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Morsellised sawbones is an acceptable experimental substitute for the in-vitro elastic and viscoelastic mechanical characterisation of morsellised cancellous bone undergoing impaction grafting.

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Abstract

Impaction grafting using morsellised bone chips is widely used during surgery to mitigate the effects of bone loss. The technique typically involves the packing of morsellised allograft cancellous bone into bone defects, and has found extensive application in revision hip and knee surgery. In the ideal situation, the presence of the bone graft prevents subsidence of the revised prosthesis in the short term, and integrates with the host bone in the longer term However, the configuration of particles within the graft remains to be optimised, and is highly likely to vary across potential sites and loading conditions. Human bone, for use in experimental investigation, is often difficult to obtain with properties that are relevant from a clinical point of view. This study, therefore, has explored the mechanical response of a Sawbones based experimental substitute. An established confined compression technique was used to characterise the morsellised Sawbones material. Comparison of the results with published values for bovine and human bone indicate that the mechanical response of the morsellised Sawbones material map well onto the elastic and viscoelastic response of bone of a biological origin.

Introduction

Knee and hip replacements are very widely performed procedures: The UK National Joint Registry (NJR) reports 80,314 hip replacements and 84,653 knee replacements for 2011 in England and Wales alone: The ratio of primary to revision procedures is reported as 6.1% for knees and 11% for hips [1]. Younger patients are more likely to need revision surgery [2]. Patients who have had a revision are more than five times more likely to need a re-revision, compared with a primary arthroplasty [3]. Worldwide the figures are expected to increase substantially over the next few years [4].

Patients frequently present for revision with a significant loss of bone stock, and this can be exacerbated during the removal of the old prosthesis [5]. Stabilisation of the revision implant may well require that bone stock is enhanced in key areas, leading to the use of techniques such as allograft bone impaction grafting. The technique was first developed in 1984 by Sloof et al [26] to improve bone stock deficiency in protusio acetabuli and, in 1991, it was adapted by the Exeter group to address femoral bone deficiency [27]. Impaction grafting essentially involves using packed chips of cancellous bone to mitigate the effects of bone loss in revision hip or knee surgery whereby the graft surrounds the revision implant granting it immediate post-operative stability. It has been demonstrated that, when appropriate conditions are met, bone stock can be restored in the long term with the graft being incorporated into the host [28]. Reported clinical outcomes are generally good, however the success rates achieved by the developers of the technique appear to be largely unmatched by other centres [29]. There is long established general agreement that success in allograft impaction grafting is strongly linked to the creation of a favourable mechanical environment, hence the surgical technique and the care with which it is adopted are paramount [30,31]. Future improvement depends upon further understanding of the mechanics of the bone construct and the factors that affect its consolidation and, eventually, remodelling and incorporation into the patient’s own tissue.

(line 60)

Impaction grafting has been demonstrated to be a successful and progressively improving surgical technique at its best producing good long term bony support [6]. However, availability of human allograft bone is an issue, with demand exceeding supply [7,8]. Transmission of disease is also a significant concern [9], as is the degradation of longer term mechanical performance associated with sterilisation techniques such as irradiation [32].

Clinically, this has led to an interest in synthetic graft extenders eg hydroxyapatite [10,11] which may also change to the mechanical environment [12].

The level of availability of human allograft bone has had a significant impact on biomechanical studies exploring impaction grafting. Bovine, porcine and ovine bone have all been investigated as substitutes that can potentially be used in experimental investigations of the mechanical response of morsellised cancellous bone (MCB) [13]. The challenge in mechanical characterisation of morsellised bone is to devise an experimental protocol which separates out the pressure dependent elastic properties from the time dependent viscoelastic and the plastic properties. Methodologies to do this, based on a confined compression testing procedure originating in soil mechanics, have been presented most recently by Phillips et al [14,15] and Lunde et al [16]. In this study, we have used the methodology of Phillips et al [15] and postulate that a synthetic “Sawbones” morsellised bone substitute (Solid Rigid PU Foam, code 30pcf) will exhibit similar mechanical behaviour to the biological based alternatives. 30pcf was chosen as it readily available and falls in the mid-range of the different densities of solid rigid polyurethane foam testing blocks produced by Sawbones and conforming to ASTM F-1839-08 “Standard specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments”.

Experimental investigations into the primary stability of impacted bone graft use variants of the confined compression test to represent physiological loading constraints. Many studies have focussed on the comparison of the effect of a particular parameter e.g. hydraulic and manual driven impaction loading protocols (Putzer et al [33] and size of the morsellised bone particles (Board et al., [34] , Toms et al., [35] , Bolder et al., [36] , Arts et al., [37] , Brewster et al., [38] , Dunlop et al [39]]). Unfortunately, direct comparison of findings across different experimental studies is problematic due to the lack of standardisation in (i) the test configuration (e.g. Butler et al [40] , Lunde et al ([41]), Putzer et al [33], Aquarius et al [42], Bolland et al [43]; (ii) the magnitude and frequency of loading (Bavadekar et al [19], Fosse et al [23], Grimm [18], Voor et al [22]; (iv) the origin and treatment of the bone chips (Cornu et al [20], Datta et al [13], Lunde et al ([44]). One approach that potentially alleviates the difficulties of comparison across studies is to use experimental protocols which enable the bone graft material to be characterised using consolidation models from soil mechanics, such as the Drucker-Prager and Mohr-Coulomb yield criteria. This then offers the possibility of employing computer based stress analysis techniques to help inform experimental and clinical observations (e.g. Phillips et al [45], Lunde & Skallerud [25], Albert et al [46])

(l**Materials and Method**

The testing procedure used in this study was similar to that developed by Phillips et al [15] and subsequently adopted by Lunde at al [16] with minor modifications. This allows for direct comparison with the results obtained in these previous studies.

Testing arrangement:

Confined compression testing was used, where the samples were confined within a die produced from a cylindrical section of mild steel with an internal diameter of 51mm, a wall thickness of 9mm and a length of 100mm (Figure 1). The diameter of the die meant that the size of the bone graft particles would be small in comparison, minimising any interaction between the particles and the die [14,15]. The large wall thickness prevented radial strains from significantly altering the geometry of the cavity during testing. The die was secured to its base plate using three screws threaded through its wall, allowing easy removal of the samples following testing. Loading was applied to the samples through a plunger, rigidly attached to a materials testing machine (Instron, model no. 3360, High Wycombe). The plunger was a solid steel cylinder with a diameter of 50mm. The 1mm clearance allowed between die and plunger was small enough to ensure adequate constraint of the bone graft, whilst minimising interaction between both components.

Specimen preparation:

Polyurethane foam produced by Sawbones (Sawbones, product no. 1522-04, Malmö, Sweden) was used to create a dry morsellised bone substitute material. With a compressive strength of 18MPa and a compressive modulus of 445MPa, in its solid test block form, the material has mechanical properties that are within the range of human cancellous bone. A Norwich bone mill (Howmedica now Stryker, Mahwah, New Jersey USA) was used to create synthetic MCB particles. The morsellised Sawbones particles were passed through a series of sieves to ensure their distribution ranged in size between 1-6mm; visual inspection was used to remove particles larger than 6mm. This size range not only is consistent with that of clinically used particles for femoral impaction grafting [ref d] but it also reduced the risk of edge effects affecting the results. Particle size distribution was not recorded in this study.

Experimental procedure: Elastic and viscoelastic characterisation

Samples were introduced into the die in three roughly equal layers; a 20N static load was applied to each layer for approximately 5 sec in order to standardise the compression applied to each sample at the time of insertion into the die. A standardised loading profile was then applied to each sample in three stages: conditioning, re-loading and unloading. During the conditioning stage, samples were subject to 750 cycles, with each cycle loading the sample to a maximum nominal stress of 3.0MPa and unloading to an minimum nominal stress of 0.01MPa (close to zero). The load was applied at a constant displacement rate of 10mm/min. Time, plunger displacement and load applied to the samples were continually recorded. The aim of this conditioning stage was to ensure that the specimen was very well packed so that subsequent testing at physiological stress level would produce a response which could be assumed completely elastic in nature. Following the conditioning cycles, the plunger was removed from the test chamber and the sample was left to rest for 16 hours while still inside the die. Five samples were then re- loaded to each of six stress levels (0.5, 1.0, 1.5, 2.0, 2.5 and 3.0 MPa), and were left to stress relax by for a period of 6 hours. This was achieved by maintaining the displacement of the plunger constant once the required loading level had been reached and by monitoring the fall in load versus time. Given that the geometry of the sample can be approximated to the internal geometry of the die the decreasing uniaxial compressive stress can be plotted as a function of elapsed time.

Data analysis procedure: Elastic and viscoelastic response.

Data analysis was carried out following the theoretical framework developed by Phillips et al [15] and adopted, with only some slight changes in notation, by Lunde et al [16]. This is briefly described below; wherever possible the same notation as Phillips et al [15] has been adopted.

The equilibrium constrained elastic modulus of MCB (E^{∞}) can be expressed as a linear function the equilibrium of hydrostatic pressure (p^{∞}) [15,16]:

$$\mathrm{E}^{\infty} = \mathrm{c}_1 + \mathrm{c}_2\mathrm{p}^{\infty} \qquad (1)$$

Where c_1 and c_2 are constants, E^{∞} and p^{∞} are the elastic modulus and hydrostatic pressure at $t = \infty$, hence once equilibrium conditions have been reached by the sample.

For uniaxial confined compression, the hydrostatic equilibrium pressure p^{∞} is related to the uniaxial equilibrium stress, σ^{∞}, via a Poisson's ratio, ν:

$$\sigma^{\infty} = p^{\infty}\left(\frac{1}{3} + \frac{2\nu}{3(1-\nu)}\right) \quad (2)$$

For each stress relaxation experiment the uniaxial equilibrium stress, σ_n^{∞}, can be extrapolated. Phillips [17] has shown that, for MCB samples, the instantaneous uniaxial stress, $\sigma_n(t)$, can be described by a modified third order Prony series:

$$\sigma_n(t) = \sigma_n^{\infty} + k_n\left(e^{\frac{-t}{100}} + e^{\frac{-t}{1000}} + e^{\frac{-t}{10000}}\right) \quad (3)$$

where t is the time elapsed and k_n is a constant.

In summary, the elastic behaviour of MCB is characterised by the magnitude of the constants c_1 and c_2; while the viscoelastic behaviour by the parameters σ^{∞} and k.

<u>Testing procedure: Plastic characterisation</u>

Prior to testing, samples of dry bone substitute were packed into the test chamber in 5 roughly equal layers. Following the insertion of each layer, five impactions were applied to each test sample. These impactions were designed to simulate the impaction of the bone graft during surgery and were performed through the use of an impaction rig developed by Grimm [18]. The impaction rig allowed the standardization of the impaction procedure in a way that would not be possible if the samples were impacted by hand. The impaction rig is shown in Figure 2 and consisted of a mass that could be dropped along a guide wire and onto a plunger resting on the dry bone substitute sample. The guide wire was screwed into both the bottom of the test die and the top of the impaction rig. Tensioning the guide wire allowed the mass to pass smoothly over it. A drop-height was selected such that values for momentum and energy of the mass were consistent with the literature [18-23]. Selecting a drop height of 0.28m for a 1.4kg mass produced a momentum of 3.28Ns and energy of 3.85J upon impact with the plunger. After each layer of dry bone substitute was added to the die, the drop height was re-measured such that the momentum and energy supplied to the sample remained constant.

After impacting the dry bone substitute up to a height of 100mm into the die, the guide wire was removed, taking care not to disturb the compacted material. It was noticed that upon removal of the guide wire, a 4mm diameter hole was left in the sample. This hole was not accounted for since the influence of a similar sized hole on a comparable sample of MCB was found to be negligible [16]. The sample was then subjected to 600 cyclic loading cycles applied under uniaxial compression by a plunger rigidly attached to a materials testing machine (Instron, model no. 3360, High Wycombe) at a constant displacement control rate of 10mm/minute. The 600 cyclic loading cycles were applied in twelve sets of 50 cycles. The first 50 cycles had a maximum uniaxial compressive stress of 0.25MPa and a minimum uniaxial compressive stress of 0.01MPa (near zero). The maximum uniaxial compressive stress increased by a further 0.25MPa for each subsequent set of loading cycles, with the twelfth set of loading cycles having a maximum uniaxial compressive stress of 3.0MPa. The minimum uniaxial compressive stress remained at 0.01MPa for each set of loading cycles. After each set of loading cycles, the sample of dry bone substitute was allowed to stress relax for 600 seconds. A flowchart showing the testing procedure is presented in Figure 3. Throughout the testing procedure, the force exhibited by the load cell and extension of the plunger were recorded at a frequency of 2Hz. This resulted in the number of measurements for each cycle being between 50 and 100.

Data analysis procedure: Plastic response.

Phillips et al [15] described the development of axial plastic strain as a function of the axial stress:

$$\sigma = c_3(e^{(c_4 \in_a^p)} - 1) \qquad (4)$$

Where σ is the maximum axial stress to which the series of cycles was subject, $\in_a^p$ is the plastic strain defined as the strain following the 50th load cycle at each of the 12 stress levels and c_3 and c_4 are constants.

In summary, the plastic behaviour of MCB is characterised by the magnitude of the constants c_3 and c_4 .

Results

Elastic and viscoelastic response

The stress decay versus time behaviour of the bone graft substitute material during the relaxation period for each of the 6 loading levels applied in this study is illustrated in Figure 4. Each set of experimental data was fitted with equation (3) to calculate the values of σ_n^∞ and k_n where n=1...5

and represents the number of repetitions of each experiment at each of the 6 load levels adopted in the study. Curve fitting was performed using Matlab R2011b 24 bit (Matworks, USA); in particular the curve fitting tool was set up to take advantage of a non-linear least squares algorithm available within this software package. For each load level, average values for σ^{∞}, k, were calculated from σ_n^{∞} and k_n ; these are presented in Table 1 alongside with the standard error of the mean.

In the present study a value of 0.2 for Poisson's ratio was used in equation (2) to calculate the hydrostatic equilibrium pressure, p^{∞}, at each applied load level given the uniaxial equilibrium stress, σ^{∞}. The relationship between E^{∞} and p^{∞} , equation (1), was determined using a liner regression technique that allowed the effect of uncertainties arising from experimental data to be accounted for. This was achieved by fitting the experimental data points by means of a weighted least square technique, using the reciprocal value of the uncertainty in E^{∞} as the weights and assuming the uncertainty in p^{∞} to be negligible [24]. This allows the determination of the two constants $\boldsymbol{c_1}$ and $\boldsymbol{c_2}$ of equation (1) and the associated standard error (Table 2). The values thus obtained can be compared to those obtained in similar studies [15,16], also reported in Table 2.

<u>Plastic response</u>

The uniaxial confined compressive stress and the uniaxial compressive plastic strain experienced by the Sawbones MCB samples were calculated. The uniaxial compressive plastic strain is defined as the uniaxial compressive plastic strain following the 50th load cycle for each of the twelve stress levels [15]. Therefore, following the completion of the twelve sets of 50 load cycles, twelve distinct values of uniaxial compressive plastic strain at twelve separate uniaxial confined compressive stress levels were obtained (Figure 5).

Each set of experimental data was fitted with equation (4) to calculate the values of c_3 and c_4. Curve fitting was performed using the curve fitting tool using a non-linear least squares algorithm in

Matlab R2011b 24 bit (Matworks, USA). Average values of c_3 and c_4 were then calculated and are reported in Table 3 alongside with the standard error of the mean. The values thus obtained can be compared to those obtained in similar studies [15,16], also reported in Table 3.

Discussion

The present study examined the mechanical behaviour of a sawbones morsellised cancellous bone substitute and compared this with published data for human MCB [16], and bovine MCB [15,16]. The elastic and viscoelastic behaviour compared well, but differences were apparent in the quantification of the plastic response. How significant these differences are is problematic to establish due to the terms of reference of these previous studies: In particular, the study of Phillips et al [15] is of limited value in performing comparisons as only one repetition per experiment was reported, and in the work of Lunde et al [16] the graft particle size is large compared to the loading rig dimensions. Lunde et al [16] also report the early loading behaviour, after one cycle of load. The present study and that of Phillips et al [15] report longer term behaviour.

Further complicating factors in any comparison across studies include the influence of the fat content of the MCB which has been shown to significantly influence the consolidation behaviour [22,25]. The advantage of morsellised sawbones in this regard is in its standardized nature with zero instrinsic fat content, which makes it attractive when attempting to control experimental conditions.

In our study, as in those of Phillips et al [15] and Lunde at al [16], the loading mode is axial consolidation. However, clinically, the effect of torsional loading may well be important.

This was a pilot study providing an initial exploration of mechanical behaviour. There was, therefore, insufficient data to provide a meaningful statistical comparison. Now that we have completed this study, we are in a position to design a statistically relevant experimental protocol for future work. Identification of a good experimental analogue material will allow us to explore the effect of the large number of variables known to influence the mechanical performance of Morsellised cancellous bone eg magnitude and frequency of loading, distribution of particle sizes, graft impaction protocol etc.

Conclusion

This study aimed to establish the mechanical properties of an experimental substitute for morsellised cancellous bone based on Sawbones polyurethane bone chips. Comparison of the mechanical behaviour in confined compression demonstrated agreement with published elastic and viscoelastic properties of natural bone. However, further work is needed to match the plastic response of the construct, and to characterise the behaviour under different loading modes.

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Competing interests: None declared

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Ethical approval: Not required

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Table 1: Summary of the parameters characterising the viscoelastic response of morsellised Sawbones.

Table 2: Comparison of the parameters c_1 and c_2, characterising the elastic response of MCB, obtained in this study and from other studies available in the literature. Please note that the values in parenthesis obtained in this study for Sawbones MCB[1] represent the Standard Error while those presented by Lunde et al [16] for human MCB[2] represent the Standard Deviation.

Table 3: Comparison of the parameters c_3 and c_4 obtained in this study and from other studies available in the literature. Please note that the values in parenthesis obtained in this study for Sawbones MCB[1] represent the Standard Error while those presented by Lunde et al [16] for human MCB[2] represent the Standard Deviation.

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Figure 1

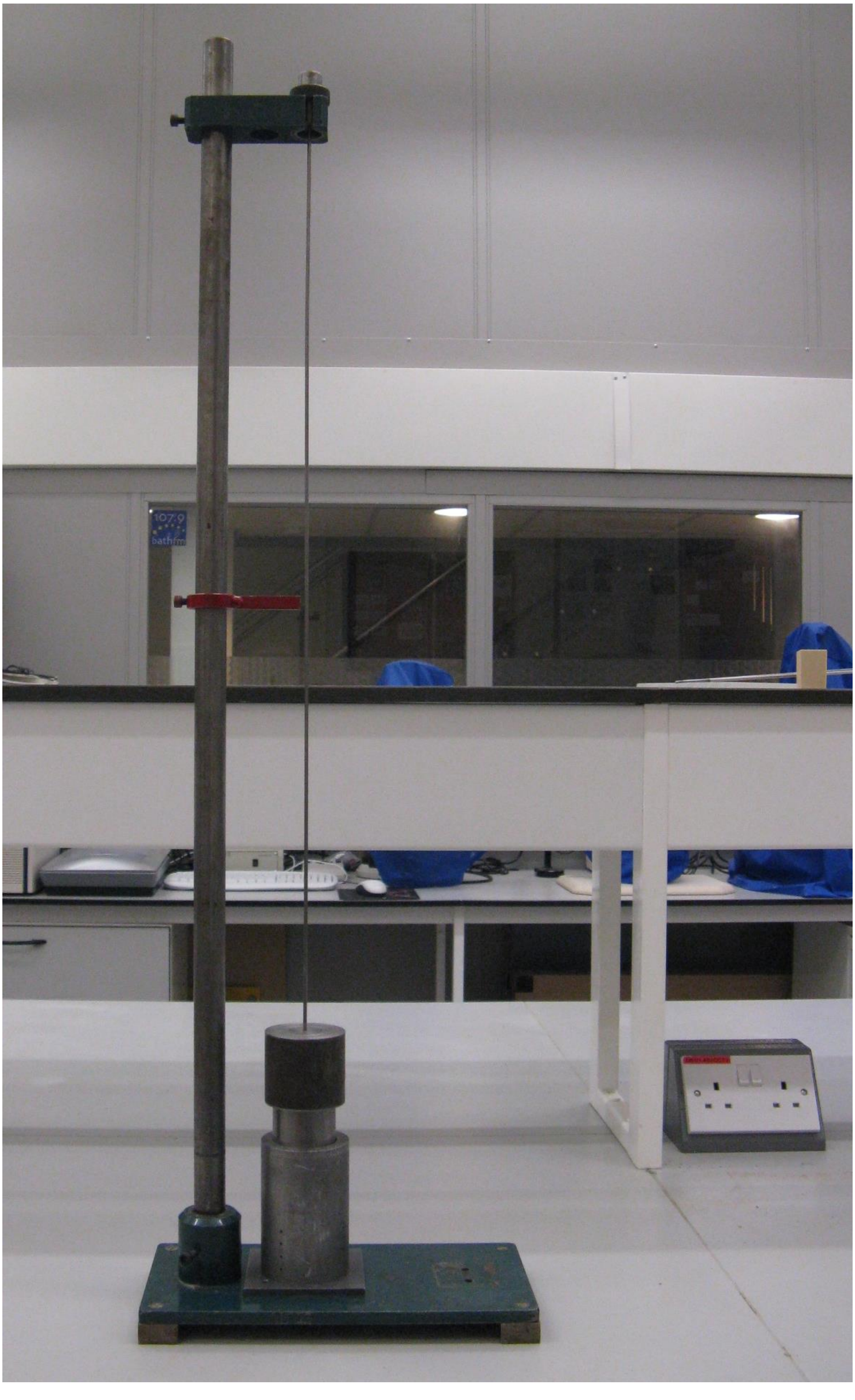


Figure 2

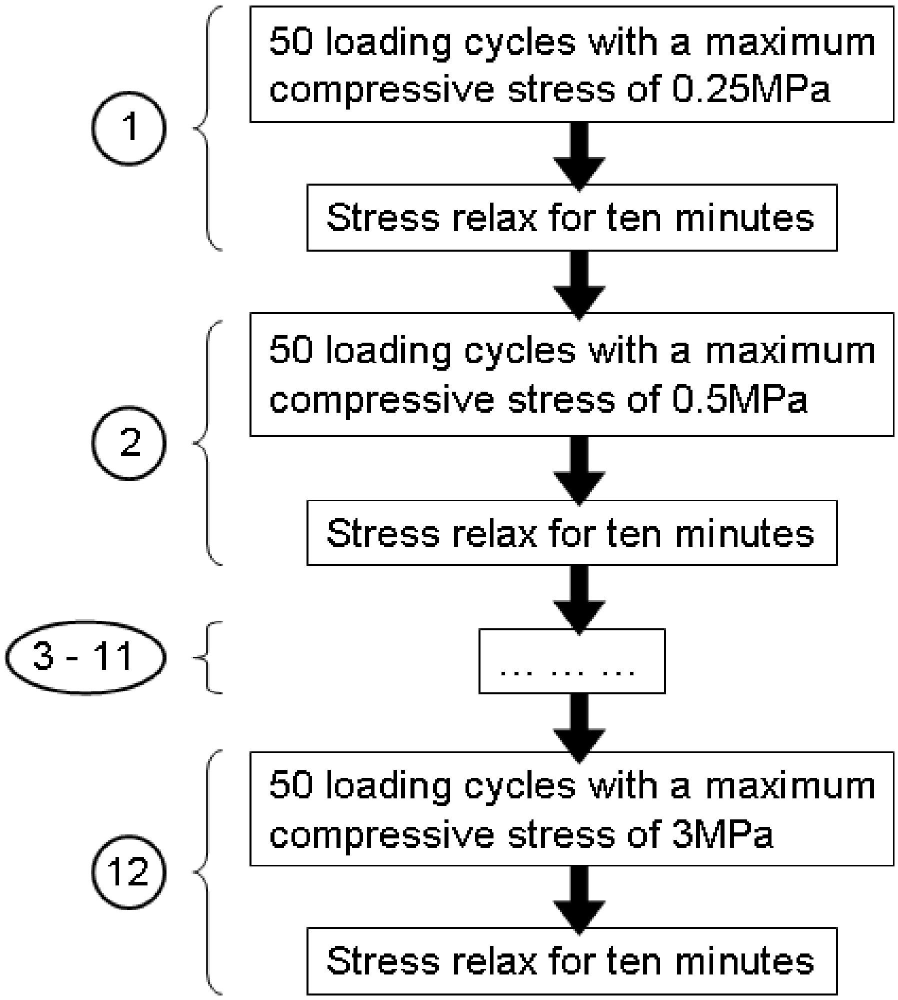

1
50 loading cycles with a maximum compressive stress of 0.25MPa
Stress relax for ten minutes
2
50 loading cycles with a maximum compressive stress of 0.5MPa
Stress relax for ten minutes
3 - 11
… … …
12
50 loading cycles with a maximum compressive stress of 3MPa
Stress relax for ten minutes

Figure 3

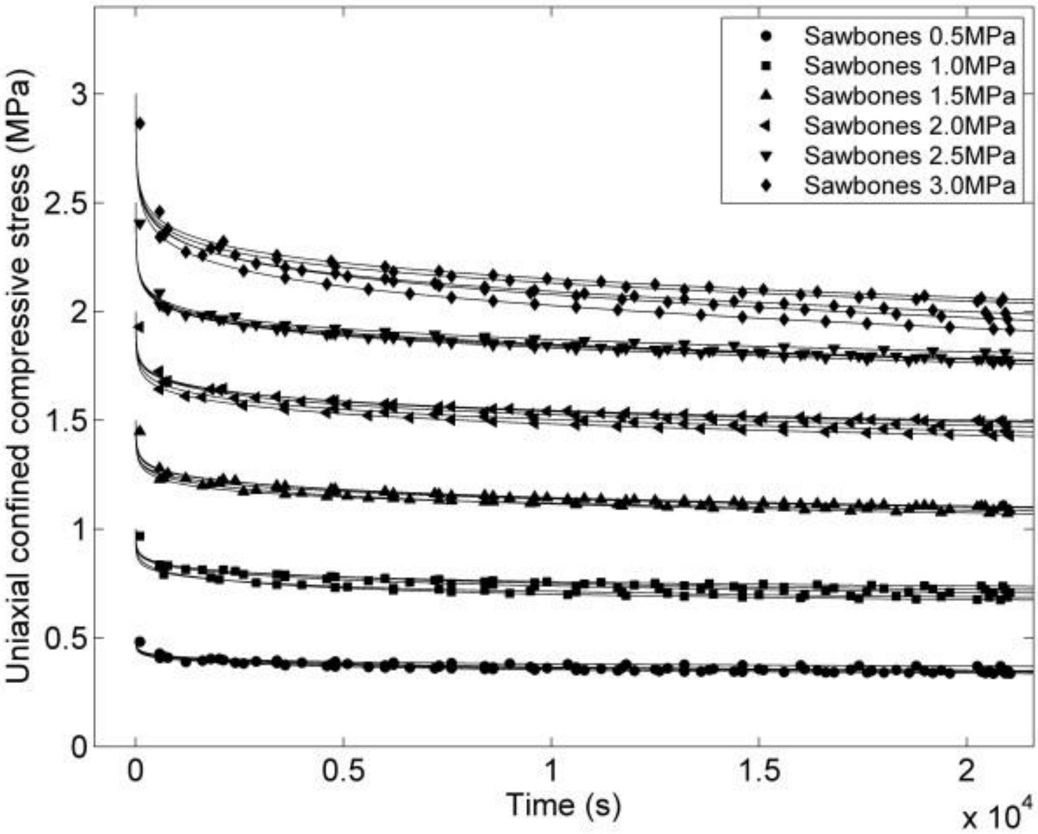
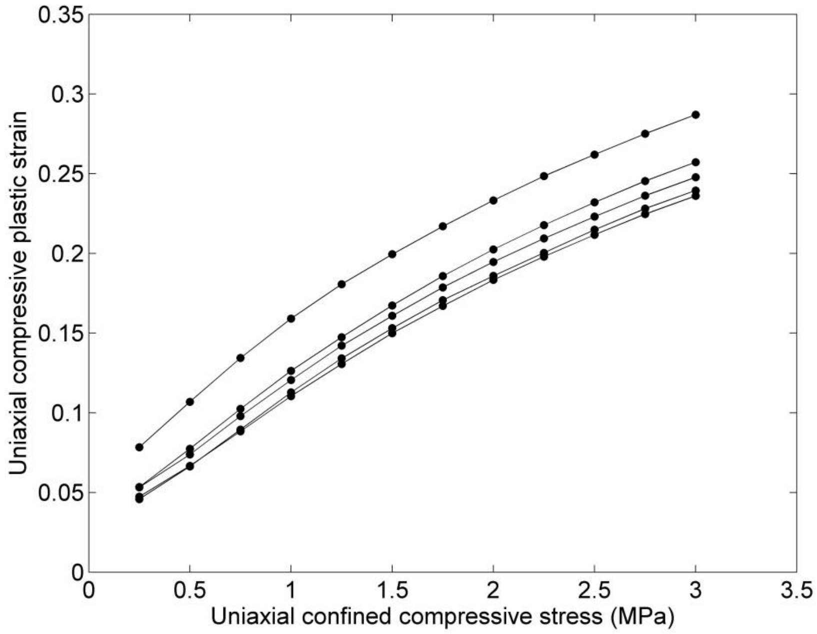

Sawbones 0.5MPa
Sawbones 1.0MPa
Sawbones 1.5MPa
Sawbones 2.0MPa
Sawbones 2.5MPa
Sawbones 3.0MPa
Uniaxial confined compressive stress (MPa)
0
0.5
1
1.5
2
2.5
3
0
0.5
1
1.5
2
Time (s)
x 10^4

Figure 4



0.35
0.3
0.25
0.2
0.15
0.1
0.05
0
0
0.5
1
1.5
2
2.5
3
3.5
Uniaxial compressive plastic strain
Uniaxial confined compressive stress (MPa)

Figure 5

	First period of stress relaxation					
$\boldsymbol{\sigma^0}$	0.5	1.0	1.5	2.0	2.5	3.0
$\boldsymbol{\sigma^\infty}$	**0.3413±0.0065** *0.2937*	**0.6931±0.0117** *0.6296*	**1.0778±0.0060** *0.9430*	**1.4482±0.0129** *1.388*	**1.7626±0.0083** *1.605*	**1.9648±0.0264** *1.969*
$\boldsymbol{k}$	**0.05846±0.00463** *0.04109*	**0.10575±0.00622** *0.06900*	**0.14496±0.00716** *0.1122*	**0.19028±0.00367** *0.1515*	**0.22250±0.00517** *0.2185*	**0.34126±0.01434** *0.2904*

Table 1

Material	**c_1 (N/mm^2)**	**c_2**
Sawbones[1]	6.76(0.45)	14.6(0.58)
Bovine (Phillips et al [15])	3.00	26.64
Human - finger packing (Lunde et al [16])[2]	3.90(0.29)	13.00(0.32)
Human – one layer impaction (Lunde et al [16])[2]	4.10(0.60)	15.20(0.43)
Human – two layer impaction (Lunde et al [16])[2]	5.10(0.10)	13.00(1.16)

Table 2

Material	**c_3 (N/mm^2)**	**c_4**
Sawbones[1]	1.300(0.156)	5.3(0.3)
Bovine (Phillips et al [15])	0.5464	4.9120
Human - finger packing (Lunde et al [16])[2]	0.076(0.018)	10(0.4)
Human – one layer impaction (Lunde et al [16])[2]	0.041(0.008)	18(1.6)
Human – two layer impaction (Lunde et al [16])[2]	0.073(0.015)	17(0.9)

Table 3