How much bone cement is utilized for component fixation in primary cemented total knee arthroplasty ?

Abstract

Purpose:

No scientific evidence exists regarding the amount of bone cement used and discarded in primary cemented Total knee arthroplasty (TKA). The aim of this study was to identify the exact amount of bone cement utilized for component fixation in primary TKA.

Methods:

In a prospective study carried out at five centers, 133 primary cemented TKAs were performed. One pack of 40g Palacos bone cement (PBC 40) was hand mixed and digitally applied during the surgery. After fixation of the TKA components, the remaining bone cement was methodically collected and weighed on a digital weighing scale. The actual quantity of cement utilized for component fixation was calculated.

Results:

On an average, 22.1 g of bone cement was utilized per joint, which accounted to 39 % of 57g , the solidified dry weight of PBC 40. Among 133 knees, the cement usage was 20 % to 50% in 109 knees, more than 50% in 20 knees and less than 20% in 4 knees. Knees which received larger sized femoral implant required more cement compared to medium and small sizes. Knees which had pulse lavage had more cement utilization compared to knees which had simple syringe lavage before implantation.

Conclusion:

Large quantity of bone cement was handled than actual requirements in primary TKA when a standard 40g pack was used with the digital application technique, resulting in sizeable discard

of bone cement. Customizing cement pack according to the implant size can potentially avoid this cement wastage. Future research is required to study the utility and economic impact of smaller packs (20 g or 30 g) of bone cement in primary TKA.

Key words: Bone cement quantity, primary knee arthroplasty, cement utility

Introduction:

Primary total knee arthroplasty (TKA) is a common procedure performed for most end stage arthritis with gratifying results. While there is a recent renewal of interest in cementless TKA [1,2], cemented TKA remains the reference standard with successful long term outcome [3,4]. Several studies have focused on the role of bone cement in TKAs with regard to the cementing technique, cement mantle thickness, cement penetration, antibiotic usage and limb alignment [5-14].

Despite the usage of bone cement since the beginning of knee arthroplasty, the quantity of bone cement that is actually utilized in a given knee is not known and not reported in Orthopedic literature. Some surgeons use two packs of 40g cement especially when vacuum mixer and cement gun are used, while others use a single pack of 40g cement for implanting all three components [15,16]. Many surgeons do not resurface the patella and hence use a single 40g cement pack for implanting both femoral and tibial components. Irrespective of the quantity used, because of the accurate bone cuts and good fit of the implants, a sizeable quantity of cement gets extruded after fixing the final components. Often only a small quantity of bone cement gets retained as a thin layer between the cut bony surfaces and the replaced components and large quantity of bone cement gets discarded at the end of surgery.

If the quantity of bone cement required for TKAs could be estimated, unnecessary cement usage with potential retention and third body wear, cumbersome removal after excess application and subsequent wastage can be avoided. The present study aims to find out the exact amount of bone cement utilized in the fixation of the implants and identify the factors that can influence the cement usage in primary TKA.

Methods:

We prospectively studied 109 patients who underwent cemented primary TKA between December 2015 and August 2016 for painful knee arthritis at five centers. The exclusion criteria were: usage of other brand cements , bone defects, bone cysts, requirement of stem extensions or augments, previous surgery with metal work and revision TKAs. Informed consent was obtained from all individual participants included in the study.

In all cases a pneumatic tourniquet was used. None of the surgeons altered his surgical technique for the study. The TKA surgery was performed in the standard fashion using intramedullary guide for distal femoral cut and extramedullary guide for proximal tibial cut. After taking bone cuts, the cut surfaces were cleaned off debris and irrigated with saline. The femoral intramedullary canal was blocked with a bone plug. A dry bloodless field was secured. In all cases, fast setting medium viscosity cement- Palacos bone cement 40g pack (PBC 40) (Palacos MV, Hereaus Medical GmbH, Germany) was used. The liquid and powder were hand mixed as per the manufacturer's instructions in an open stainless steel bowl with spoon and the starting time was noted.

Once the cement reached a doughy state, it was applied manually as follows: On the tibial side, a layer of cement was applied on the cut tibial bony surface and a small quantity of cement was pushed into the keel area. A layer of cement was applied underneath the tibial component base plate (Fig 1 a&b) [8]. On the femoral side, cement was applied on the anterior, anterior chamfer and distal cut bony surfaces. A layer of cement was applied in the femoral component posterior chamfer and posterior surfaces (Fig 2 a&b) [9] . Vacuum mixer or pressurized gun was not used in any of the patients.

To ensure the adequacy of cement mantle, cement was applied in such a way that at least some quantity would get extruded all around the tibial component and at the anterior, medial and lateral margins of the femoral component. After impaction of the components, the extruded cement material was meticulously removed from the margins of the component with a cement curette in the early stage or with a sharp blade in the later stage. Care was taken to see that all loose cement materials were retrieved (X). This material was cleared off any blood and tissue debris and placed in the bowl, which was used to mix the cement. There could be some/minimal left over mixed cement in the bowl (Y). The trial insert was selected and slid over the tibial base plate, the joint was reduced and held in extension. After cement hardening, the knee was flexed and trial insert removed. The extruded cement along the femoral and tibial component margins was removed with a thin sharp osteotome . These hardened cement bits collected (Z) were also placed in the bowl, which was handed over to a non-scrub staff. The bowl was weighed with all cement materials (X+Y+Z) 30 minutes after the start of cement mixing. The weight of the bowl with spoon was predetermined. The difference between the two was the weight of discarded cement in grams (DC) (Fig 3 a&b).

The standard weight of PBC 40 was predetermined as follows: The entire contents (44 g powder in sachet and 20 ml liquid in ampoule) were emptied in a bowl and mixed with a spoon. The bowl with cement was weighed 30 minutes after the start of cement mixing. The weight of the bowl with spoon was predetermined. The difference between the two gave the weight of standard cement in grams (SC). The difference of weights in grams between the standard cement (SC) and discarded cement (DC) was calculated as the utilized cement (UC) (UC = SC - DC).

Cement weighing was done on a standard digital weighing scale with sensitiveness that ranged from 0.1 g to 500 g (Fig 3). All surgeons had used the same brand digital weighing scale. All weighing scales were procured by a single surgeon, checked for any inter-machine variability and then distributed to the other surgeons. There was no more than 0.1 g of difference between the five weighing scales, when the same bowl with spoon and cement was weighed in all of them.

Other factors that could influence the quantity of cement usage in TKA such as component design and component sizes were noted. Simple statistical measures were used with unpaired t-test to compare the cement utilization among the various groups.

Results:

The study was done in 133 knees involving 109 patients. The mean age was 54 years (range 45 - 76 years). Mild varus deformity ($< 10^0$) was seen in 40 knees and mild fixed flexion deformity ($< 10^0$) was seen in 12 knees. No patella was resurfaced and all patients received metal backed modular tibial components.

On an average 22.1 g (range 10.7g to 39.9g) of bone cement was utilized per knee implantation. When compared to the total weight of standard cement which was 57g , on an average 39% (range 19% - 70%) of the cement was utilized ie, 61 % was discarded. Maximum number of patients had utilization between 30-40% (Table 1)

There was no significant difference in cement usage between the implants that required femoral box cut (Posterior stabilized - PS) and the implants without box cut (Cruciate retaining - CR)(Table 2). There were differences in the cement quantity between the smallest and the largest component size but the differences were variable. The knees were categorized into three groups based on femoral component sizes: small (first three sizes), medium (mid three sizes) and large (last three sizes). There was no statistically significant difference in the cement usage between the small and medium groups. However the large group had a statistically significant higher usage of cement compared to the small (P<0.0001) and medium groups (P<0.0001) (Table 3).

Of the twenty four patients who underwent bilateral total knee replacement, none had exactly the same amount of cement utilized for both the knees. The difference in cement utilization between the two knees ranged from 0.1 to 7.6 g.

Among the five surgeons who participated in the study, the cement usage ranged from 28% to 50% (Table 4).

Discussion:

Cemented total knee arthroplasty is a well established procedure performed all around the world in increasing numbers [17]. Bone cement in replacement arthroplasty is generally used as a grout between the cut bony surface and implant surface [5] .The actual quantity of bone cement utilized in a given TKA depends on multiple factors (Table 5). If cement is applied in a less viscous state, penetration into bone may be better but more cement "flows" out of bone surface easily with routine impaction of the components. On the other hand, cement applied in a more viscous state can result in less penetration and thicker cement mantle with routine impaction. Therefore the application of cement should be in an "ideal" dough state [7] .

From a Palacos cement pack of 40g, with an average weight of 57 g of solidified cement, on an average, 22.1 g of cement was utilized per TKA, which accounted for 39 % of the cement per knee. The cement discarded per knee on an average was 34.9 g . This means that more than 50% of mixed cement from PBC 40 (57 g) was discarded. Considering the volume of TKAs performed world wide, this is a huge wastage of bone cement. For example, if we consider the annual number of TKAs done in the United States of America (USA) with a conservative estimate of 500,000 per year [17] , the total quantity of cement discarded would be around 17,450 kg (17.4 tonnes) per year in USA alone.

The cementing technique being a grouting procedure, surgeons generally need to put "little extra" cement on the bone and prostheses to ensure good cement mantle thickness. When huge quantity of cement is available at disposal, this " little extra" can become excessive. Excess cement application can result in passage of cement into unwanted areas resulting in cumbersome removal and unintended retention. When unintended retained cement get loose it can result in pain, crepitus, loss of range of motion, third body wear and difficult revision at a future date. Retained excess cement in the postoperative radiographs have been documented in several cases of unicompartmental knee arthroplasty producing complications [18-21]. Otani et al reported impingement after TKA caused by cement extrusion and proximal tibiofibular instability in a rheumatoid patient [22].

The TKAs with large sized femoral components required more cement compared to smaller and medium sized implants. While the differences were statistically significant, the clinical differences were not large. In absolute terms of cement usage, small , medium and large sized femoral components had mean cement usage of 19.9g, 20.8 g and 26 g respectively corresponding to 35%, 36.5% and 46.5% of the solidified dry weight of PBC40.

The five surgeons who participated in the study had a minimum experience of 10 years in performing TKA. Despite standardizing the cement application technique [8,9], there were huge variations in the quantity of cement usage among the surgeons (Table 4). Three surgeons had significantly higher cement usage when compared to the other two. Two reasons could be identified for this higher utility of cement : bigger sized implants and usage of pulse lavage. Among 29 knees which had large sized femoral implants, 22 were contributed by these three surgeons. These three surgeons had regularly used pressure pulse lavage before cementation of the components, while other two surgeons had not used the same. Pulse lavage can remove loose bone, tissue and blood particles and open up the cancellous bone resulting in better cement penetration. In an in vitro study, Schelegel et al [23] showed improved bone cement penetration and interface strength in tibial tray cementation with pulse lavage compared to syringe lavage .

In our study there was a significantly higher utility of bone cement with knees implanted after pulse lavage compared to the knees which were implanted without pulse lavage ($P<0.0001$) (Table 6) . There was 15% increase in cement utilization in pulse lavage group . In actual weight, on an average, the cement utility was 8.3g more in the pulse lavage group. Opening of cancellous bone alone could not have amounted to this much increased utility. In the pulse lavage group, the numbers of large knees were significantly higher (23 knees) compared to non pulse lavage group (7 knees). The percentage of small, medium and large knees in pulse lavage group and non pulse lavaged group were 27%, 40%, 32% and 32%, 57%, 11% respectively. This higher number of large knees in the pulse lavage group also have contributed for higher cement utility resulting in increased average cement usage in this group.

The highest quantity of cement utilized was 70% and more than 50% was utilized only in 20 cases among the total of 133 cases (Table 1) . Among these 20 knees, 19 had pulse lavage before cementation; 12 had received large sized femoral implants and 8 had received medium size components. The other reason that could have contributed to the increased cement usage but could not be identified and quantified was the variable cement uptake on the tibial side. Multiple brands of TKA implants were used by surgeons, each surgeon had used at least three different brands (Table 7). The femoral component geometry (posterior stabilized -PS and cruciate retaining-CR types) was nearly uniform across all brands. However, there were small but wide variations in the geometry of base plate keel and stem designs in the tibial components. A meaningful categorization of different tibial implants and comparison of cement utilization between them could not be done due to the wide variations in the implant geometry.

Since on an average at least 50% of cement was discarded from a PBC40 as per our study, a half packet of 20 g may be mathematically enough for a single TKA. However, in the clinical setting, for cement handling and satisfactory application higher quantity of cement will be needed. Considering other factors as standardized and pulse lavage as a routine step, the factor that could alter the cement utility is the implant size. Therefore we feel that, rather than using a 40g bone cement pack for all cases, a tailor made decision can be made in the operating room based on the size of the femoral component in a primary TKA without bone defects. Based on calculations from the current study, we theorize that a 20 g pack may suffice for a "small " sized knee and a 30 g pack may suffice for a "medium' and "large" sized knees. As on date, a 30g bone cement pack is commercially not available. Availability of 30 g cement pack along with the existing 20 g and 40 g may allow the surgeon to choose the cement pack according to the need. Further research on individualizing cement pack selection based on implant size is required to confirm our theory.

Maheswari et al [16] evaluated the economic impact and the clinical outcome based on the amount of bone cement needed (one packet Vs two packets) for a primary TKA. At a minimum of 3 years follow-up, they observed no difference in implant survivorship or Knee Society scores, but did observe substantial cost savings when one packet was used instead of two in combination with hand mixing and manual application technique. By eliminating several extra cement mixing products, they achieved approximately $1,000 cost saving per case. While this study proposed one packet of bone cement instead of two packets, our study shows that a 40 g packet itself may be more for a single TKA. The cost implications of using smaller quantity cement packs in primary TKAs needs to be explored in future studies.

Vacuum mixing reduces cement porosity, provides homogenous mix and is supposed to be superior. However the supremacy of vacuum mixing over hand mixing has been questioned in both laboratory and clinical studies [16,24-28]. Kopec et al [29] and Maheswari et al [16] identified no obvious advantage of vacuum mixing with gun pressurization for components cementing in TKA and suggested continued use of the hand-packing technique. In an experimental study, Schlegel et al [30] compared three commonly used cementing techniques: layered application, stem cementation and cement gun for tibial component fixation in paired tibiae. Specimens underwent computed tomography scanning for three-dimensional analysis of cement penetration and mechanical testing for assessing interface strength, which showed no difference between the three techniques. Vanlommel et al [8] in their study on saw bone models demonstrated excessive cement penetration with the use of cement gun in tibial implantation and advised application with spatula or finger packing technique. Maheswari et al [16] showed equivalent clinical outcomes with or without the usage of cement gun and vacuum mixer in TKA. Future studies, similar to the current study design are needed to estimate the actual cement utilized in the settings where vacuum mixers and cement gun are routinely used. These studies are expected to reveal a high quantity of unutilized cement.

To our knowledge, this study is the first of its kind to estimate the actual cement quantity utilized for implant fixation in primary cemented total knee arthroplasty. The strengths of the study are: multi centric study, uniform cement application protocol, same brand of cement and experienced surgeons performing all the TKAs. The limitations of the study may be the factors that could have influenced the cement utility but could not be controlled: multiple implant brands and designs, cement storage settings, the temperature regulation of the operation room and the ideal "dough" stage timing for cement application. However these limitations may not have serious bearings on the outcome of the study. Also the study findings are not applicable in settings where cement gun and vacuum mixer are "routinely" used in TKAs.

In conclusion, in primary total knee arthroplasty, with the usage of a single 40 g cement pack (57 g of solidified dry weight) by hand mixing and manual application technique, an average of only 39% (22.5 g) was utilized. Larger sized implants and pulse lavage utilized more quantity of bone cement. Significantly higher quantity of bone cement was handled than what was necessary for actual fixation, resulting in unwarranted cement discard. We propose that rather than using a 40 g cement pack routinely for TKAs, a tailor made decision can be made in the operating room based on femoral implant size. Future research using smaller quantity bone cement pack (20g and 30 g) in primary TKA with long term follow up is warranted for a conclusive evidence.

Figure Captions:

FIG 1a & 1b Tibial component cementing technique

FIG 2a& 2b Femoral component cementing technique

FIG 3a& b Weighing of mixing bowl alone and bowl with discarded cement on a digital weighing scale.

Ethical approval: "All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards."

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