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Citation (APA)

Brouwer, A. J., Hesseling, B., Verburg, H., Goossens, R. H. M., & Mathijssen, N. M. C. (2026). Cement compression device for cemented total knee arthroplasty a randomized controlled trial. *Bone and Joint Open*, 7(7), 944-951. <https://doi.org/10.1302/2633-1462.77.BJO-2025-0242.R2>

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Cement compression device for cemented total knee arthroplasty

a randomized controlled trial

From Reinier Haga Orthopaedic Centre, Zoetermeer, Netherlands

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Cite this article:
Bone Jt Open 2026;7(7):944–951.

DOI: 10.1302/2633-1462.77.BJO-2025-0242.R2

Aims

Optimal fixation of the tibial component is crucial to prevent aseptic loosening in total knee arthroplasty (TKA). This involves cement penetrating the tibia by 3 mm to 4 mm. Cement application is not standardized, and ideal penetration depth is not achieved frequently. Therefore, a cement compression device (CCD) was developed. The CCD is positioned around the tibial component, prevents cement leakage, and compresses cement into the tibia. It is hypothesized that the CCD enhances cement penetration and distribution in TKA.

Methods

Patients were randomized into two groups: cement application using the finger-packing technique or the CCD. A CT scan was performed postoperatively to determine the percentage of cemented surface (PCS) per quadrant in the proximal tibia, up to 7 mm from the tibial baseplate. Differentiation between bone, cement, and prosthesis on the CT scans was performed using a previously validated method in MATLAB, based on differences in Hounsfield units. PCS was compared per quadrant for the mean of 3 mm and 4 mm depth slices and for each millimetre up to 7 mm depth. Additionally, operating time was compared.

Results

In 16 patients, the finger-packing technique was used and in 16 patients, the CCD. In the anterolateral and posterolateral quadrants, PCS was 54% in the finger-packing group versus 72% in the CCD group (95% CI –28.85 to –8.17; $p < 0.001$), and 34% versus 46% (95% CI –22.78 to –2.05; $p = 0.025$), respectively. In the posteromedial quadrant, PCS was 28% versus 39% (95% CI –22.39 to –0.15; $p = 0.047$). In the anteromedial quadrant, PCS was higher in the CCD group, but the difference was not significant. Operating time was 66 minutes in the finger-packing group, compared with 68 minutes in the CCD group (95% CI –8.0 to 3.4; $p = 0.416$).

Conclusion

The CCD results in improved cement penetration and distribution in TKA at the mean of 3 mm to 4 mm and reaching up to 7 mm depth from the tibial baseplate. Implementing the CCD does not prolong the procedure.

Take home message

- Optimal fixation of the tibial component in total knee arthroplasty (TKA) is essential to prevent aseptic loosening.
- However, optimal cementing is not achieved frequently in clinical practice.
- The cement compression device was developed to optimize cement penetration and distribution in TKA.
- Our results show a statistically significant increase in cement penetration and distribution when using the cement compression device in TKA compared with the finger-packing technique.

Introduction

Total knee arthroplasty (TKA) is a commonly performed procedure with a high success rate.¹ Nevertheless, complications can significantly impact the longevity of the implant. For example, aseptic loosening of the tibial component is a common indication for revision surgery.²⁻⁴ Therefore, optimal fixation of this component is essential for the long-term success of the implant.⁵

In most TKAs, bone cement is used for fixation of the tibial component.^{6,7} Literature indicates an association between cement penetration depth and radiolucent lines, which can lead to aseptic loosening in TKA.⁸ The recommended depth of cement penetration is 3 to 4 mm, and it has been suggested that a lower cement mantle thickness of the tibial component could be associated with aseptic loosening in TKA.^{8,9}

However, bone cement application is not standardized, and a variety of techniques are used, including a spatula, syringe, finger packing, or a cement gun.¹⁰ Among these methods, a cement gun and finger packing have demonstrated the highest cement penetration.¹⁰⁻¹³ However, due to the lack of consensus on cement volume, various application techniques, surgeons' preferences, and cement leakage, the ideal penetration depth may not always be achieved.⁵ To optimize penetration and distribution of cement in the proximal tibia, a cement compression device (CCD) was developed (Figure 1). The CCD fits closely around the tibial component and has a 5-mm ridge, creating a cement pocket. The ridge also prevents cement leakage during placement of the tibial component. Because of the added pressure and prevention of cement leakage, it is hypothesized that the CCD enhances cement penetration and distribution compared to common practice (e.g. finger packing). The CCD showed promising results in a study on human specimens (unpublished data at the time of writing).

In this study, we compared the CCD with the finger-packing technique regarding cement penetration and distribution in the proximal tibia, expressed as the percentage of cemented surface (PCS) for each individual quadrant. The primary aim was to determine whether the CCD was superior to finger packing in terms of PCS at 3 mm to 4 mm depth from the tibial baseplate. The secondary aim was to assess whether the CCD was superior to finger packing in terms of PCS up to 7 mm from the tibial baseplate. Finally, the objective was to determine whether the operating time was comparable with finger packing when using the CCD.

Methods

This study received approval from the Medical Ethics Committee (METC Leiden, The Hague, Delft, Netherlands, METC-number Z19.035, NL70830.098.19). The study is registered in the Dutch OMON trial registry under the number NL8109.¹⁴ All participating patients provided written informed consent.

Development of the CCD

After identifying variations in cementing techniques and the resulting concerns regarding cement penetration depth in TKA, the CCD was developed in collaboration with the Department of Industrial Design Engineering at Delft University of Technology, Netherlands. The CCD is a

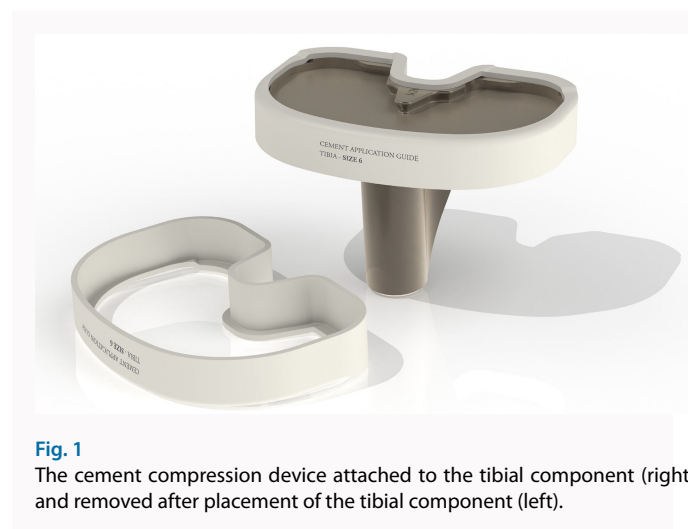


Fig. 1

The cement compression device attached to the tibial component (right) and removed after placement of the tibial component (left).

simple-to-use device designed to enhance cement application, distribution, and penetration into the proximal tibia by compression, while minimizing cement spillage outside the boundaries of the tibial baseplate. It was developed in accordance with medical device regulation regulations for in-house development, manufacturing, and use. The CCD is a non-commercial and nonindustrial product. Implant manufacturers were not involved in its development. The full background and development are detailed in the Supplementary material.

Screening and inclusion

Patients were initially included from the outpatient clinic of the Reinier de Graaf Hospital (Delft, Netherlands). During the course of this study, a new orthopaedic centre was opened, the Reinier Haga Orthopaedic Centre (RHOC; Zoetermeer, Netherlands). The entire orthopaedic department of the Reinier de Graaf Hospital was relocated to the RHOC, from which inclusion continued. All consecutive patients with an indication for primary TKA due to noninflammatory degenerative joint disease or traumatic arthritis were eligible for inclusion. Potential participants had to be aged over 18 years, able to consent to study participation, and comply with the study protocol. Patients with comorbidities that could impair bone metabolism, such as osteomalacia and Charcot's arthropathy, were excluded. Patients with insufficient bone stock, neurological disorders, and previous knee surgery, apart from arthroscopy, were also excluded.

The CCD was developed for the NexGen Legacy (Zimmer Biomet, USA) tibia component sizes 4, 5, and 6, as these were the most commonly used implants during this study. However, the definitive size of the prosthesis could not be determined preoperatively. Therefore, eligible patients were asked for informed consent prior to surgery. In cases where the tibial component size was confirmed as size 4, 5, or 6, a surgical assistant performed randomization during the procedure for patients who had given informed consent. Patients were excluded if a different size was required. Included patients were randomly allocated to one of two study groups using variable block randomization. Block sizes were 4, 6, and 8, stratified per hospital using Castor EDC. As the surgeon had to apply cement using the finger-packing

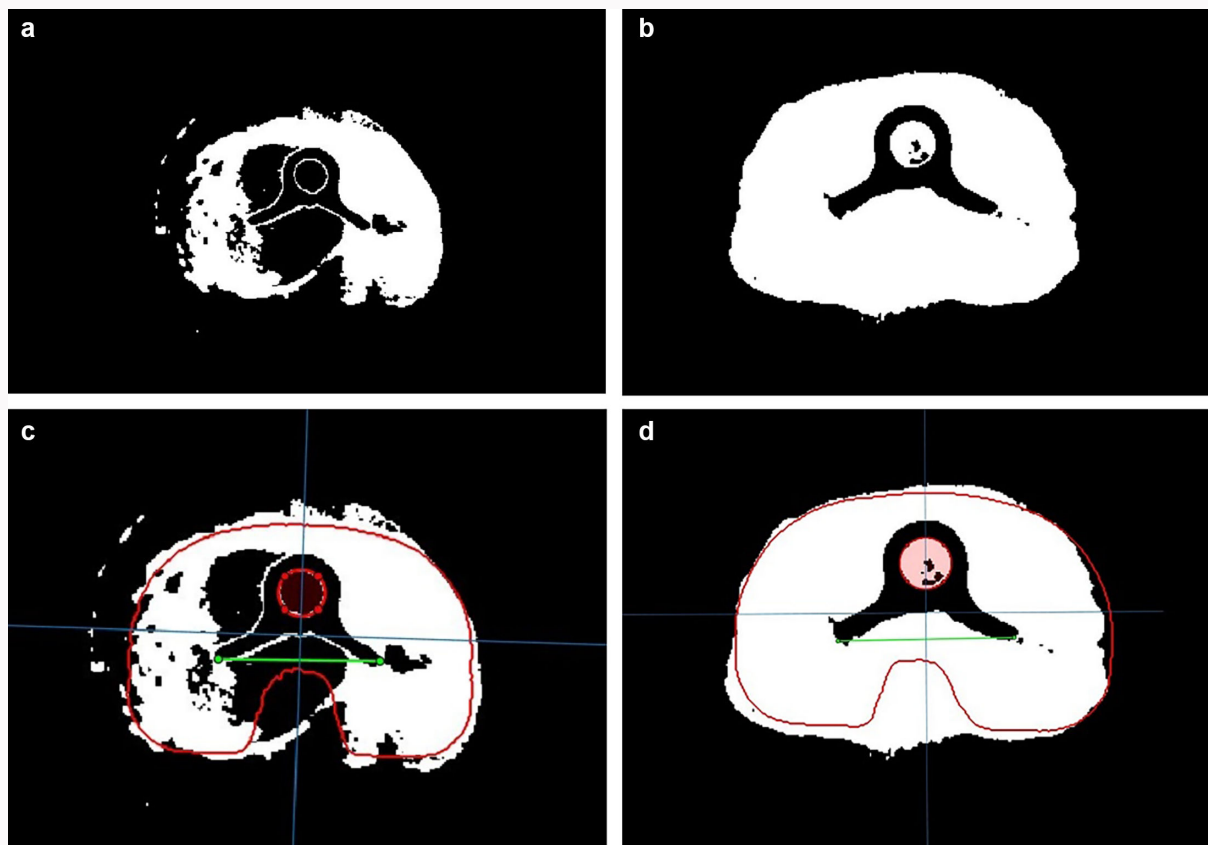


Fig. 2

Each scan was uploaded in MATLAB (a and b) and divided into four quadrants (c and d). Subsequently, the percentage of the cemented surface was calculated from the differences in Hounsfield units among bone, cement, and prosthesis. In a and c, a scan of a proximal tibia, cemented with the finger-packing technique is shown. In b and d, a scan of a proximal tibia, cemented with the cement compression device is shown.

technique or the CCD, the surgeon could not be blinded. The participating patients, the research coordinator, and the executive researcher remained blinded until the final analyses were completed.

Surgery

All procedures were performed by the same fellowship-trained and experienced knee surgeon (HV). The procedures were carried out without a tourniquet. The aim was to restore mechanical alignment with a hip-knee-ankle angle of 180°. Once bone removal was completed, the bone surfaces were prepared using pulsatile lavage and suction, followed by drying the surface with sterile gauze. All tibial components were cemented with high-viscosity PALACOS gentamicin bone cement (Heraeus Medical, Germany), using the surface cementing technique. In the control group, the finger-packing technique was applied, using the layered technique. In the intervention group, cement was applied using the CCD. During the procedure, the CCD is attached to the tibial component, as illustrated in [Figure 1](#). It fits closely around the tibial component and features a 5 mm ridge, creating a cement pocket. The tibial component, enclosed by the CCD, is then turned over to allow controlled application of cement to its undersurface within the cement pocket. Cement is applied until the pocket is fully filled, ensuring a consistent cement volume across procedures. Subsequently, the tibial component with the CCD is positioned on the prepared tibial surface and

is implanted by hammering on the introducer, similar to standard procedure. As the tibial tray slides along the inner surface of the CCD, cement is evenly pressurized into the cancellous bone of the proximal tibia. Simultaneously, the ridge of the CCD prevents cement leakage. Since the CCD prevents cement leakage and pressurizes cement into the proximal tibia, cement was not applied to the tibial surface in the CCD group, in line with the non-layered technique. After implantation, the CCD can be easily removed without disturbing the tibial component's position. Except for the use of the CCD, all other procedural steps were identical in both study groups. Local infiltration anaesthesia containing ropivacaine and epinephrine solution was administered intermittently, three times throughout each procedure.

Follow-up and data collection

In conformity with usual care, patients were assessed at outpatient clinics at two and six weeks postoperatively. For research purposes, each patient underwent a CT scan three months after surgery. Based on the Hounsfield unit differences between bone, cement, and the prosthesis, the percentage of cement in each CT slice was calculated. This was expressed as the PCS. Following a standardized protocol, the tibial component was divided into four quadrants (anteromedial (AM), anterolateral (AL), posteromedial (PM), and posterolateral (PL)), as shown in [Figures 2c and 2d](#). For each quadrant, PCS was determined in 1 mm increments up to a depth of

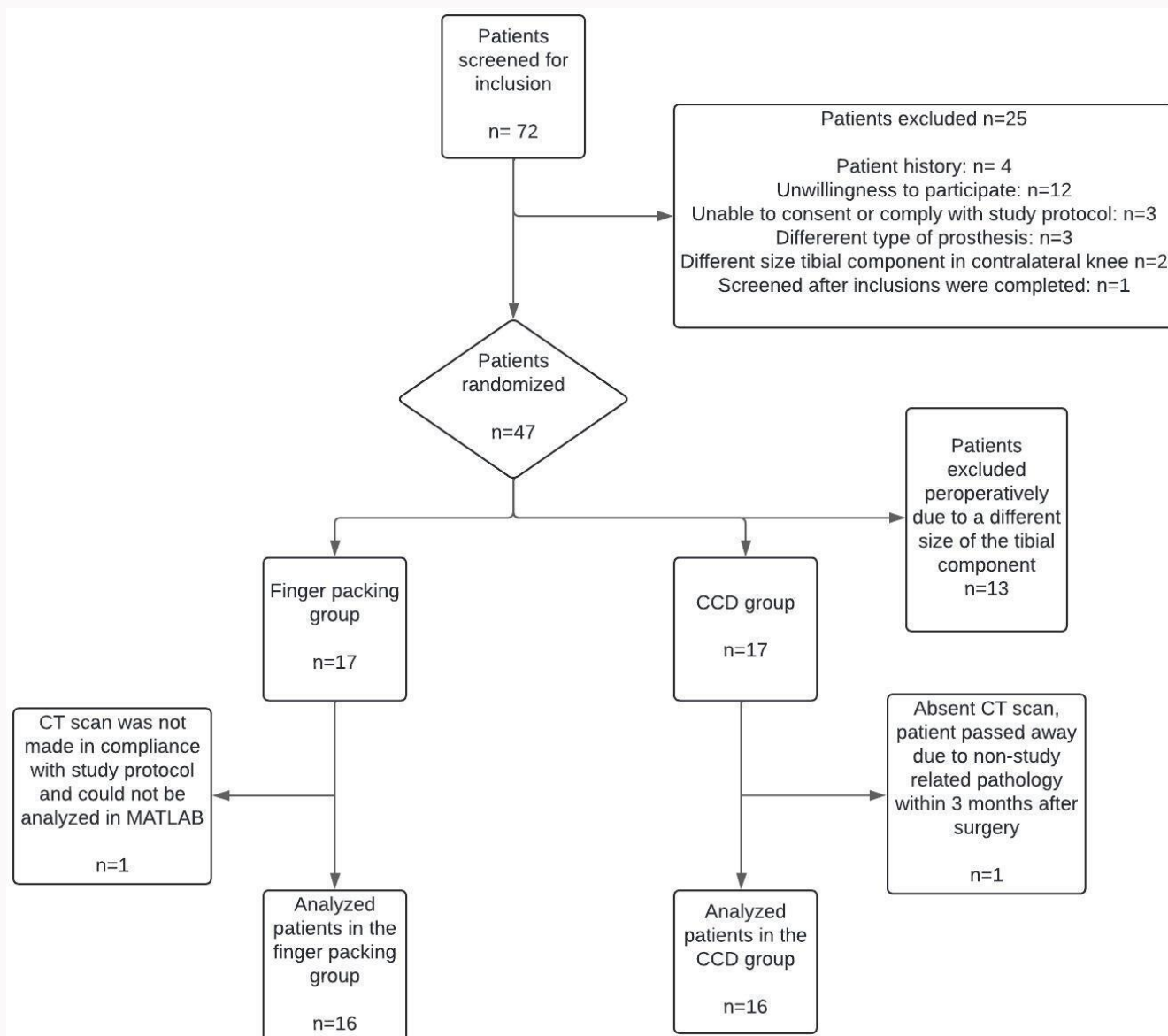


Fig. 3
Flowchart displaying the process of patient selection.

7 mm from the tibial baseplate. Calculating PCS based on Hounsfield units in MATLAB is a previously validated method.¹⁵

Outcomes

Demographic data and treatment characteristics were assessed. As literature indicates that optimal fixation of the tibial component requires penetration of cement at a depth of 3 to 4 mm⁸, the primary endpoint was the mean PCS at 3 mm to 4 mm depth from the tibial component. The PCS per quadrant at 3 mm to 4 mm was calculated by averaging the PCS from the 3 mm and 4 mm slices. Secondary endpoints were PCS per quadrant at 1 mm to 7 mm depth, operating time, and clinical limb alignment at six weeks postoperatively. Operating time was measured from skin incision to wound closure.

Statistical analysis

The sample size was determined based on a study on human specimens (unpublished data at the time of writing), with PCS at 3 mm to 4 mm depth of 12.6% (SD 7.6%) in the finger-packing group and 24.5% (SD 10.5%) in the CCD group. Using a power of 90% and an α of 0.05, the required sample size was 15 patients per group. To account for a potential 10% dropout rate, the final sample size needed was 34. Demographics and operative details were presented as numbers and percentages, with means and SD or medians and ranges, depending on the data distribution. Differences in PCS at 3 mm to 4 mm depth, PCS from 1 mm to 7 mm depth, and operating time were analyzed using unpaired *t*-tests or Mann-Whitney U tests, depending on the data distribution.

As PCS was determined per quadrant, four unpaired *t*-tests were conducted. Given that the primary aim of this study was to evaluate whether the CCD achieves superior cement penetration and distribution compared with finger

Table I. Baseline characteristics and demographic data.

Variable	Finger-packing group (n = 16)	CCD group (n = 16)
Sex, n (%)		
Female	11 (69)	11 (69)
Male	5 (31)	5 (31)
Mean age, yrs (SD)	71 (8.2)	77 (8.0)
Mean BMI, kg/m ² (SD)	30.9 (6.7)	31.2 (4.9)
Diagnosis, n (%)		
Osteoarthritis	16 (100)	16 (100)
KLclassification, n (%)		
Grade 0 to 2	0 (0)	0 (0)
Grade 3	9 (56)	5 (31)
Grade 4	7 (44)	11 (69)
Preoperative alignment, (n%)*		
Neutral	9 (56)	7 (44)
Varus	4 (25)	8 (50)
Valgus	3 (19)	1 (6)
Operated side, n (%)		
Left	10 (63)	7 (44)
Right	6 (37%)	9 (56)
ASA score, n (%)		
1	1 (6)	1 (6)
2	9 (56)	10 (63)
3	6 (38)	5 (31)
4	0 (0)	0 (0)
Previous arthroscopies of the lower limb, n (%)	13 (81)	12 (75)
Anticoagulant use, n (%)	2 (13)	5 (31)
Complications, n (%)	0 (0)	0 (0)

*Limb alignment was assessed clinically, in conformity with the Knee Society Score.¹⁹ A neutral alignment was defined as an alignment between 2 to 10° valgus, varus alignment as < 2° valgus, and valgus alignment as > 10° valgus.
ASA, American Society of Anesthesiologists; CCD, cement compression device; KL, Kellgren-Lawrence.

packing, even a difference in a single quadrant was deemed relevant. Based on this individual testing principle, corrections for multiple testing were not necessary.¹⁶ Statistical significance for PCS was subsequently defined as a p-value < 0.05.

Results

Included patients and baseline characteristics

A total of 34 patients were included in this study and 32 were included in the final analysis, as is illustrated in Figure 3. One patient passed away due to non-study-related pathology before the CT scan was made, and one CT scan was not adequately performed, which made analyzing this scan in MATLAB impossible. Therefore, each study group consisted of 16 patients. The majority of included patients were female (69%, n = 22). The mean age was 71 years (SD 8.2) in the finger-packing group and 77 years (SD 8.0) in the CCD group. All patients underwent a TKA because of grade

Table II. Percentage of cemented surface per quadrant at 3 mm to 4 mm depth from the tibial baseplate.

Quadrant	Finger-packing group, %	CCD group, %	p-value	95% CI
AM	39.41	44.63	0.300	-15.31 to 4.88
AL	53.60	72.11	< 0.001	-28.85 to -8.17
PM	27.85	39.12	0.047	-22.39 to -0.15
PL	33.77	46.19	0.025	-22.78 to -2.05

AL, anterolateral; AM, anteromedial; CCD, cement compression device; PL, posterolateral; PM, posteromedial.

3 or 4 osteoarthritis (OA) according to the Kellgren-Lawrence (KL) classification^{17,18} At baseline, limb alignment was assessed during the outpatient clinic visit, in conformity with the Knee Society Score.¹⁹ A total of 56% of patients (n = 9) in the finger-packing group had a neutral limb alignment, defined as a limb alignment between 2 to 10° valgus. In the CCD group, 44% of patients had a neutral limb alignment (n = 7). There were no complications or adverse events during the three-month follow-up period (Table I).

The primary endpoint, the mean PCS of the 3 mm and 4 mm depth slices from the tibial baseplate, was calculated for each quadrant and shown in Table II. In each quadrant, PCS was higher in the CCD group compared with the finger-packing group. In the AL, PM, and PL quadrants, the difference was statistically significant (Table II).

Secondary endpoints: the mean operating time was 66 minutes in the finger-packing group, compared with 68 minutes in the CCD group (95% CI -8.0 to 3.4; p = 0.416). PCS at 1 mm to 7 mm depth from the tibial baseplate is displayed in Table III. PCS was significantly higher in the CCD group than in the finger-packing group in the AL quadrant at 3 mm to 6 mm; in the PM at 2 mm, 4 mm, 6 mm, and 7 mm; and in the PL at 2 mm to 7 mm depth from the tibial baseplate. All patients achieved neutral limb alignment (2° to 10° valgus), except for one patient who exhibited a clinical valgus alignment exceeding 10°.

Discussion

In conclusion, this study shows that implementing a CCD in TKA is superior to finger packing, considering the PCS at 3 mm to 4-mm depth from the tibial baseplate. Implementing the CCD does not increase the operating time in TKA.

Baseline characteristics and differences between quadrants
When comparing baseline characteristics, it is notable that OA severity is higher in the CCD group. Overall, 44% of patients (n = 7) in the finger-packing group have grade 4 OA in the KL classification, compared with 69% (n = 11) in the CCD group. The KL classification assesses joint space narrowing, osteophytes, subchondral sclerosis, and deformity of bone ends.¹⁸ Subchondral sclerosis, characterized by increased bone mass with fewer but thicker trabeculae,²⁰ may interfere with cement penetration and distribution. Despite higher OA severity, the CCD group showed higher PCS than the finger-packing group. An even greater difference might have been observed if OA severity had been comparable. However, further research is

Table III. Percentage of cemented surface per quadrant at 1 mm to 7 mm depth from the tibial baseplate.

Quadrant	Depth, mm	PCS, %		Difference scores PCS*	p-value	95% CI
		Finger packing	CCD			
AM	1	84.98	88.83	3.85	0.431	-13.57 to 5.88
	2	77.17	78.52%	1.35	0.789	-11.50 to 8.79
	3	51.55	55.73	4.18	0.431	-14.87 to 6.51
	4	27.27	33.79	6.52	0.206	-16.74 to 3.71
	5	14.96	20.56	5.60	0.143	-13.24 to 2.02
	6	9.67	12.67	3.00	0.210	-7.72 to 1.72
	7	6.71	9.74	3.03	0.103	-6.71 to 0.64
AL	1	84.00	85.91	1.91	0.731	-13.21 to 9.39
	2	85.26	89.76	4.50	0.212	-11.66 to 2.67
	3	66.01	81.39	15.38	0.003	-25.26 to -5.51
	4	41.19	63.99	22.80	< 0.001	-34.62 to -10.99
	5	23.83	40.91	17.08	0.009	-29.36 to -4.81
	6	15.29	24.92	9.63	0.016	-17.29 to -1.96
	7	10.42	15.66	5.24	0.055	-10.59 to 0.11
PM	1	86.67	86.82	0.15	0.972	-8.82 to 8.51
	2	64.12	76.10	11.98	0.050	-23.95 to -0.01
	3	36.72	50.21	13.49	0.060	-27.64 to 0.65
	4	18.98	28.42	9.44	0.035	-18.20 to -0.70
	5	12.92	18.64	5.72	0.084	-12.25 to 0.82
	6	8.97	13.80	4.83	0.025	-9.01 to -0.65
	7	6.45	11.84	5.39	0.004	-8.89 to -1.87
PL	1	78.80	85.29	6.49	0.171	-15.96 to 2.99
	2	63.00	75.78	12.78	0.031	-24.24 to -1.31
	3	41.75	55.68	13.93	0.027	-25.97 to -1.88
	4	25.79	37.68	11.89	0.016	-21.25 to -2.53)
	5	17.46	25.67	8.21	0.013	-14.47 to -1.94
	6	13.28	19.48	6.20	0.010	-10.54 to -1.87
	7	9.86	15.35	5.49	0.009	-9.54 to -1.46

*The difference score was calculated as the %PCS of the CCD group, minus the %PCS of the finger packing group.

AL, anterolateral; AM, anteromedial; CCD, cement compression device; PCS, percentage of cemented surface; PL, posterolateral; PM, posteromedial.

necessary to determine the definitive impact of OA severity on cement distribution and penetration in TKA.

The percentage of patients using anticoagulants was higher in the CCD group (31%, $n = 5$) compared with the finger-packing group (13%, $n = 2$). Additional blood loss can complicate cement application, which could result in lower PCS in the CCD group. Still, results show higher PCS in the CCD group, which may be partly due to meticulous cleaning and drying of the bone surfaces prior to cementing in both groups, as is recommended in literature.^{12,21} In addition, the ridge of the CCD prevents blood and other debris particles from re-entering the site of cementing, allowing faster and easier cementing compared with the finger-packing technique, where blood and debris are mostly manually removed

from the cementing site.¹² Therefore, as a result of the CCD design, it is expected that anticoagulant use did not negatively affect the quality of cementing in this study.

Other patient-related factors, such as BMI, diabetes, osteoporosis, rheumatoid arthritis, and inflammatory bowel disease (IBD), may influence cement quality and aseptic loosening rates in TKA.²² In this study, BMI was comparable across groups, and patients with conditions affecting bone metabolism were ineligible. Although diabetes and IBD histories were not recorded, their distribution would theoretically be balanced between groups as a consequence of the study's randomized design. However, due to the small sample size, this cannot be stated with certainty. Therefore, these factors should be considered in future research.

To prevent aseptic loosening of the tibial component and the need for revision surgery,^{2,4,5} extensive research has been undertaken to optimize fixation in TKA. For instance, different cementing techniques,^{10–12,23,24} various types of prostheses,²⁵ and different kinds of bone cement have been studied.²² Some studies suggest a higher rate of aseptic loosening with high-viscosity bone cement; however, a recent meta-analysis did not support these findings.²² In this study, the same high-viscosity PALACOS gentamicin bone cement (Heraeus Medical, Germany) was used in both study groups. As the duration of surgery and the time required for cement application were similar between groups, no differences in cement viscosity are expected due to the CCD. Although finger packing is a common technique for cement application, other methods are also used in clinical practice.¹¹ Further research is necessary to determine the effect of the CCD compared with these other techniques.

A final interesting finding was that higher rates of PCS were observed in the lateral quadrants. In OA, the medial compartment of the knee is more frequently and more severely affected. Therefore, subchondral sclerosis is generally more pronounced in the medial compartment.²⁶ As a consequence, penetration and distribution of bone cement is expected to be lower in the medial quadrants, and this is also reflected in the results of this study.

Strengths and limitations

A limitation of this study is that PCS was used as a primary outcome rather than aseptic loosening. However, for the first in vivo study, it was essential to assess the effectiveness of the CCD in small groups with a short-term follow-up. Due to late presentation and low prevalence, it was impossible to determine the rate of aseptic loosening in this study. Nonetheless, literature indicates that optimal fixation of the tibial component and lower rates of aseptic loosening are achieved through proper penetration and distribution of cement at a depth of 3 mm to 4 mm from the tibial tray.⁸ Therefore, implementing the CCD in TKA is likely to be associated with reduced rates of aseptic loosening.

No short-term complications were observed in this study. However, the nature of the study did not permit reporting on longer-term adverse events or complications. Since the CCD is used only during the implantation process and is subsequently removed from the tibial component, it is unlikely to increase long-term complication risk. Nonetheless, further research will be necessary to assess long-term outcomes, particularly regarding aseptic loosening and potential long-term complications.

The main strength of this study is the simplicity of the CCD's design and mechanism. Although the CCD was initially designed for a specific knee implant (NexGen Legacy, Zimmer Biomet, USA), its design can be adapted so it can be widely used with other implant types. Its straightforward design facilitates development and production for various prostheses. Since the CCD can be easily manufactured with a 3D printer, large-scale implementation across various prosthesis types is highly feasible. The process of inserting and removing the CCD after placing the tibial component is simple. As a result, any surgeon experienced in TKA can use it. Implementing the CCD does not increase operating time, allowing the same number of procedures per day as with the finger-packing technique.

Another strength of this study was deriving our primary and secondary outcomes from CT scans. With clinical determinants or radiographs, determining the quality, penetration, and distribution of cement in the proximal tibia can be challenging, since cement penetration on an radiograph is measured with a ruler in the coronal or sagittal plane.²⁷ A CT scan allows additional assessment of the transverse plane and the actual distribution of cement in the tibia. Therefore, calculating PCS per quadrant based on a CT scan was the most reliable method for assessing the benefit of the CCD in TKA. However, further research is necessary to compare cementing quality between CT scans and radiographs. Prior use of the CCD in human specimens (unpublished data at the time of writing) and implementing the CCD in this randomized controlled trial with short-term follow-up did not cause any adverse effects. Therefore, the CCD is ready for implementation at a larger scale, enabling future research to determine the long-term rates of aseptic loosening and other complications.

In summary, this first in vivo study of the new CCD for improving cementing in TKA demonstrates promising results. Even in small groups, the CCD shows a statistically significant increase in the PCS in the tibia compared with finger packing. As optimal fixation of the tibial component in TKA is associated with lower rates of aseptic loosening, it is anticipated that the CCD will be associated with lower rates of aseptic loosening when applied on a larger scale in clinical practice.

Supplementary material

Available on the TU Delft repository: Venderbosch RWF, Goossens RHM, Valstar ER. Control of cement penetration in TKA, 2015. Control of cement penetration in TKA. <https://resolver.tudelft.nl/uuid:99e98784-eb49-41e0-aa3c-a55931809ad6>

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Funding statement

The author(s) received no financial or material support for the research, authorship, and/or publication of this article.

ICMJE COI statement

The authors have no conflicts of interest to disclose.

Data sharing

The data that support the findings for this study are available to other researchers from the corresponding author upon reasonable request.

Acknowledgements

We would like to thank R. Venderbosch for providing his thesis, in which the background and development of the CCD are extensively discussed; I. Blom (radiology technician; Reinier Haga Orthopaedic Centre, Zoetermeer, Netherlands; Department of Orthopaedics, Reinier de Graaf Hospital, Delft, Netherlands) for assistance with the radiological aspect and preparing the CT scans for a transfer to MATLAB; and N. de Esch (research coordinator, Reinier Haga Orthopaedic Centre, Zoetermeer, Netherlands; Department of Orthopaedics, Reinier de Graaf Hospital, Delft, Netherlands) for assistance with patient inclusion and study logistics.

Ethical review statement

This study received approval from the Medical Ethics Committee (METC Leiden, The Hague, Delft, Netherlands; METC-number Z19.035, NL70830.098.19)

Open access funding

The open access fee was self-funded.

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