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ORIGINAL STUDY

Experimental investigation of negative pressure intrusion techniques of acetabular cementation in total hip arthroplasty

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The main mode of failure of the acetabular component in total hip arthroplasty is aseptic loosening. Successive generations of cementation techniques have evolved to alleviate this problem.

This paper evaluates one such method, Negative Pressure Intrusion Cementation. Two groups of machined bovine cancellous bone samples were created ; experimental (n = 26) and control (n = 26). The experimental group was cemented using the negative pressure technique and the control group was cemented in the absence of negative pressure. The relative cement intrusion depths were then assessed for each group using MicroCT. These samples were then further machined and tested to failure in torsion to estimate their mechanical properties.

Results show mean cement intrusion depth for the negative pressure group to be 8,676 µm and 6,042 µm for the control group ($p = 0.078$). Mechanical testing revealed a greater mean torque in the negative pressure group (1.6223 Nm versus 1.2063 Nm) ($p = 0.095$).

This work quantifies the effect of negative intraosseous pressure on cement intrusion depth in cancellous bone and for the first time relates this to increased mechanical strength.

Keywords : hip arthroplasty ; cementation techniques ; negative pressure intrusion.

INTRODUCTION

In vivo mechanical studies of the hip joint reveal that it is almost constantly under compression load even during sitting and recumbent positions (*12,17,20*). This almost constant loading leads to wear of the cartilaginous linings of the joint eventually leading to bone on bone articulation presenting as groin, thigh and knee pain, limp, stiffness, deformity and disability i.e. the clinical entity referred to as arthritis.

The main treatment modality for advanced osteoarthritis of the hip is Total Hip Arthroplasty (THA). THA is presented to the patient as primarily a pain relieving procedure (*7*). It does also

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provide in many patients an increased range of movement and in the majority an increase in function and quality of life (*8,11,18*). It's success as a treatment is reflected by the large numbers of THAs performed worldwide, with over 2,785 performed per year in Ireland and greater then 300,000 per year worldwide (*5,16*).

The majority of these procedures comprise of cemented femoral components with all polyethylene acetabular components secured with polymethylmethacrylate bone cement. These procedures have provided great improvements in the quality of life of patients with hip arthritis with functional assessment scores and quality of life assessments showing a marked improvement postoperatively (*10*). However the length of time for which this improvement can be sustained has been an area of interest and research for some time (*9*) due to the time and activity dependant phenomenon of implant failure by aseptic loosening.

In cemented THA, the acetabular component most commonly used is an all ultra high molecular weight (UHMW) polyethylene prosthesis secured in the acetabulum with polymethylmethacrylate (PMMA) cement.

It has been suggested that loosening is initiated when mechanical failure occurs at the cement bone interface and multiple generations of cementation techniques have evolved in order to delay the process of implant failure through aseptic loosening (*3,4,15*).

The negative pressure intrusion cementation technique (NPI) represents a more recent phase in the evolution of cementation techniques. This technique involves the introduction of a vacuum into the peri-acetabular bone immediately prior to cement application. This aims to decrease the deleterious effects of the systemic bleeding pressure, remove fat and debris from the path of the advancing cement and cause deeper cement ingress through the direct effects of negative pressure.

We hypothesise that the presence of negative intraosseous pressure during acetabular cementation increases the cement intrusion depth. We further hypothesise that this increased intrusion depth imbues the cement bone construct with increased resistance to torsional forces.

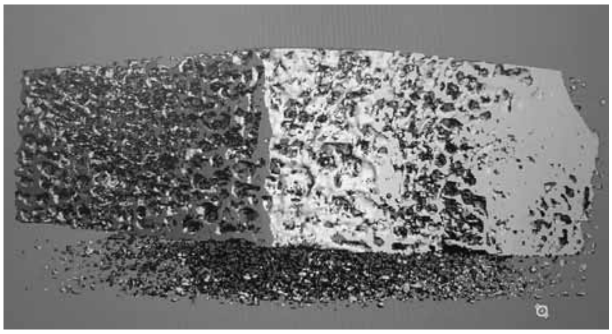

Fig. 1. — Three dimensional reconstruction

MATERIALS AND METHODS

Twenty six fresh frozen bovine greater trochanters were obtained from a local abattoir (Boyne Valley Meats, Dublin, Ireland) and were machined to create 52 cylindrical cores of cancellous bone (23 × 40 mm) using a modified core saw (Starrett, Skipton, North Yorkshire, UK) and a generic milling machine. All samples were stored at -18°C. The samples were randomly assigned into equal experimental and control groups.

These samples were matched for porosity using microCT (Scanco 40, Bassersdorf, Switzerland) (fig 1) using the proprietary IPL (Scanco 40, Bassersdorf, Switzerland) image processing software.

These cores were then introduced into the vacuum chamber of the custom designed rig (fig 2) and were subjected to a minimum negative pressure of –50 kPa using a clinical suction machine (Cherion, Czech Republic). A 3:1 mixture of dental Simplex (Kemdent, Wiltshire, UK) and surgical Simplex (Stryker, Limerick, Ireland) polymethylmethacrylate cement was created using a digital scales (Avery Berkel, UK). The mix contained 15 g of dental Simplex and 5 g of barium containing surgical Simplex in order to allow the microCT to differentiate between bone, cement and cancellous voids as pure dental Simplex is radiolucent and indistinguishable from inter-trabecular voids and surgical Simplex is radio opaque and is indistinguishable from bone on microCT, mixture allows the cement to be isolated within the cancellous bone (*19*).

The cement was then introduced to the bone sample and the experimental apparatus was sealed with silicone and subjected to positive external pressure via the application of a 2 kg weight to the vertical actuator of the custom designed rig.

The cement was allowed to set for 30 minutes and the constructs were removed en bloc and stored at -18°C.

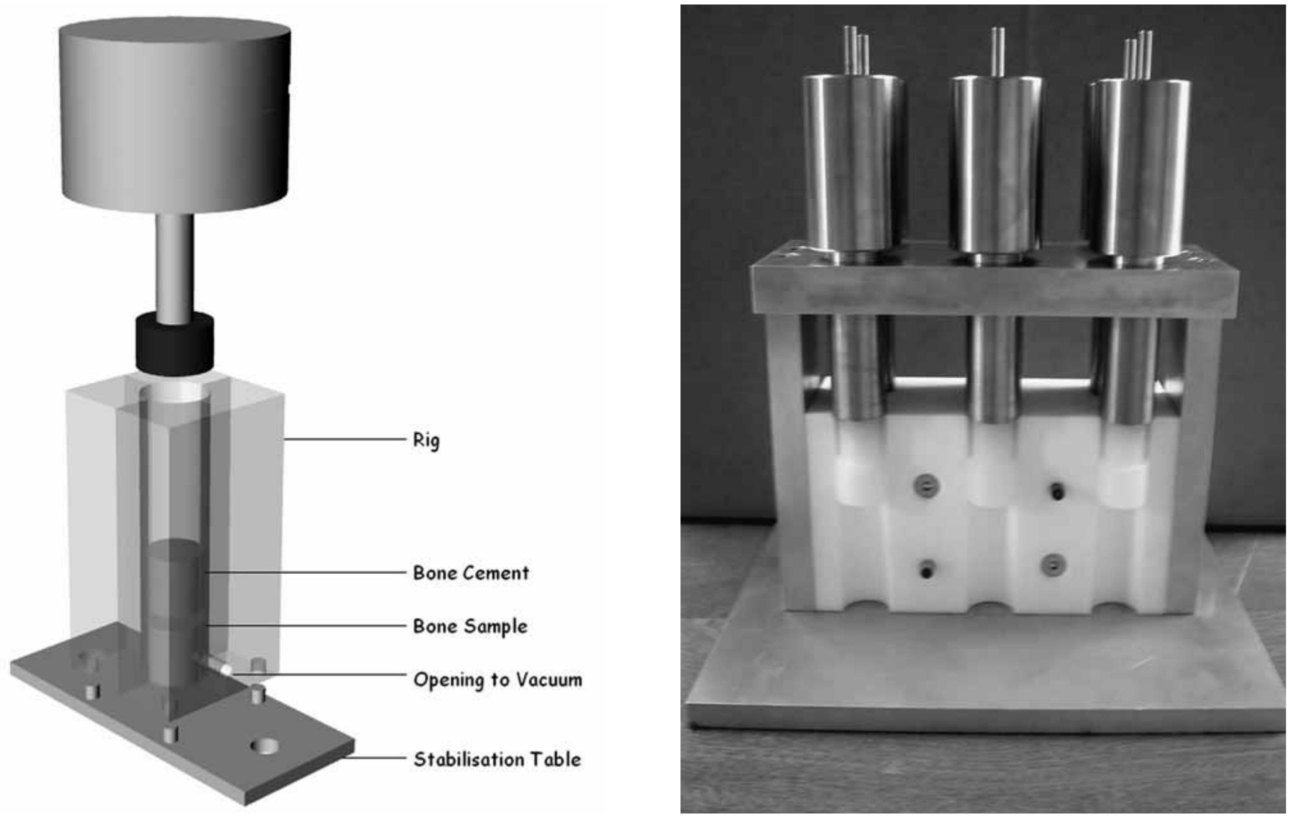

Fig. 2. — Experimental apparatus modified for multiple specimen processing

MicroCT was used to measure the cement intrusion depth using a novel technique. A Scanco 40 scanner was utilised to identify key tomogram slices of known (30 µM) diameter, i.e. the most proximal and distal extent of cement intrusion within the bone-cement construct. Cement intrusion depth was calculated non-destructively by multiplying the number of tomogram slices between the above index slices by the 30 µM diameter of those slices giving the actual depth of cement intrusion in microns. Other variables such as mixing time, temperature, magnitude of negative pressure applied and magnitude of positive pressure applied, as stated above, were carefully controlled as part of the laboratory protocol.

The samples were then machined with a 12 mm notch centred on the bone-cement interface and then machined flat to a diameter of 12 mm (fig 3) and tested to failure in torsion in an Instron 8870 materials testing machine (Norwood, Mass, USA).

The machined samples were mounted in the 'M 12' grippers of the Instron (max. diameter 12.5 mm) after careful defrosting of the bone-cement interface and secured using the lowest hydraulic pressure to avoid damage to the cancellous bone in the specimen.

No preload was applied to the specimens with load in all axes 'zeroed' prior to commencement of testing. Each specimen was subjected to a torsional displacement at 0.5°/second through an arc from 0° to 35° in the clockwise direction. Data collection was carried out a rate of 1 Hz. Thirty five such tests were successfully carried out (n = 16 negative pressure intrusion, n = 19 control) and all specimens failed at the bone cement interface (BCI). These data were collected using the Instron data collection system which provides data in Microsoft Excel (Redmond, Washington, USA) format.

In these tests torque was seen to rise rapidly to a peak at which the bone cement interface failed and then return more gradually to base line. This peak represents the peak torque at failure and is an index of the rotational force required to cause failure of the bone cement interface and was taken as a surrogate for interface strength.

Statistical analysis on cement intrusion depth and bone cement interface strength data was carried out using the Wilcoxon Rank Sum test as these data were

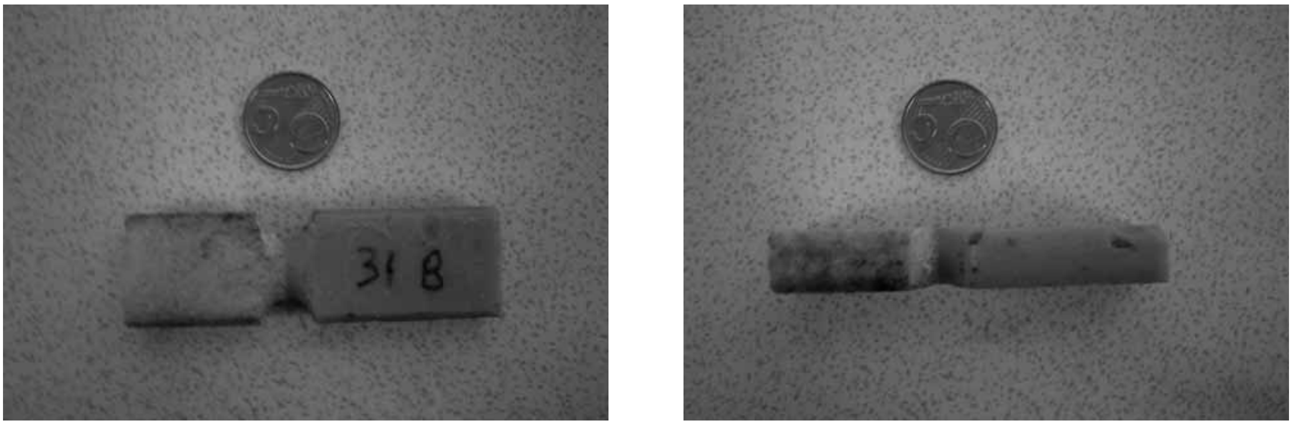

Fig. 3. — Machined cement bone construct

not normally distributed. The Student's t-test was applied to bone porosity data with $p = 0.05$ being taken as significant in all cases.

RESULTS

1) Mean Intrusion Depth

A definite trend toward greater cement intrusion depth was identified in the negative pressure intrusion group when compared to the control group ($p = 0.078$) (table I).

Mean intrusion depth was greater for the negative pressure intrusion group (8676 ± 1269 µm) than for the control group (6042 ± 1521 µm) (fig 4). The non-parametric test, the Wilcoxon Rank-Sum test, was applied as a frequency plot revealed that the data was not normally distributed ($p = 0.078$).

2) Torsional Mechanical Testing

Thirty five successful torsion tests were carried out (n = 16 negative pressure intrusion and n = 19 control). Torque was seen to rise progressively and then peak at cement interface failure, followed by a rapid decrease in torque (fig 5). Mean peak torque was greater for the negative pressure intrusion group (1.6223 +/- 0.558 Nm) than for the control group (1.2063 +/- 0.4182 Nm) (fig 6).

The negative pressure intrusion group also manifested a trend toward greater bone cement interface strength ($p = 0.095$) (table II).

Table I. — Raw data for mean intrusion depth (MID) for negative pressure intrusion (NPI) and positive pressure intrusion (control) samples. Bone porosity (expressed as percentage volume) is also shown for each specimen (Specimen numbers 6, 7, 9, 10, 11 & 12 were discarded due to defects identified during preparation)

NPI Sample No	Porosity (% Vol)	Mean Intrusion Depth (µm)	Control Sample No	Porosity (% Vol)	Mean Intrusion Depth (µm)
1	73.61	9120	1	73.89	10680
2	80.03	18870	2	78.08	11460
3	66.66	9180	3	65.28	10020
4	67.05	7560	4	69.55	4020
5	61.02	8580	5	48.73	3300
8	73.4	14805	8	56.65	8130
13	81.18	5250	13	87.43	4965
14	77.35	9540	14	83.63	7050
15	84.41	7275	15	86.36	3915
16	84.23	5925	16	84.65	4950
17	85.63	2805	17	85.66	1110
18	77.57	11835	18	84.47	8775
19	79.35	14880	19	81.91	11715
20	86.96	5850	20	85.66	2340
21	87.71	5325	21	84.56	5970
22	84.07	19485	22	82.43	5490
23	75.65	1545	23	76.97	2115
24	78.42	2370	24	83.62	1905
25	81.17	6600	25	83.81	7230
26	80.71	3675	26	80.08	1890
27	79.14	1890	27	84.89	3060
28	78.33	4785	28	82.25	10905
29	83.89	30270	29	79.65	15315
30	82.31	10830	30	80.99	600
31	82.41	2265	31	78.71	1785
32	86.46	5070	32	87.89	8400

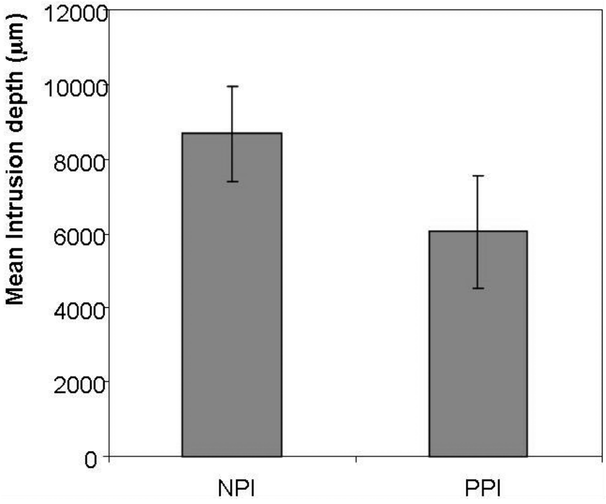

Fig. 4. — Mean intrusion depth for the negative pressure intrusion and control groups (error bars indicate 95% confidence intervals). Higher mean intrusion depth and lower variability was observed for the negative pressure intrusion group than for the control group.

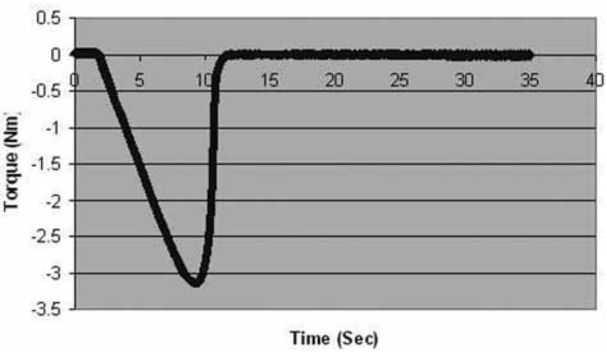

Fig. 5. — Graph of typical torsion test to failure

Porosity in the negative pressure intrusion group was 79.18% ± 1.26 and 79.15% ± 1.82 in the control group. The groups therefore were well matched with no statistical difference between the two groups ($p = 0.988$ using a Student's t-test).

Furthermore, no correlation between bone sample porosity and cement intrusion depth was identified (figs 7 & 8). These plots indicate that, in this particular study, the porosity of the bone samples used did not have an influence on mean intrusion depth.

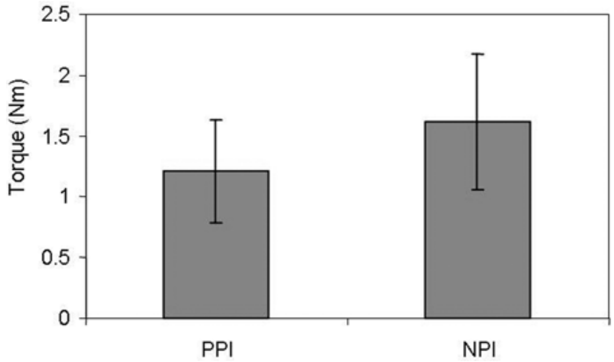

Fig. 6. — Mean peak torque for the negative pressure intrusion and control groups (error bars indicate 95% confidence intervals). Higher mean peak torque was observed for the negative pressure group than for the control group.

Table II. — Raw data for torsion testing expressing peak recorded torque in Nm for negative pressure intrusion and control samples showing significant variability. (XX represent samples lost in machining, also sample numbers 1, 2, 3, 4 & 27 were not included as their mechanical testing results were considered to be biased by the 'learning curve' in the use of the testing equipment)

NPI Samples	Peak Torque (Nm)	Control Samples	Peak Torque (Nm)
5	3.861	5	3.145
8	3.622	8	3.298
13	1.332	13	0.937
14	XX	14	1.628
15	0.739	15	1.491
16	1.308	16	1.761
17	XX	17	0.479
18	2.542	18	1.318
19	1.463	19	XX
20	1.643	20	0.437
21	1.242	21	0.171
22	0.296	22	0.448
23	1.753	23	1.359
24	XX	24	0.711
25	XX	25	0.595
26	2.728	26	1.099
28	1.101	28	0.541
29	0.877	29	XX
30	XX	30	0.543
31	0.617	31	1.876
32	0.827	32	1.078

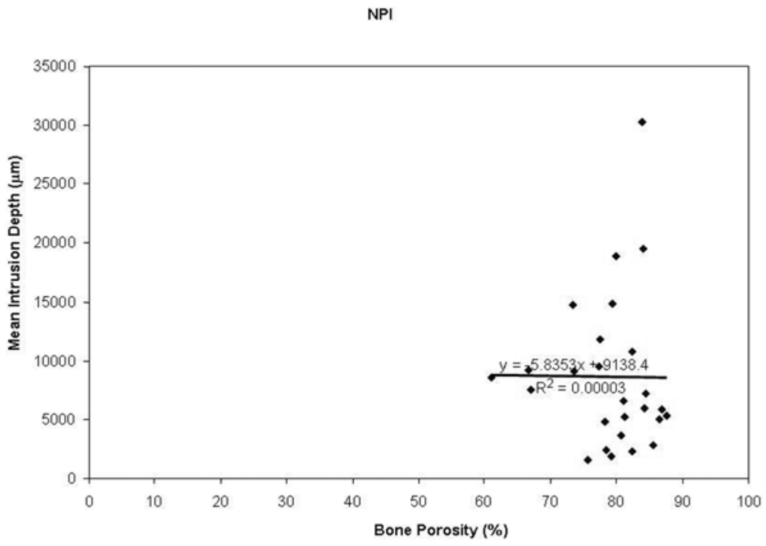

Fig. 7. — Scatter plot of porosity Vs mean intrusion depth for the negative pressure intrusion group showing no correlation between porosity and cement intrusion depth.

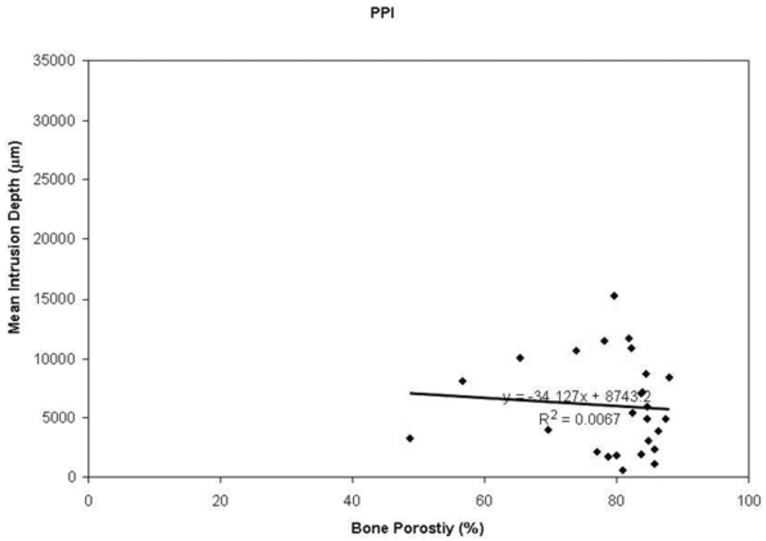

Fig. 8. — Scatter plot of porosity Vs mean intrusion depth for the control group showing no correlation between porosity and cement intrusion depth.

DISCUSSION

Several investigators have postulated that the strength of the bone cement interface is related to the amount of bone interdigitated with cement (*1,2*) based on the observation that specimens which have higher strengths are often associated with more trabecular bone interdigitated with cement.

Mann *et al* (*14*) in 1997 went on to investigate this formally in laboratory testing, revealing that this was indeed the case *in vitro*. Increasing cement intrusion depth is associated with increasing amounts of trabecular bone interdigitated with cement, which is in turn related to increasing interface strength. In this study, we have taken mean cement intrusion depth as a surrogate for the amount of bone interdigitated with cement.

This series of *in vitro* experiments provides important information about this currently used, but poorly understood technique. The association of increased cement intrusion depth demonstrated here in the laboratory model compares favourably with other investigations in this area. This study, for the first time establishes the association between NPI cementation and increased bone cement interface strength, it does however not prove it definitively in the absence of absolute statistical significance.

Although not significant at the 0.05 level, a definite trend of greater mean cement intrusion depth was found for the negative pressure intrusion specimens ($p = 0.078$). This indicates that mean intrusion depth has potential value as an indicator of bone cement interface quality/strength (*14*).

Cancellous bone specimen porosity in both groups was statistically well matched with a mean porosity in the negative pressure intrusion group of 79.182 ± 1.26% and 79.146 ± 1.82% in the control group.

Figures 7 and 8 show that there is no correlation between porosity and cement mean intrusion depth (negative pressure intrusion $R^2 = 0.000035$, control $R^2 = 0.0067$) in this particular study. Porosity was therefore effectively removed as a significant factor in determining cement intrusion depth and was not therefore a confounding factor.

With all other factors controlled, the remaining significant variable, i.e. the presence or absence of negative intra-osseous pressure during cementation is more likely to account for the trend toward greater mean intrusion depth in the negative pressure intrusion compared control groups illustrated here.

As previously discussed, increased PMMA cement intrusion depth has been linked by other investigators to greater bone cement interface strengths (*13,14*). In this study an association has, for the first time in a laboratory setting, been established between the presence of negative intra-osseous pressure during cementation and increased intrusion depth. This finding correlates favourably to those of Hogan *et al* (*6*) in the clinical setting. Furthermore, evidence from this study reinforces the link between increased cement intrusion depth and bone cement interface strength hypothesised and found by others (*1,2*).

Consequently this study for the first time establishes a link between the use of negative pressure intrusion cementation techniques and greater cancellous bone-cement interface strength, an association which, despite the fact that this technique is currently in clinical use, has heretofore been only assumed.

It was necessary initially to design and manufacture a model which would faithfully reproduce the surgical environment to test the basic scientific principles of the negative pressure intrusion technique. This necessitated a certain amount of simplification of the process in order to create a manageable, practical bench based process that would simulate the process as realistically as possible but allow simplicity of operation and minimisation of variability. This study was limited to some extent by this simplification as the absence of a bleeding environment diminishes the absolute realism of the model. We also acknowledge the limitations on this study caused by or relatively small specimen numbers which contributed to our inability to demonstrate absolute statistical significance.

CONCLUSIONS

This study presents a novel method which faithfully models the negative pressure intrusion technique. In addition, a new method for measuring polymethyl-methacrylate cement intrusion depth in cancellous bone specimens in a non-destructive manner is also presented.

It also demonstrates that the use of the negative pressure intrusion cementation technique was associated with a strong trend towards greater mean cement intrusion depth. Our results also suggest that the porosity of the bone samples did not have a significant effect on cement mean intrusion depth.

We have also developed and illustrated a novel method for the mechanical testing of bone cement constructs. Using this we have shown that bone-cement constructs created using the negative pressure intrusion technique show a modest increase in the mechanical strength of the bone-cement interface, manifested as a greater mean peak torque at failure.

The use of the negative pressure intrusion technique therefore appears to be associated with a greater depth of intrusion of PMMA cement into cancellous bone. This in turn appears to be associated with a greater bone cement interface strength.

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