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Does use of a “Rim Cutter” improve quality of cementation of the acetabular component of cemented Exeter THA?

A prospective randomized controlled trial

Abstract

A randomized controlled trial was performed to assess the effect of a rim cutter device on cement mantles in modern elective total hip replacement using a flanged acetabular component. Forty patients were randomized to a rim cutter (21) or control (19) group. A statistically significant improvement in cement penetration was demonstrated in zone 1 (10.1 versus 8.6mm (p=0.023)), and in cement mantle thickness in zones 2 and 3 (7.8mm and 6.7mm versus 5.7 and 5.4mm (p<0.001 and p=0.017); with a reduced incidence of bottoming out of the socket (1/21 versus 8/19 (p=0.007). Cement mantle thicknesses greater than 8mm were achieved more consistently in the rim cutter group (30% versus 2%). This technique improves cement penetration and mantle thickness in a reliable manner.

Word count: 122 words

Key words: Total hip replacement; rim cutter; cement mantle; cement penetration; acetabulum

Running head: Use of the “Rim Cutter” to improve cementation in THR

Introduction

The rim cutter is a device designed to cut a shelf or rim in the acetabular rim to allow the flange to seat accurately. [Figures 1-3] It was developed to try to improve the cement mantle quality, improve the accuracy of cup centering, reduce the incidence of bottoming out, and allow a trial reduction with a cemented component (the flange in the rim allows a trial reduction prior to cementing in a similar way to a trial uncemented liner).

Cemented total hip arthroplasty (THA) has come a long way since its inception more than forty years ago. Despite our growing knowledge about bone cement and its handling characteristics, aseptic loosening is still the most common mode of failure for cemented THA.[1] Recent focus has been on improving the cementing technique which is a key determinant of cement mantle longevity. Modern cementing techniques have improved the long term survival of femoral stems and to a lesser extent of the acetabular cups.[2-8] Cemented acetabular components behave differently to their femoral counterparts because of the cyclical changes in the acetabular geometry under different physiological loads, difficulty in controlling the bleeding and pressurization of the cement in the acetabulum and a different tissue response in the acetabulum to micro movement.[9]. A major problem surrounding cemented acetabular fixation is technique related and one of the difficulties experienced with cementing is the inability to adequately pressurize the cement into the bony bed[13] Pressurization of the cement is particularly difficult as the acetabulum is a wide and shallow open cavity with a large surface area and an irregular non continuous rim.[14] Cement often escapes around the edges of the advancing cup.

Charnley introduced the flanged cup in 1976 to improve pressurization of cement during cup insertion.[18] The flange often needs to be trimmed to fit precisely inside the irregular acetabular rim which is not readily achievable. It would be desirable to cut a flat rim along the acetabular margin for the flange to sit on. The "Rim Cutter" was developed for this reason. The technique involves cutting a shelf of bone on the acetabular rim to seat the flanged cup.

Our aim in this study was to test the influence of this device on the quality of the acetabular bone cement interface. The hypothesis was that apposition between the flange and the rim should create an efficient seal preventing the leakage of cement, thus increasing the intraacetabular pressure and cement penetration. The rim should also provide a stable base and prevent the cup from "bottoming out".

Material and methods

The study comprised of 40 cemented Exeter THAs in 39 patients performed between March and December 2006 at our institution. All routine total hip replacement patients older than 50 years with a diagnosis of osteoarthritis were considered eligible for the study. Following informed consent, patients were randomly allocated to 2 groups; Rim cutter (RC) and Control (C), using sealed envelopes, opened in theatre at the time of surgery. Randomization was performed by a statistician (SLW) using the Sampsize program [15] with a block size of 4. There were 21 hips in the rim cutter group, and 19 in the control group due to one incorrect randomization. Intention to treat analysis has not been performed as there should be no placebo effect on the control group. There were 10 males (47.6%) and 11 females in the rim cutter group and 7 males (36.8%) and 12 females in the control group (not significant using the chi-squared test, p=0.49). The mean age was 68.0 yrs (range 28-88 yrs) in the rim cutter group as compared to 67.9 yrs (range 43-81yrs) in the control group which was not significant (p=0.99). The groups were similar when compared using Bombelli’s classification [16]. There were 4 hypertrophic patients in each group and 1 atrophic in the control and 2 in the rim cutter group (not significant p=0.87).

Ethics Committee approval was granted by our institutional Ethics Committee.

Surgical technique

The operations were performed by 5 different surgeons (two consultants and three fellows) using a standardized technique. A standard posterior approach to the hip was used. The acetabulum was reamed using hemispherical reamers with increasing diameters in 2mm increments until bleeding cancellous bone was exposed. Zone 1 was selectively debrided, if necessary, and any remnant sclerotic bone was removed. Multiple drill holes were made with a stop drill 5mm in diameter and 10mm in length.

At this stage in the rim cutter group, a rim was cut along the acetabular margin using the rim cutter device. A flanged cup (Contemporary cup -Stryker) of appropriate size (generally 2mm smaller than the last reamer) was prepared for insertion by trimming the flange as required. The flange was cut to fit inside the acetabulum in the control group. In the rim cutter group a 2mm rim of flange was preserved to sit on the cut acetabular rim.

In all patients reamings from the last reamer were placed under the transverse ligament to prevent cement extrusion. The acetabulum was washed with pulsatile lavage and then dried and packed with a hydrogen peroxide swab. A single mix of antibiotic cement (Simplex-Howmedica) was placed into the acetabulum at about 3 minutes and then pressurized using an Exeter pressuriser. The acetabular component was then inserted at about 6 minutes and the pressure maintained till the cement cured. Insertion of a cemented Exeter femoral stem followed by closure was carried out in a standard manner in all the patients.

Radiographic evaluation

Postoperative plain digital radiographs were analyzed for cement penetration in DeLee and Charnley Zone 1, cement mantle thickness in all three DeLee and Charnley zones and presence of radiolucent lines (RLL). Fine cut CT scans were analyzed for cup "bottoming out" which was defined as contact of any part of the cup or the pods with bone. Measurements were performed by 2 groups of observers on 3 different occasions blinded to the patient groups using a digital scale (Agfa PACS tools). A collective agreement was reached to resolve any doubts. The average of these values was taken for analysis.

Statistical analysis

The primary endpoint for analysis in this study is cement penetration. Power analysis was performed using Sampsize [15] based on the work published by Hogan et al. [17] In order to detect a difference in penetration of 3mm, with a standard deviation of 3mm, power of 80% and significance level of 5%, a minimum of 17 patients were needed in each group. Allowing for withdrawals, loss to follow up or non compliance, we aimed to recruit 20 patients in each arm.

As the data was Normally distributed, parametric methods were utilized and the significance level was set to 5%. The secondary endpoints were cement mantle thickness in the 3 Charnley zones (which were also Normally distributed and analyzed using ANOVA). Bonferroni's correction was applied for multiple testing. The number of cases 'bottoming out' and radiolucent lines were analyzed using the Fishers Exact Test.

Results

Cement penetration was significantly higher in the rim cutter group when analyzed using ANOVA (p=0.023) (Table 1). The cement mantle thickness in the 3 Charnley zones was also greater in the rim cutter group (Table 1), although this was only statistically significant in zones 2 and 3 after correction for multiple testing. Cement mantle thicknesses greater than 8mm were achieved more consistently in the rim cutter group (30%) as compared to the control group (2%) (p<0.001).

Cup "bottoming out" was significantly higher in the control group (42.1%) compared to rim cutter group (4.8%) (p=0.007). This "bottoming out" phenomenon was more consistent with the posterior pod (81% of the cups bottomed out on the posterior pod) probably as a result of posteriorly directed force applied during cup insertion in posterior approach THAs. RLL's were observed more frequently in the rim cutter group (14.3%)

(2 in zone 1; 1mm and 2mm thickness, 1 in zone 2; 1mm thickness) compared to the control group (5.3%) zone 1, 2mm thickness), although this difference was not statistically significant.

Discussion

Various studies have reported the rate of aseptic loosening for cemented acetabular components to be about 10% at 10-15 years even with the use of modern cementing techniques.[8,10] Though both biological and mechanical factors contribute to aseptic loosening, there is an indication that early secure mechanical interlock at the bone cement interface may result in more predictable long term survival of cemented cups.[8,11,12] Factors governing the initial cement fixation include meticulous acetabular preparation and adequate cement pressurization. The fate of the acetabular interface and the life of the acetabular component is largely determined by the initial cement penetration and interface created by the surgeon at the time of surgery. Secure fixation of the cup depends on multiple factors including a clean and dry acetabular bed with open cancellous surface and a high cement intrusion pressure. Removal of the subchondral plate to expose the cancellous bone, cleaning of marrow and debris using a jet lavage, achieving haemostasis with hydrogen peroxide/vasoconstrictive agents, complete coverage of the component and pressurization of the cement are essential components of the modern cementing technique targeted to achieve a good micro and macro interlock.[19] High intrusion pressure is desirable during cup insertion to achieve this close mechanical interdigitation.[20] The depth of the cement penetration has been shown to increase with applied pressure, time of pressure application, lower viscosity of cement and greater porosity of bone.[21] Krause et al noted penetration of greater than 10 mm in their experimental study on cadaveric proximal tibias, when a pressure delivery system was used. They reported an increase in the tensile and shear strength with the depth of penetration.[22]

The question still to be answered though is how much penetration is required for adequate fixation? 3-5 mm of cement penetration is believed to be optimal in the proximal tibia.[23] Pressures of up to 1500-2250 mmHg are required for this ideal penetration especially in arthritic bone.[24] These pressures are relatively easily achievable in the femoral canal as compared to the acetabulum which is a wide, open, shallow cavity with a non continuous rim and thus hard to compartmentalize.[25] Cement often escapes around the edges of the advancing cup and under the transverse ligament leading to loss of intra-acetabular pressure. Charnley designed the flange at the periphery of a cup to act as a restrictor for the escaping cement thus increasing the intrusion pressure[18]. Though in vitro studies confirmed the same [20, 26] and good long term results have been published with the Charnley “oogee” cup [27], Parsch et al in a recent cadaveric study noted that flanged cups did not increase the average intra-acetabular pressure or the cement penetration despite the high peak pressures generated during flanged cup insertion when the implantation was carried out by a surgeon in paired human acetabuli with simulated bleeding.[28] They attributed this to the somewhat ineffective sealing action of the flange in the presence of irregularities of the acetabular rim and variation in the realistic force applied by the surgeon during pressurization to maintain cup position and prevent “bottoming out”. Some of these conditions were overlooked in the earlier in vitro studies using simulated acetabuli with unrealistic robotic insertion forces not otherwise achievable by the surgeon in the clinical situation.[20, 26] Flivik et al reported that highest peak pressures inside the acetabulum were recorded during cup insertion but were quickly lost due to escape of cement around the cup edges.[14] Instantaneous high pressure is less effective in producing increased penetration as compared to a sustained pressure even if the latter is of a lesser magnitude.[29] The penetration achieved in our study is above the recommended 3-5 mm in both the groups. Though meticulous precautions were taken to create an effective seal at the flange rim interface, less appreciable differences in penetration between the 2 groups might be due to the more viscous nature of the cement at the time of cup insertion. More viscous cement when combined with late insertion and use of the flange still achieved reasonable penetration in the control group. In one study most of the cement penetration was shown to occur in the first 30 seconds of initial pressurization.[23]

Patients in the rim cutter group achieved thicker mantles more consistently. Thicker mantles, especially greater than 6mm, have been shown to protect against osteolysis.[30] Cement mantles less than 3mm are more likely to result in cement fragmentation, polyethylene wear and subsequent loosening. [31]

A cup without flange and pods is more likely to be seated eccentrically and “bottom out” depending on the amount and direction of force applied. Shelley et al in an in vitro study noted that unflanged cups produced a lower intrusion pressure as compared to the flanged ones and the same was lost as the unflanged cup “bottomed out” making further pressurization and concentric seating impossible.[26] A concentric mantle reduces stresses and transfers the load more evenly to a larger area of the acetabulum.[31] A combined design feature of a flange and pods of equal height was shown to ensure a concentric cement mantle in vitro.[32] Sandhu et al in a recent retrospective radiological review of a 100 cemented THA's showed that only 22% were concentrically placed in their mantles[33]. The Charnley oogee cup did significantly worse with only 13% of them achieving concentricity showing that it is not always possible to reproduce the in vitro results in the more realistic surgical situation. The importance of avoiding direct contact between the cup and the bone was realized long ago as it may propagate external wear leading to loosening.[34] 42.1% of the cups in the control group bottomed out mostly on the posterior pod (which is made of PMMA cement) as against the polyethylene.

Early radiolucencies at the bone cement interface may be attributable to surgical technique depending on bone preparation, patient selection, cement pressurization and control of bleeding at the bone cement interface.[8] Walker et al in their radiographic study noted that cement penetration of 1.5mm or less under the tibial component led to development of a radiolucent line at the interface.[23] In a recent study vacuum aspiration of the socket increased the cement penetration and eliminated RLL's at the bone cement interface.[33] Radiolucencies in any of the three zones of DeLee and Charnley are good predictors for migration loosening.[8,11,12] Without maximal microinterlock the surface area of the bone cement interface is suboptimal and the total surface area of load bearing bone is decreased. Incomplete penetration may lead to channel formation for migration of polyethylene wear debris that promotes biological failure.[8] Flanged sockets have been shown to be associated with a lower incidence of radiological demarcation at the bone cement interface.[27] The flange, when apposed to the acetabulum, as in the rim cutter group, may act as a more effective seal to the ingress of polyethylene debris. 13% of the patients in the rim cutter group in our series developed a RLL which might be a cause for concern. Ritter et al noted that despite their attempts to improve acetabular fixation with meticulous technique of acetabular preparation and cement preparation, 11% of the patients still developed a RLL in Zone1.[34] Possible explanations for the RLL's seen in our study could be the cup seating early on the rim and preventing further pressurization, or poor surgical technique.

Conclusion

A statistically significant improvement in cement penetration, preventing cup "bottoming out" and increasing cement mantle thickness of acetabular component was found with the use of a rim cutter in cemented Exeter THAs. The long term effects of these findings remain to be seen.

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Tables

Table 1. Mean (SD) measures in each group

	Rim Cutter Group	Control Group	p-value
Cement penetration *Mean (SD)*	10.1 (2.3)	8.6 (1.5)	0.0023*
Mantle thickness Z1 *Mean (SD)*	7.0 (1.5)	6.1 (1.3)	0.062
Mantle thickness Z2 *Mean (SD)*	7.8 (1.5)	5.7 (1.4)	<0.001*
Mantle thickness Z3 *Mean (SD)*	6.7 (1.8)	5.4 (1.6)	0.017*
Bottoming out *Number (%)*	1 (4.8)	8 (42.1)	0.007*
Radiolucent lines *Number (%)*	3 (14.3)	1 (5.3)	0.61

*statistically significant at the 5% level (after correction for multiple testing where necessary)

Figures

Figure 1. The rim cutter device.

Figure 2. The rim cutter during cutting

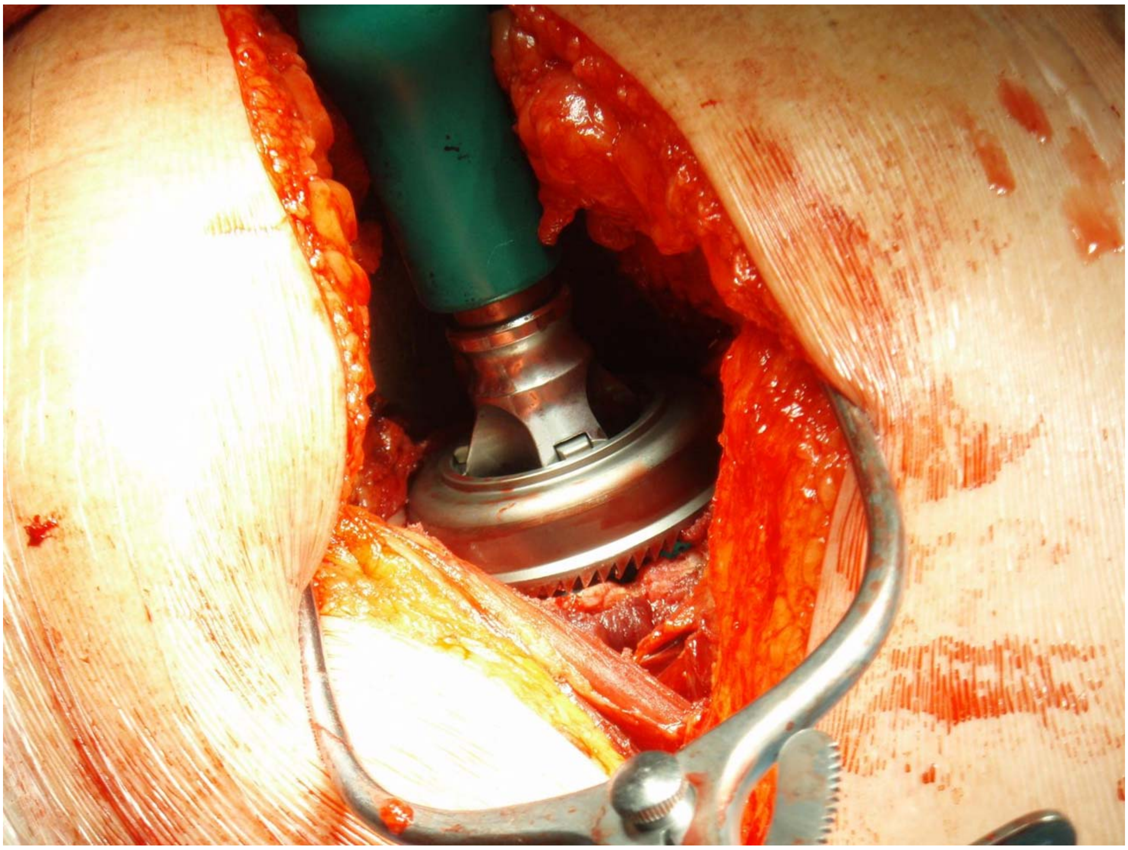

Figure 3. The rim in the acetabulum seen after use of the rim cutter