Vibration-assisted bone-graft compaction in impaction bone grafting of the femur

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The complications of impaction bone grafting in revision hip replacement includes fracture of the femur and subsidence of the prosthesis. In this *in vitro* study we aimed to investigate whether the use of vibration, combined with a perforated tamp during the compaction of morsellised allograft would reduce peak loads and hoop strains in the femur as a surrogate marker of the risk of fracture and whether it would also improve graft compaction and prosthetic stability.

We found that the peak loads and hoop strains transmitted to the femoral cortex during graft compaction and subsidence of the stem in subsequent mechanical testing were reduced. This innovative technique has the potential to reduce the risk of intra-operative fracture and to improve graft compaction and therefore prosthetic stability.

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Revision procedures in 2005 accounted for approximately 7500 (15%) of all total hip replacements (THRs) carried out in the United Kingdom.[1] With an ever ageing population, and a trend for performing joint replacements in younger patients, the number of primary and revision operations is likely to further increase from here on. Revision operations are costly to perform, have a higher rate of complications, a longer mean operating time and a greater estimated blood loss than primary procedures.[2,3] In addition, the outcome is often inferior to that of the primary operation. Impaction bone grafting is a recognised technique for reconstructing extensive bone loss in both the femur and acetabulum.[4-6] The technique requires the morsellised allograft to be adequately compacted to provide initial stability for the prosthesis. This prevents early massive subsidence and induces bone remodelling, the absence of which is thought to be key in the collapse of the graft and subsequent failure of the implant.[7,8] In revision of the femoral component, a thin-walled proximal femoral cortex is often encountered and intra-operative fractures are common given the high forces which must be applied to the graft in order to gain adequate graft compaction, with reported rates ranging from 12% to as high as 27%.[9-13] There is no specific indicator or guideline to enable the surgeon to determine when the graft is adequately compacted. Concern regarding fracture may lead to under-compaction of the graft and subsequent subsidence of the prosthesis.

Morsellised allograft shares many of the characteristics of aggregate materials such as soils, sands and ballasts used in applications in civil engineering.[14] The behaviour of these aggregates under load has been studied extensively and this knowledge may be used to improve the mechanical characteristics of bone graft. The strongest aggregate should be a mixture of different sizes in appropriate proportions, have a low state of hydration, be well compacted using an appropriate quantity of applied compaction effort, preferably by sequential compaction of layers of aggregate, and should be adequately contained during compaction.[15,16]

Vibration is commonly used in civil engineering to improve the compaction (assembly) of aggregate particles and to increase the compressive and shear strengths of the aggregate.[14] If the aggregate is subjected to vibration in an unconfined space, the particles forming the aggregate are moved into a denser packing, which improves its shear strength. When the aggregate is saturated with a fluid phase, the interstitial fluid needs to be drained out as it becomes more densely packed. This is usually not a problem in an unconfined space. However, in a contained environment, such as in the space between the prosthesis and femur, the increase in fluid pressure generated by the vibration can lead to an increase in pressure in

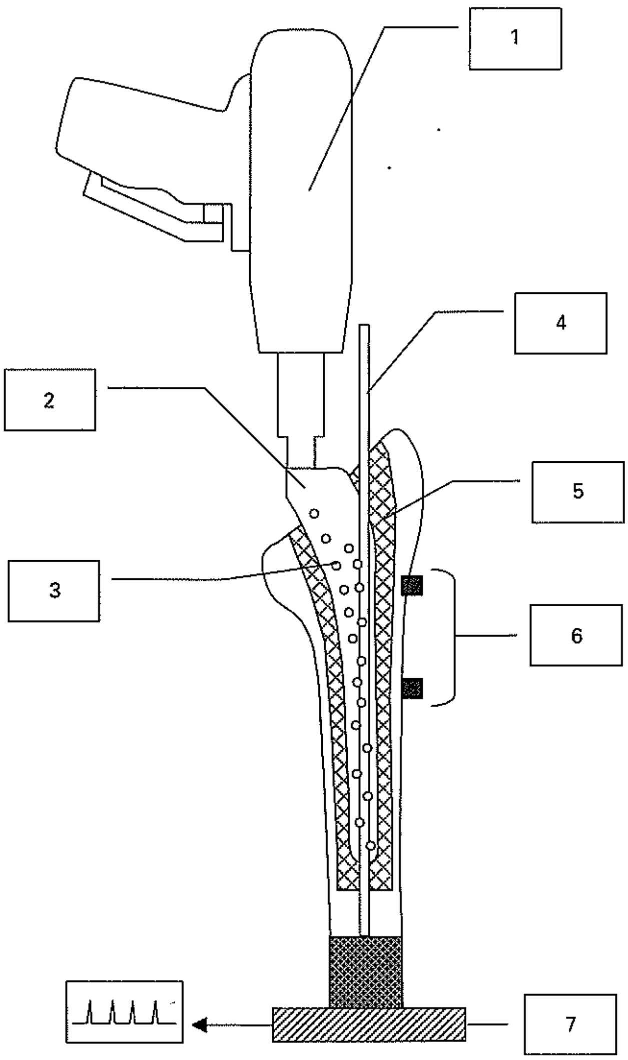

Fig. 1

Diagram showing the vibration-assisted impaction bone graft device for the femur (1, the vibration hammer; 2, the phantom/tamp; 3, holes in the phantom/tamp; 4, the centralising rod; 5, the bone graft; 6, strain gauges and 7, the load cell).

the fluid phase that will be exerted on the solid particles forming the aggregate. Under strong vibration, the fluid pressure can become large enough to push the solid particles apart, causing loss of contact. This phenomenon is known as 'liquefaction',[17] and is often witnessed in saturated granular media during earthquakes, known to result in the sinking of large buildings or bridges. Liquefaction can be avoided if adequate drainage is provided for the fluid phase.

In this study, we tested two hypotheses using an *in vitro* model. The first was that the use of vibration and a perforated tamp in the compaction of highly-washed morsellised bone would reduce peak loads and hoop strains in the femur and, secondly that graft compaction and prosthetic stability would be improved by vibration.

Materials and Methods

Preparation of bone graft. Morsellised bone graft was prepared from freshly-frozen femoral heads defrosted in warm saline solution. After removal of the articular cartilage and residual soft tissues, the heads were milled using a Noviomagus bone mill (OrthoLink Ltd, Prestonpans, Scotland), washed with hydrogen peroxide (which acts to remove most of the fat), cleaned using pulsed lavage with normal saline solution, and drained through a sieve (300 μm). Previous studies by the senior author (DGD) have measured the particle size distribution from the Noviomagus, and found this to be the most optimal grading compared with other bone mills.[15,18] As such, this process did not need to be repeated for this study. The graft was then placed in a polythene bag, sealed and wrapped in moist swabs in order to maintain constant hydration. Approximately three femoral heads were required for each experiment. Ethical approval was gained. The weight of bone graft used for each experiment was recorded. All graft was taken from the Noviomagus bone mill and used in both groups. Therefore, the grading was the same in both groups.

Instrumentation. A polished, collarless tapered tamp (phantom) from the 'X-change' Stryker impaction bone grafting kit (Stryker UK Ltd., Newbury, United Kingdom) was modified by drilling multiple holes through its flanks into the central guide-wire hole.

With a Woodpecker vibration device (Minnesota Bramstedt Surgical Inc., St. Paul, Minnesota) vibrations were applied to the phantom. The Woodpecker is a pneumatic hammer developed for broaching the femoral canal. Initial trials with the device indicated that the energy imparted per blow was too great when the device was operated at air-supply pressures recommended by the manufacturer for broaching applications. These were trial and error experiments performed without any formal measurements of strain and load. The optimum parameters have yet to be defined and are currently under investigation. For this reason, a pressure regulator was fitted in the air-supply line. Preliminary experiments established that the optimum working pressure was 2.4 bar with the control on the body of the Woodpecker set in the maximum (+) position.

The apparatus and experimental set-up are shown in Figure 1. The Woodpecker was coupled to the phantom in such a way that the vibration generated was transmitted to the morsellised allograft, with the coupling between the Woodpecker and tamp disengaging on retraction of the hammer.

A total of 12 biomechanical models of the femur were prepared, six in each group (standard femoral compaction with slap hammer for the control group, and vibration-assisted compaction for the experimental group). We used medium left third-generation composite femora manufactured from short glass-fibre re-inforced epoxy resin (Model number 3303; Sawbones Europe AB, Malmö, Sweden). These have been shown to approximate to the mechanical

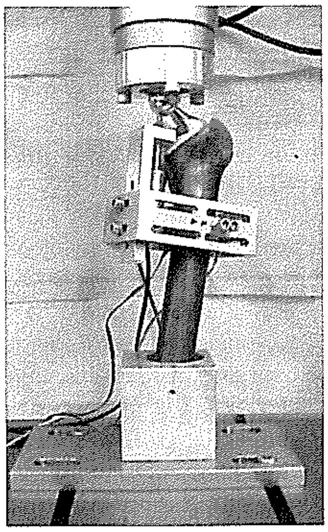

Fig. 2a

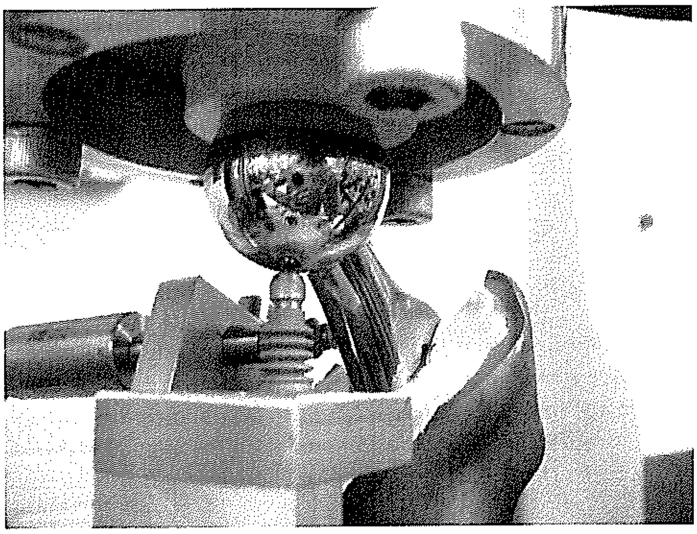

Fig. 2b

Photographs showing the experimental step-up for cyclical loading and measurements of stability. Figure 2a – A potted femur fixed at 10°/10° below the Instron testing machine. Figure 2b – Axial and rotational transducers positioned on the prosthesis held by an aluminium bracket.

properties of the human femur, but with much less variability than that found in cadaver material.[19]

Each model femur was modified to resemble that encountered during revision THR. The foam core was removed to increase the diameter of the canal to 22 mm. All the foam from the proximal femur was removed in each case, leaving the cortex as moulded by the manufacturer. The distal canal of each femur was occluded 25 mm beneath the anticipated position of the tip of the prosthesis using bone cement.

Uniaxial strain gauges (type FLA-9-11; Techni Measure Ltd, Studley, United Kingdom) were attached to each femur using cyanoacrylate adhesive at the medial calcar and in the mid-shaft. Measurements were taken from the lesser trochanter and the same bones were used for each group of tests to allow direct comparison. Care was taken to ensure the consistency of the position and alignments of the gauges. The gauges were aligned to measure strains perpendicular to the medullary axis of the femur in the circumferential direction ('hoop strain'). The strain gauges and their electrical connections were coated with a layer of low-modulus silicone rubber to protect them from fluids exuded by the bone graft during compaction of the graft.

Each proximal femur was potted in an aluminium cup using Technovit resin (TAAB Laboratory Equipment, Aldermaston, United Kingdom). A potting jig was used to ensure that the cup was concentric with the intramedullary canal of the composite model femur. The cup was then fitted into a precision-machined mating hole in the base block of the mechanical testing jig and retained using grub screws. The cup and jig positioned the femur such that the central line of the medullary canal at the distal cut was orientated at 10° to the vertical in both the frontal and sagittal planes passing through the centre of the femoral head. The accuracy of alignment with this mounting system was estimated to be better than 0.5°. This was determined by the consideration of the known accuracy of the machining centre used to produce the jig and the engineering tolerances between the components. This presented the femur in a similar position and orientation to that described for fatigue testing of hip prostheses (ISO 7206-4:2002 Implants for surgery -- Partial and total hip joint prostheses -- Part 4: Determination of endurance properties of stemmed femoral components), which is designed to represent the loading of the hip at heel strike during a typical gait cycle.

Operative procedure and per-operative measurements. Impaction bone grafting was carried out using a standard protocol for the control and vibration-assisted groups, using 'Exeter' instrumentation (Stryker UK Ltd). Approximately 15 ml of graft were introduced into the distal intramedullary canal and the graft compacted using the distal tamps. This step was repeated twice more. Further portions of graft were then added to the femur. At each stage, the graft was compacted before the next portion was added. In the control group, a standard technique of applying 20 blows per portion of graft was maintained. In the experimental group, the graft was compacted by application of the Woodpecker to the tamp/phantom for approximately ten seconds. The end-point of impaction in the control group was defined as no further movement of the tamp after ten consecutive blows with the slap hammer, and in the vibration group, by no further movement of the tamp despite application of force to the Woodpecker. Movement

Table I. The load profiles used for experimental testing of subsidence of the prosthesis

Sequence	Number of cycles	Minimum load (N)	Maximum load (N)	Mean load (N)	Load amplitude (N)
1	20	50	200	125	75
2	980	50	800	425	375
3	1000	50	1200	625	575
4	1000	50	1600	825	775
5	47000	50	2100	1075	1025

was determined by markers on the phantoms, referenced against a fixed point, such as the femoral neck of the sawbone. Preliminary experiments confirmed that the end-point in the vibration group correlated with the end-point in the control group; i.e., after vibration-assisted compaction, the addition of ten further blows using the slap hammer resulted in no further movement of the tamp. After completion of graft compaction, a single mix of bone cement (Smartset CMW; DePuy CMW Ltd., Blackpool, United Kingdom), prepared in a vacuum-mixing system (Cemvac; DePuy CMW Ltd) was inserted retrograde using a revision nozzle and cement gun, and pressurised by a proximal cement pressuriser. This was followed by the insertion of a 44 No. 2 Exeter femoral prosthesis (Medway House, Newbury, United Kingdom).

Loads transmitted through the femur during impaction were measured using a load cell taken from a materials testing machine (Instron 1193, kN capacity; Instrong Ltd., High Wycombe, United Kingdom) upon which the femur was rested.

Load and strain data were recorded at each stage of compaction using a computer equipped with a data acquisition card and signal conditioning unit (DAQCard-AI-16XE-50 and SC-2345; National Instruments Ltd., Newbury, United Kingdom). Data were sampled at a frequency of 10 kHz to ensure capture of the high-frequency components of the load and strain signals produced by the compaction.

Measurements of stability. Approximately 48 hours after implantation, the stability of the prosthesis was tested using an Instron 8878 servohydraulic materials testing machine (Instron Ltd, High Wycombe, United Kingdom) (Fig. 2). In addition to the strain gauges used in the per-operative measurements, two displacement transducers (Solartron DFg 2.5 LVDT; RS Components Ltd, Corby, United Kingdom) were mounted on the femur using aluminium brackets so that axial and rotational relative movements between the prosthesis and bone could be measured. The axial displacement transducer was aligned with the long axis of the femur in the anteroposterior and medial/lateral planes. The rotational transducer was aligned perpendicular to the axial transducer. The latter made contact with the prosthesis on the underside of the femoral head and the rotational transducer approximately 10 mm medial to the intersection of the mid-shaft and neck axes of the prosthesis (Fig. 2b). We calculated that the out-of-plane movement during subsidence would be negligible since we were primarily studying axial and rotational subsidence with loading. After fixing the potted femora rigidly to the base plate of the testing machine, loads were applied to the femoral head through a bearing which minimised off-axis loading of the femur and testing machine actuator (Fig. 2a).

The femur was loaded according to a protocol developed by Westphal et al.[20] In order to replicate physiological loading sinusoidally varying cyclical loads were applied to the femoral head. The mean loads, load-amplitudes and the number of cycles for each sequence are shown in Table I.

Statistical analysis. This was performed using Student's *t*-test (two sample, unequal variance) and linear regression analysis (GraphPad Instat Software; GraphPad Software Inc., San Diego, California).

Results

Per-operative observations. The impaction procedure in the control and experimental groups was performed by a single surgeon (DGD). Every attempt was made to standardise the procedures in each group. In all procedures in both groups, three sets of distal impactions were performed with matching portions by weight of graft before moving on to the proximal impaction. In the control group during the impaction process one sawbone developed a mid-shaft longitudinal fissure extending proximally. There were no fractures in the experimental group.

The mean amount of allograft used in the control group was 73.1 g (69.8 to 75.3) and in the experimental group 79.5 g (72 to 85). The amount of graft used in the experimental group was significantly higher than that in the control group ($p = 0.01$).

Per-operative measurements: impaction loads and hoop strains. The peak load and peak hoop strain were determined from the load and strain recordings for each femur from each set of impactions. The means and SDs of these peak values were then calculated (Figs 3 to 5).

The mean peak load transmitted through the phantom/tamp, bone graft and composite femur to the load cell during proximal impaction was 3.28 kN (2.8 to 4,7) in the control group and 1.71 kN (1.6 to 1.8) in the experimental group. This difference was statistically significant ($p = 0.005$). During distal impaction there was no statistically significant difference in the mean peak loads (control group, 1.59 kN (0.92 to 2.26); experimen-

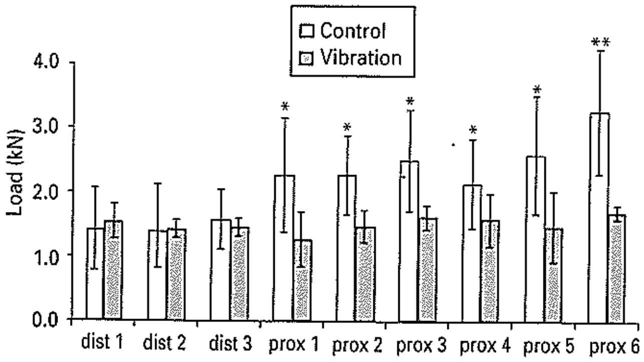

Fig. 3

Bar chart showing the mean peak loads (SD of five samples) during each sequence of distal and proximal impactions (** $p < 0.01$, * $p < 0.05$) for both groups.

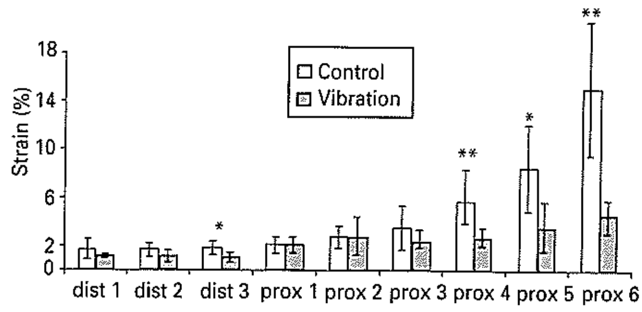

Fig. 4

Bar chart showing the mean peak proximal hoop strains (SD of five samples) during each sequence of distal and proximal impactions (** $p < 0.01$, * $p < 0.05$) for both groups.

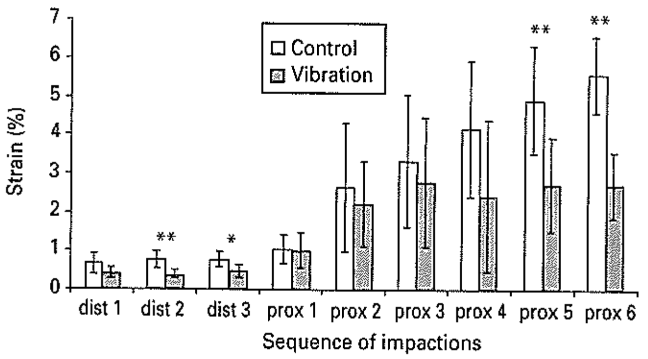

Fig. 5

Bar chart showing the mean peak mid-shaft hoop strains (SD of five samples) during each sequence of distal and proximal impactions (** $p < 0.01$, * $p < 0.05$) for both groups.

tal group, 1.47 kN (1.22 to 1.62)). With each consecutive set of proximal impactions the mean peak load was significantly higher in the control than in the experimental group (Fig. 3).

The mean peak proximal hoop strain was 13.2% (5.2% to 18.6%) in the control group and 4.2% (1.9% to 6.1%) in the experimental group. This difference was statistically significant ($p = 0.09$). The mean peak mid-shaft hoop strain was 5.6% (4.7% to 7.4%) in the control group and 2.7% (1.8% to 3.9%) in the experimental group. Again this difference was statistically significant ($p = 0.006$). These correlated closely with the mean peak load in each sample (control group, $R^2 = 0.80$, $p = 0.007$; experimental group, $R^2 = 0.70$, $p = 0.001$).

With each consecutive set of impactions the mean peak proximal and mid-shaft hoop strain increased in the control group, whereas in the experimental group a steady state was achieved (Figs 4 and 5).

The range of values recorded for load and strain measurements was smaller in the experimental group compared with that for the control group.

Measurements of stability. No specimens failed during cyclical loading. Most subsidence occurred in the initial loading phases. By 50 000 cycles there was only very minor subsidence of the prosthesis relative to the bone. In both groups visual observations suggested that subsidence was as a result of movement between the cement and the graft, between the graft and the bone or within the graft itself rather than between the prosthesis and cement, although this was not directly measured.

The mean total axial subsidence after 50 000 cycles was 2.47 mm (1.78 to 3.23) in the control group compared with 1.79 mm (1.37 to 2.21) in the experimental group. This difference was statistically significant ($p = 0.03$).

There was no statistically significant difference in mean rotational subsidence between the groups (control group, 0.66 mm (0.06 to 1.67); experimental group, 0.57 mm (0.11 to 1.35)).

Discussion

The risk of fracture and massive subsidence of the prosthesis post-operatively are the two most important obstacles to greater adoption of femoral impaction grafting in revision THR. The rate of fracture has been highlighted as a concern in a number of studies[9,11,21] and varies significantly between series (up to 27%).[13] In the absence of methods for establishing when the graft has been adequately compacted there is a significant learning curve between over-impaction causing a fracture of the femur and under-impaction leading to instability of the prosthesis and subsidence.[22]

Our experimental study has demonstrated that vibration-assisted impaction grafting gives reduced peak loads and strains in the femur during compaction, and the potential therefore to lower the risk of femoral fracture. In addition, the vibration-compacted graft bed provides enhanced stability of the implant with less prosthetic subsidence. Adoption of this technique may reduce the length of the surgical learning curve with subsequent improvement in outcome.

Studies on soil mechanics have established that vibration applied to an aggregate results in more efficient alignment of particles and reduces the energy required to impact the aggregate.[14] The use of vibration-assisted graft compaction in our study gave a significant reduction in both the peak impaction loads experienced by the femur and in the peak hoop strains transmitted to the femoral cortex. The range of values observed for both peak loads and strains were also much smaller in the experimental group. Changing the loading applied to the vibration device by the surgeon (DGD) resulted in a negligible increase in peak load and peak hoop strain. It appeared that the peak loads were limited by the vibration device itself rather than by the surgeon, which was a potentially useful characteristic. By contrast, the loads and strains transmitted in the standard technique were dependent on how hard the tamp was hit with the slap hammer and therefore were prone to increased variability, as indicated by the higher SD values in the control group.

Previous studies have standardised the amount of energy transmitted to the bone graft by the use of a weight that is dropped from a known height. In our study, the impaction force was not standardised in this way because the variability of the standard technique caused by human factors was thought to be an important characteristic of the procedure. This variability was observed when a surgeon (DGD), highly experienced in the field of impaction grafting, performed all the impactions. This was in contrast to the vibration technique which resulted in less variable load and strain values in the hands of the same surgeon, therefore offering greater control and reproducibility over the existing technique.

One of the fundamental difficulties of impaction grafting is the intra-operative determination of when the graft is adequately impacted. Only one study to date has suggested a potential method by assessing intra-operative rotational stability of the femoral phantom using a modified torque wrench.[23] In vibration-assisted graft compaction a plateau is reached whereby further use of the vibration device does not result in the generation of higher loads and strains. This provides a 'safety net' against inducing strains at which a fracture is more likely to occur. In addition, it was noticed that when graft compaction was complete as indicated by cessation of further subsidence of the phantom/tamp within the bone-graft mantle, there were clear auditory and tactile changes. This was quantified using the standard deviations for peak load and strain in each group. The standard deviations in the experimental group were smaller. The ability to determine the point of adequate compaction intra-operatively would be a significant advantage to the surgeon and should potentially avoid overimpaction and its potential risk of fracture.

The second associated complication in impaction grafting is post-operative subsidence of the prosthesis. The frequency of massive subsidence (10 mm) has been reported to be as high as 11%.[22] Our study has shown that less subsidence occurs in vibration-assisted compaction. This can be explained by the principles of basic soil mechanics. According to the Mohr Coulomb theory of the strength of granular materials, the shear strength of a granular aggregate such as bone graft depends upon the internal friction (ϕ), expressed as the angle at which the aggregate will slide, and the interlocking of the particles (c), expressed as a stress. The frictional resistance varies in proportion with the normal (compressive) stress (σ) produced by the load supported by the aggregate. The relationship between the parameters can be expressed by the Mohr Coulomb failure law ($\tau = c + \sigma\tan\phi$) which allows the calculation of the shear strength of an aggregate.[15,16,24] It is postulated that vibration improves the packing of the aggregate particles increasing the particles interlocking ($\uparrow c$) and according to the Mohr Coulomb failure law, shear strength of the aggregate ($\uparrow\tau$) as follows:

$$\uparrow\tau = \sigma\tan\phi + \uparrow c$$

It is hypothesised that the holes drilled in the phantom/tamp reduce strains in the femoral cortex and contribute to improved graft compaction by allowing the relief of pressure spikes generated within the fluid phase of the bone graft during impaction. It has previously been shown that removing excess fluid from the graft improves its resistance to shear.[15] The relatively high state of hydration of the graft and the incompressibility of the fluid mean that both the fluid and solid phases of the graft transmit loads. The holes allow excess fluid to escape, reducing the intensity of the pressure spikes and allowing fluid to drain and the graft to reach the optimum hydration state, improving graft compaction and consequently shear strength.

Our study has shown that the use of vibration and drainage, in the form of a perforated tamp, can lead to an improvement in the strength of the graft and lower peak hoop strains and loads. Although it has been established that vibration alone will improve aggregate strength, provided there is free drainage of fluid, we do not know the effect of the perforated tamps (i.e. drainage alone) in the absence of vibration. We hypothesise that the perforations alone will reduce the hoop strains and loads, but on their own will not improve realignment and interlocking of the particulate and therefore not improve graft compaction and strength to the extent which was found. We plan to test this hypothesis along with investigating parameters characterising the vibration hammer and perforated tamps to establish the optimum impaction conditions, including the effects of vibration frequency and amplitude, air pressure and the number, size and position of the holes in the tamps.

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