbon dioxide lavage needs extra devices, sterilization and carbon dioxide gas cylinders, which need adequate storage and the exact following of safety instructions. Moreover, the additional time needed for the procedure extends duration of operation and time of anesthesia. Since we saw similar results for single use carbon dioxide lavage (Group B) compared to single use of pulsatile lavage (Group A) it has to be considered, that using carbon dioxide lavage only, might be faster, less wet and more controlled to saline lavage. Studies showed that using high-pressure lavage to clean contaminated wounds can cause irreversible insult to tissue, resulting in myonecrosis and dystrophic calcification [43,44]. Even bacteria can be propagated into soft tissue or significant damage to the architecture of the bone can occur [45,46]. Therefore, lower impact pressure as shown in our investigation can hold advantages. Despite these potential advantages case reports are published showing gas embolisms occurred during femoral intramedullary usage of carbon dioxide lavage [33,34]. Further investigation focusing on in vivo impact can help revealing, if a specific range of pressure orchestrates all benefits while avoiding complications.

In this experimental in vitro study where we compared high-pressure saline lavage to carbon dioxide lavage and its combination, we detected significant lower impact pressure and a deeper cleaning effect with carbon dioxide lavage used additionally to high-pressure pulsatile saline lavage in standardized carbon foam specimens representing cancellous bone. However, these effects were statistically not significant. We found no evidence that using carbon dioxide lavage reduces the effect of saline lavage. Using carbon dioxide lavage only had similar outcomes compared to high-pressure pulsatile lavage. Since aseptic loosening still is the main reason for implant failure due to poor cementing, better cleaning of cancellous bone prior to cementing will have a positive effect on implant durability. In conclusion, using a combination of high-pressure saline lavage followed by carbon

dioxide lavage showed a clear tendency of resulting in improved cleaning effects prior to cementing and therefore seems to have a positive effect on stability of endoprosthesis. Further investigation in human bone and larger clinical trials will determine, if using additional carbon dioxide lavage will confirm its positive effect on bone cement interface and therefore on success of endoprosthesis implantation itself.

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