13 APPENDIX

	Modulus									Relaxation		Recoil
GRAFT MATERIAL	*1. comp. 0-500N* [MPa]	*SD* [MPa]	*SD* [%]	*2. comp. 0-500N* [MPa]	*SD* [MPa]	*SD* [%]	*2. comp. 0.5-1kN* [MPa]	*SD* [MPa]	*SD* [%]	*from 500N* [%]	*from 1kN* [%]	*from 500N* [%]
HUMAN GRAFT												
Norwich mill fresh	3.65	*0.11*	*3.0*	10.66	*1.38*	*13*	12.02	*0.84*	*7.0*	33.5	32.7	10.6
5 freeze/thaw cycles	3.76	*0.13*	*5.4*	-	-	-	-	-	-	36.9	-	-
Dried	3.66	*0.14*	*3.8*	-	-	-	-	-	-	34.1	-	-
Washed & dried	3.78	*0.21*	*5.4*	10.7	*0.79*	*7.4*	11.97	*0.44*	*3.7*	36.7	36.9	12.5
Formalin fixed	3.68	*0.14*	*3.8*	-	-	-	-	-	-	32.4	-	13.1
Irradiated 2.5MRad	3.87	*0.22*	*5.6*	-	-	-	-	-	-	36.1	-	-
Irradiated 5MRad	3.84	*0.15*	*3.9*	-	-	-	-	-	-	38.5	-	-
Howex mill fine blade	4.04	*0.07*	*1.7*	10.82	*0.39*	*3.6*	15.51	*0.45*	*2.9*	33.8	34.0	13.1
Howex mill coarse	4.14	*0.08*	*1.8*	12.54	*1.12*	*9.0*	13.98	*0.93*	*6.6*	33.1	32.7	11.4
XENOGRAFT												
Ovine fresh from mill	4.22	*0.07*	*1.7*	15.29	*1.73*	*11*	14.63	*0.81*	*5.5*	39.6	40.7	7.7
Ovine washed & dried	3.93	*0.11*	*2.9*	-	-	-	-	-	-		-	-
Ovine formalin fixed	4.27	*0.19*	*4.5*	-	-	-	-	-	-		-	-
Bovine Howex fine	4.51	*0.11*	*3.0*	14.88	*1.24*	*8.4*	18.04	*0.52*	*2.9*	33.4	33.1	8.2
Bovine Howex coarse	4.91	*0.11*	*3.0*	14.78	*1.37*	*9.3*	16.47	*0.65*	*4.0*	32.3	32	7.7
CERAMICS												
0% porosity	29.27	*4.89*	*17*	162.0	*29.7*	*18*	33.4	*7.9*	*24*	19.4	16.5	0.42
25% porosity (Std.)	16.11	*2.17*	*14*	149.9	*31.9*	*21*	17.0	*0.3*	*2*	18.7	17.3	0.77
50% porosity	7.98	*0.82*	*10*	114.5	*32.2*	*28*	15.1	*0.6*	*4*	18.9	16.3	0.10
T_{sint}= 1050°C	10.69	*1.09*	*10*	103.0	*50.7*	*49*	19.5	*1.6*	*8*	18.7	17.1	0.26
T_{sint}= 1200°C	22.78	*5.74*	*25*	186.2	*45.4*	*24*	24.4	*4.3*	*18*	19.3	17.8	0.44
Small	23.18	*2.60*	*11*	130.3	*38.2*	*29*	24.7	*3.9*	*16*	18.9	16.3	0.40
Large	13.68	*2.03*	*15*	109.8	*38.3*	*35*	16.2	*3.1*	*19*	19.0	17.0	0.32
20:80 HA/TCP	14.42	*1.45*	*10*	103.2	*19.2*	*19*	17.0	*1.6*	*10*	19.5	16.8	-
HA, 68% porosity	3.71	-	-	56.5	-	-	12.5	-	-	21.2	21.1	-
BONE/CERAMIC MIX												
2:1 bone/ceramic mix	5.27	*0.33*	*6.2*	19.4	*2.70*	*14*	16.1	*1.37*	*8.5*	27.2	27.6	7.3
1:1 bone/ceramic mix	5.97	*0.18*	*2.9*	23.9	*1.53*	*6.4*	17.6	*0.40*	*2.3*	27.5	27.4	5.0
1:2 bone/ceramic mix	6.99	*0.52*	*7.4*	31.2	*3.99*	*13*	16.4	*0.98*	*6.0*	26.7	26.2	3.1

Table 13.1: *Moduli, relaxation and recoil values during die-plunger compression testing.*

Description	*p* -value	Confidence *i*	Colour-code
Not significant	*p* >0.05	*i* <95%	
Significant	0.01< *p* <0.05	95%> *i* >99%	
Highly significant	0.001< *p*< 0.01	99%> *i* >99.9%	
---	*p* <0.001	*i* > 99.9%	

Table 13.2: *Terminology, p-values, confidence intervals and colour codes for the statistical data analysis using the student t-test.*

		H ffm	H fff	H d	H wd	H fx	H i2.5	H i5.0	H H-c	H H-f	O f	O wd	O fx	B H-f	B H-c
Human fresh from mill	**H ffm**		0.094	0.834	0.171	0.598	0.038	0.023	6.93E-07	3.30E-05	2.95E-07	0.001	2.67E-05	4.55E-09	1.22E-08
Human fresh from frozen	**H fff**	0.094		0.308	0.897	0.281	0.325	0.383	3.86E-05	0.002	1.21E-05	0.035	2.61E-04	9.77E-08	6.45E-08
Human dried	**H d**	0.834	0.308		0.426	0.850	0.193	0.140	1.42E-04	0.002	7.74E-05	0.017	0.003	5.30E-06	2.31E-05
Human washed & dried	**H wd**	0.171	0.897	0.426		0.347	0.486	0.586	0.001	0.024	5.67E-04	0.142	0.003	9.50E-06	1.80E-06
Human fixed	**H fx**	0.598	0.281	0.850	0.347		0.093	0.082	8.08E-06	3.62E-04	3.67E-06	0.005	9.52E-05	5.02E-08	3.83E-08
Human irradiated 2.5	**H i2.5**	0.038	0.325	0.193	0.486	0.093		0.785	0.010	0.119	0.004	0.530	0.009	4.30E-05	4.85E-06
Human irradiated 5.0	**H i5.0**	0.023	0.383	0.140	0.586	0.082	0.785		0.001	0.020	1.97E-04	0.242	0.002	1.65E-06	7.43E-07
Human Howex coarse	**H H-c**	6.93E-07	3.86E-05	1.42E-04	0.001	8.08E-06	0.010	7.13E-04		0.053	0.115	0.003	0.132	5.52E-06	1.14E-06
Human Howex fine	**H H-f**	3.30E-05	0.002	0.002	0.024	3.62E-04	0.119	0.020	0.053		0.002	0.092	0.032	1.70E-06	5.06E-06
Ovine fresh	**O f**	2.95E-07	1.21E-05	7.74E-05	5.67E-04	3.67E-06	0.004	1.97E-04	0.115	0.002		3.740E-04	0.514	3.87E-05	8.59E-06
Ovine washed & dried	**O wd**	7.92E-04	0.035	0.017	0.142	0.005	0.530	0.242	0.003	0.092	3.740E-04		0.005	1.07E-06	8.12E-07
Ovine fixed	**O fx**	2.67E-05	2.61E-04	0.003	0.003	9.52E-05	0.009	0.002	0.132	0.032	0.514	0.005		0.021	3.88E-04
Bovine Howex fine	**B H-f**	4.55E-09	9.77E-08	5.30E-06	9.50E-06	5.02E-08	4.30E-05	1.65E-06	5.52E-06	1.70E-06	3.87E-05	1.07E-06	0.021		0.001
Bovine Howex coarse	**B H-c**	1.22E-08	6.45E-08	2.31E-05	1.80E-06	3.83E-08	4.85E-06	7.43E-07	1.14E-06	5.06E-06	8.59E-06	8.12E-07	3.88E-04	0.001	

Table 13.3: *Student t-test for stiffness modulus during initial 0-500N compression: 0.01<p<0.05: light grey; 0.001<p<0.01: grey; p<0.001: dark grey.*

		H ffm	H fff	H d	H wd	H fx	H i2.5	H i5.0	H H-c	H H-f	O f	O wd	O fx	B H-f	B H-c
Human fresh from mill	**H ffm**		0.034	0.416	0.002	0.053	0.002	1.30E-06	0.446	0.572	1.70E-05	0.051	1.88E-04	0.083	0.087
Human fresh from frozen	**H fff**	0.034		0.233	0.900	0.006	0.643	0.294	0.016	0.068	0.114	0.008	0.002	0.018	0.011
Human dried	**H d**	0.416	0.233		0.033	0.003	0.025	2.54E-06	0.030	0.641	0.002	0.033	4.75E-05	0.014	0.023
Human washed & dried	**H wd**	0.002	0.900	0.033		3.79E-05	0.528	0.022	1.65E-04	0.004	0.013	2.38E-04	1.03E-05	3.42E-04	2.00E-04
Human fixed	**H fx**	0.053	0.006	0.003	3.79E-05		1.29E-05	7.73E-10	0.055	0.006	8.53E-07	0.463	9.82E-05	0.824	0.902
Human irradiated 2.5	**H i2.5**	0.002	0.643	0.025	0.528	1.29E-05		0.001	7.14E-05	0.003	0.003	1.74E-04	2.02E-06	1.47E-04	1.10E-04
Human irradiated 5.0	**H i5.0**	1.30E-06	0.294	2.54E-06	0.022	7.73E-10	0.001		1.56E-09	6.47E-07	0.165	5.65E-07	4.68E-10	7.08E-08	8.47E-08
Human Howex coarse	**H H-c**	0.446	0.016	0.030	1.65E-04	0.055	7.14E-05	1.56E-09		0.104	2.16E-06	0.066	5.83E-06	0.077	0.115
Human Howex fine	**H H-f**	0.572	0.068	0.641	0.004	0.006	0.003	6.47E-07	0.104		4.18E-05	0.017	2.58E-05	0.017	0.021
Ovine fresh	**O f**	1.70E-05	0.114	0.002	0.013	8.53E-07	0.003	0.165	2.16E-06	4.18E-05		8.80E-06	1.44E-06	1.72E-05	6.35E-06
Ovine washed & dried	**O wd**	0.051	0.008	0.033	2.38E-04	0.463	1.74E-04	5.65E-07	0.066	0.017	8.80E-06		0.022	0.638	0.594
Ovine fixed	**O fx**	1.88E-04	0.002	4.75E-05	1.03E-05	9.82E-05	2.02E-06	4.68E-10	5.83E-06	2.58E-05	1.44E-06	0.022		0.001	0.002
Bovine Howex fine	**B H-f**	0.083	0.018	0.014	3.42E-04	0.824	1.47E-04	7.08E-08	0.077	0.017	1.72E-05	0.638	0.001		0.945
Bovine Howex coarse	**B H-c**	0.087	0.011	0.023	2.00E-04	0.902	1.10E-04	8.47E-08	0.115	0.021	6.35E-06	0.594	0.002	0.945	

Table 13.4: *Student t-test for relaxation percentages after initial 0-500N compression: 0.01<p<0.05: light grey; 0.001<p<0.01: grey; p<0.001: dark grey.*

	Standard	0%	50%	Small	Large	20:80	1050C	1200C	HA, 68%
Standard		4.76E-05	5.91E-05	2.37E-04	0.063	0.231	1.83E-04	0.015	1.12E-05
0%	4.76E-05		2.92E-05	0.023	2.90E-05	1.60E-05	3.83E-06	0.061	4.98E-05
50%	5.91E-05	2.92E-05		3.83E-06	7.60E-04	1.12E-04	0.003	0.001	3.12E-04
Small 1-2mm	2.37E-04	0.023	3.83E-06		3.52E-05	3.35E-05	7.57E-07	0.882	4.63E-06
Large 4-6mm	0.063	2.90E-05	7.60E-04	3.52E-05		0.370	9.78E-03	0.004	7.05E-05
20:80 HA/TCP	0.231	1.60E-05	1.12E-04	3.35E-05	0.370		9.26E-04	0.005	1.17E-05
1050C	1.83E-04	3.83E-06	0.003	7.57E-07	9.78E-03	9.26E-04		4.84E-04	1.24E-05
1200C	0.015	0.061	0.001	0.882	0.004	0.005	4.84E-04		8.11E-04
HA, 68% por.	1.12E-05	4.98E-05	3.12E-04	4.63E-06	7.05E-05	1.17E-05	1.24E-05	8.11E-04	

Table 13.5: *Student t-test for ceramic stiffness modulus during initial 0-500N compression: $0.01<p<0.05$: light grey; $0.001<p<0.01$: grey; $p<0.001$: dark grey.*

	Standard	0%	50%	Small	Large	20:80	1050C	1200C	HA, 68%
Standard		0.221	0.741	0.784	0.719	0.324	4.87E-05	8.97E-05	0.033
0%	0.221		0.270	0.223	0.401	0.993	1.36E-04	3.47E-04	0.033
50%	0.741	0.270		0.902	0.975	0.525	7.40E-04	0.002	0.029
Small 1-2mm	0.784	0.223	0.902		0.892	0.411	7.65E-05	1.86E-04	0.016
Large 4-6mm	0.719	0.401	0.975	0.892		0.520	1.53E-04	2.86E-04	0.051
20:80 HA/TCP	0.324	0.993	0.525	0.411	0.520		2.30E-04	3.33E-04	0.150
1050C	4.87E-05	1.36E-04	7.40E-04	7.65E-05	1.53E-04	2.30E-04		0.838	0.066
1200C	8.97E-05	3.47E-04	0.002	1.86E-04	2.86E-04	3.33E-04	0.838		0.089
HA, 68% por.	0.033	0.033	0.029	0.016	0.051	0.150	0.066	0.089	

Table 13.6: *Student t-test for ceramic relaxation after initial 0-500N compression: $0.01<p<0.05$: light grey; $0.001<p<0.01$: grey; $p<0.001$: dark grey.*

	Ovine	Ceramic	2:1 b/c	1:1 b/c	1:2 b/c
Ovine fixed		3.00E-07	3.81E-04	9.10E-08	1.63E-06
Ceramic	3.00E-07		7.12E-07	2.13E-07	7.62E-07
2:1 b/c mix	3.81E-04	7.12E-07		0.001	1.26E-04
1:1 b/c mix	9.10E-08	2.13E-07	0.001		0.001
1:2 b/c mix	1.63E-06	7.62E-07	1.26E-04	0.001	

	Ovine	Ceramic	2:1 b/c	1:1 b/c	1:2 b/c
Ovine fixed		1.64E-09	0.002	0.012	4.47E-06
Ceramic	1.64E-09		2.73E-07	4.47E-10	7.73E-09
2:1 b/c mix	0.002	2.73E-07		0.014	0.381
1:1 b/c mix	0.012	4.47E-10	0.014		3.10E-05
1:2 b/c mix	4.47E-06	7.73E-09	0.381	3.1E-05	

Table 13.7: *Student t-test for b/c graft mixes after initial 0-500N compression (left) and relaxation (right): $0.01<p<0.05$: light grey; $0.001<p<0.01$: grey; $p<0.001$: dark grey.*

Bone				1:1 b/c mix				1:9 b/c mix				
σ [kPa]	61.7	75.3	88.9	**σ [kPa]**	61.7	75.3	88.9	**σ [kPa]**	0.0	61.7	75.3	88.9
τ [kPa]	38.8	42.1	51.5	**τ [kPa]**	66.9	71.7	92.3	**τ [kPa]**	0.0	85.2	103.1	117.5
shear angle α	25			**shear angle α**	43.6			**shear angle α**	53.5			
cohesion c	9			**cohesion c**	5.5			**cohesion c**	0			

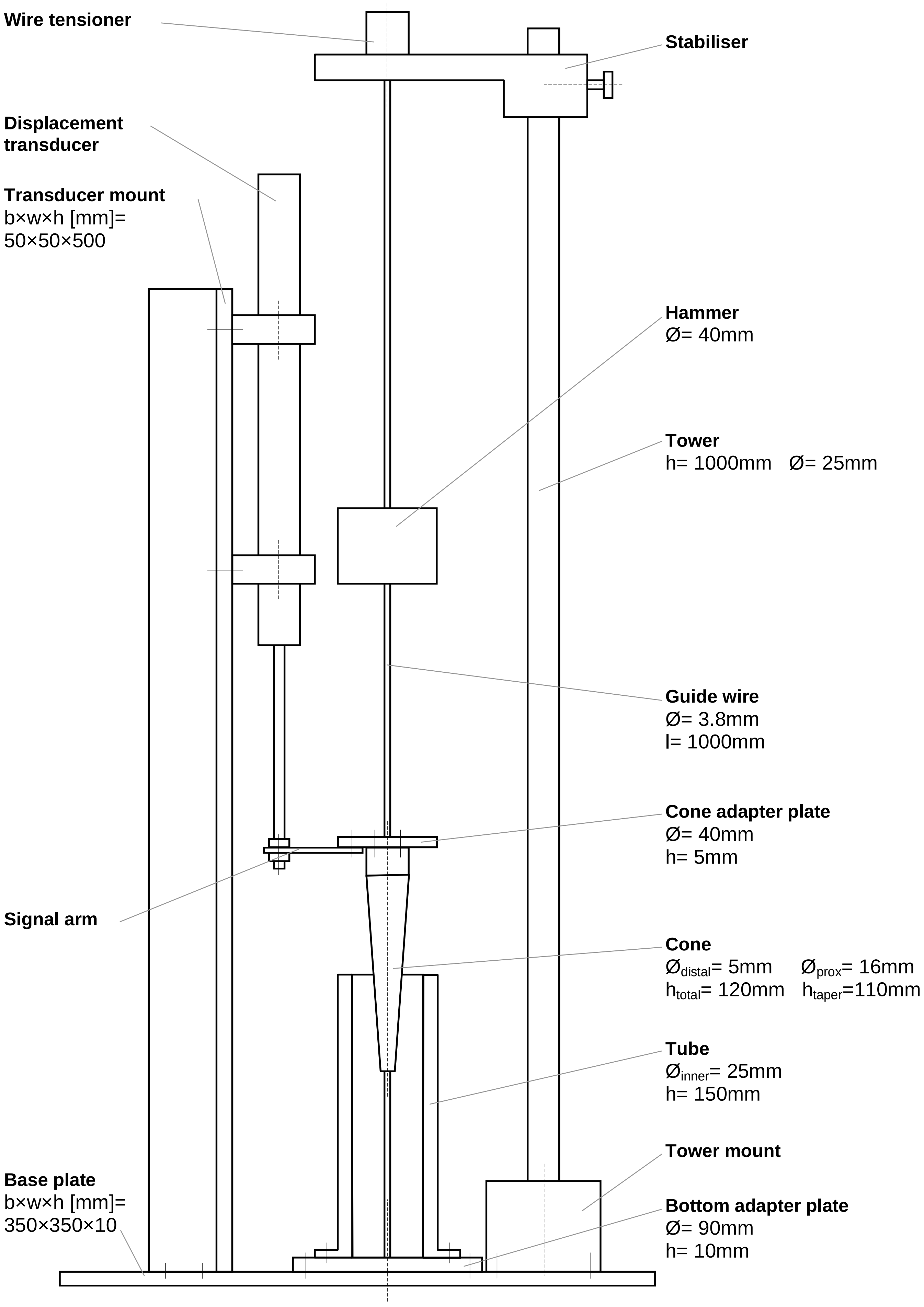
Table 13.8: *Shear box test data.*

	No	Pure ovine bone				No	1:1 bone/ceramic mix				No	1:9 bone/ceramic mix			
F[N]		**200**	**400**	**600**	**800**		**200**	**400**	**600**	**800**		**200**	**400**	**600**	**800**
Subsidence [mm]	**1**	*0.58*	*4.5*	*5.0*	*5.0*	**11**	*0.16*	*0.41*	*0.71*	*1.04*	**21**	*0.04*	*0.09*	*0.13*	*0.17*
	2	*0.12*	*0.25*	*3.14*	*4.12*	**12**	*0.17*	*0.35*	*0.55*	*0.78*	**22**	*0.12*	*0.24*	*0.35*	*0.47*
	3	*0.51*	*4.32*	*5.0*	*5.0*	**13**	*0.10*	*0.20*	*0.32*	*0.47*	**23**	*0.02*	*0.06*	*0.11*	*0.15*
	4	*1.28*	*3.10*	*4.63*	*5.0*	**14**	*0.32*	*0.50*	*0.63*	*0.76*	**24**	*0.14*	*0.25*	*0.31*	*0.40*
	5	*0.12*	*0.27*	*1.76*	*2.31*	**15**	*0.15*	*0.23*	*0.29*	*0.36*	**25**	*0.04*	*0.10*	*0.19*	*0.37*
	6	*0.36*	*1.20*	*2.29*	*3.31*	**16**	*0.06*	*0.14*	*0.24*	*0.37*	**26**	*0.13*	*0.25*	*0.37*	*0.48*
	7	*0.18*	*0.28*	*0.38*	*5.0*	**17**	*0.14*	*0.24*	*0.34*	*0.47*	**27**	*0.30*	*0.39*	*0.44*	*0.57*
	8	*0.10*	*0.22*	*0.31*	*0.41*	**18**	*0.16*	*0.28*	*0.44*	*0.57*	**28**	*0.12*	*0.21*	*0.27*	*0.32*
	9	*0.63*	*2.07*	*3.32*	*4.35*	**19**	*0.09*	*0.16*	*0.22*	*0.30*	**29**	*0.15*	*0.19*	*0.29*	*0.39*
	10	*0.43*	*1.99*	*2.87*	*3.79*	**20**	*0.07*	*0.16*	*0.25*	*0.31*	**30**	*0.06*	*0.13*	*0.22*	*0.29*
Ø [mm]		***0.43***	***1.82***	***2.87***	***3.83***		***0.14***	***0.27***	***0.40***	***0.54***		***0.11***	***0.19***	***0.27***	***0.36***
σ [mm]		*0.36*	*1.68*	*1.72*	*1.49*		*0.07*	*0.12*	*0.18*	*0.24*		*0.08*	*0.10*	*0.11*	*0.13*
σ [%]		*83*	*92*	*60*	*39*		*52*	*45*	*44*	*45*		*73*	*52*	*40*	*37*

Table 13.9: *Ovine stem-tube model subsidence.*

Statistical Analysis: Unpaired one-tailed student t-test				
	***p*-values**			
Load block / **Comparison**	***200N***	***400N***	***600N***	***800N***
1:1 bone/ceramic mix vs pure ovine **bone**	<0.025	<0.010	<0.005	<0.005
1:9 bone/ceramic mix vs pure ovine **bone**	<0.005	<0.005	<0.005	<0.005
1:9 bone/ceramic mix vs **1:1** bone/ceramic mix	n.s.	n.s.	<0.05	<0.05

Table 13.10: *Statistical significance levels for comparisons between subsidence levels for different graft materials.*


Wire tensioner
Stabiliser
Displacement transducer
Transducer mount
b×w×h [mm]= 50×50×500
Hammer
Ø= 40mm
Tower
h= 1000mm Ø= 25mm
Guide wire
Ø= 3.8mm
l= 1000mm
Cone adapter plate
Ø= 40mm
h= 5mm
Signal arm
Cone
$Ø_{distal}$= 5mm $Ø_{prox}$= 16mm
h_{total}= 120mm h_{taper}=110mm
Tube
$Ø_{inner}$= 25mm
h= 150mm
Tower mount
Base plate
b×w×h [mm]= 350×350×10
Bottom adapter plate
Ø= 90mm
h= 10mm

	Force [N]	Cycles	Subs. [mm]	Force [N]	Cycles	Subs. [mm]	Force [N]	Cycles	Subs. [mm]	Force [N]	Cycles	Subs. [mm]
human bone												
6,2J	**S 1**			**S 2**			**S 3**			**S 4**		
	Start	0	-0.0003	Start	0	-0.0032	Start	0	-0.0016			
	0.2	5000	-0.0139	0.2	5000	-0.0163	0.2	5000	-0.0099			
	0.4	10000	-0.0432	0.4	10000	-0.0349	0.4	10000	-0.0429			
	0.6	15000	-4.202	0.6	15000	-1.823	0.6	15000	-4.359			
	0.8	15100	-6.048	0.8	15470	-5.847	0.8	15200	-5.913			
23,35J	**S 1**			**S 2**								
	Start	0	-0.0009	Start	0	-0.0016						
	0.2	5000	0.0009	0.2	5000	-0.0082						
	0.4	10000	0.0004	0.4	10000	-0.0086						
	0.6	15000	-0.0103	0.6	15000	-0.0119						
	0.8	20000	-0.0338	0.8	20000	-0.0353						
	1.0	25000	-0.0887	1.0	25000	-0.093						
	1.2	30000	-3.945	1.2	29360	-5.97						
	1.4	30231	-6.028									
ovine bone												
3,1J	**S 1**			**S 2**			**S 3**					
	Start	0	0	Start	0	0.0006	Start	0	0.0007			
	0.2	5000	-0.0271	0.2	5000	-0.003	0.2	5000	-0.0096			
	0.4	10000	-0.4617	0.4	10000	-0.0146	0.4	10000	-0.0193			
	0.6	10085	-5.617	0.6	15000	-0.0767	0.6	15000	-0.0696			
				0.8	15345	-5.874	0.8	20000	-5.386			
							1.0	20013	-5.86			
6,2J	**S 1**			**S 2**			**S 3**			**S 4**		
	Start	0	-0.002	Start	0	-0.0004	Start	0	-0.0014	Start	0	0.0015
	0.2	5000	-0.0092	0.2	5000	-0.0017	0.2	5000	-0.0171	0.2	5000	0.0119
	0.4	10000	-0.0053	0.4	10000	-0.0009	0.4	10000	-0.0412	0.4	10000	0.0092
	0.6	15000	-0.0154	0.6	15000	-0.0375	0.6	15000	-0.6705	0.6	15000	-0.0072
	0.8	20000	-0.0406	0.8	20000	-1.942	0.8	15425	-5.392	0.8	20000	-0.0699
	1.0	25000	-2.952	1.0	20455	-5.545				1.0	22807	-5.59
	1.2	25405	-5.67									
6,2J	**S 5**			**S 6**			**S 7**					
	Start	0	0.0001	Start	0	-0.0007	Start	0	-0.0003			
	0.2	5000	-0.0183	0.2	5000	-0.0023	0.2	5000	-0.0053			
	0.4	10000	-0.028	0.4	10000	-0.0093	0.4	10000	-0.0268			
	0.6	15000	-0.0783	0.6	15000	-0.0311	0.6	15000	-0.1714			
	0.8	20000	-3.722	0.8	20000	-1.573	0.8	16836	-5.502			
	1.0	20151	-5.866	1.0	21296	-5.847						
9,3J	**S 1**			**S 2**			**S 3**					
	Start	0	0.0002	Start	0	-0.0005	Start	0	-0.0007			
	0.2	5000	0.0082	0.2	5000	-0.0013	0.2	5000	-0.0649			
	0.4	10000	-0.0038	0.4	10000	-0.0012	0.4	10000	-0.0541			
	0.6	15000	-0.0148	0.6	15000	-0.0096	0.6	15000	-0.0637			
	0.8	20000	-0.0301	0.8	20000	-0.0247	0.8	20000	-0.0702			
	1.0	25000	-0.0424	1.0	25000	-0.0753	1.0	25000	-0.0878			
	1.2	30000	-0.6264	1.2	30000	-3.577	1.2	30000	-0.1298			
	1.4	30844	-4.933	1.4	31000	-5.614	1.4	35000	-1.842			
							1.6	36885	-5.974			
23,35J	**S 1**			**S 2**			**S 3**					
	Start	0	0	Start	0	0.0002	Start	0	-0.0026			
	0.2	5000	-0.0048	0.2	5000	0.0224	0.2	5000	-0.0033			
	0.4	10000	-0.004	0.4	10000	0.0116	0.4	10000	0.0159			
	0.6	15000	-0.0071	0.6	15000	0.0188	0.6	15000	0.0079			
	0.8	20000	-0.0127	0.8	20000	0.0091	0.8	20000	-0.0004			
	1.0	25000	-0.0215	1.0	25000	-0.0021	1.0	25000	-0.0101			
	1.2	30000	-0.0368	1.2	30000	-0.0109	1.2	30000	-0.0319			
	1.4	35000	-0.0752	1.4	35000	-0.0272	1.4	35000	-0.1236			
	1.6	40000	-0.0904	1.6	40000	-0.0462	1.6	40000	-1.73			
	1.8	45000	-3.649	1.8	45000	-0.1119	1.8	45000	-4.205			
	2.0	45667	-4.842	2.0	50000	-0.8865	2.0	45590	-5.619			
				2.2	55000	-2.443						
				2.4	60000	-5.393						
				2.6	60059	-5.586						

Table 13.11: *Human tube-cone model subsidence, part 1.*

	Force [N]	Cycles	Subs. [mm]	Force [N]	Cycles	Subs. [mm]	Force [N]	Cycles	Subs. [mm]	Force [N]	Cycles	Subs. [mm]
1:1 mix												
3,1J	**S 1**			**S 2**			**S 3**			**S 4**		
	Start	0	-0.0003	Start	0	0.0001	Start	0	-0.0012	Start	0	-0.0018
	0.2	5000	-0.0006	0.2	5000	-0.0008	0.2	5000	0.0057	0.2	5000	0.0003
	0.4	10000	-0.0126	0.4	10000	-0.0568	0.4	10000	-0.0032	0.4	10000	-0.0045
	0.6	15000	-0.49	0.6	15000	0.0013	0.6	15000	-0.7354	0.6	15000	-0.3584
	0.8	20000	-2.449	0.8	20000	-1.57	0.8	20000	-2.778	0.8	20000	-2.256
	1.0	25000	-5.589	1.0	25000	-4.579	1.0	24851	-5.885	1.0	25000	-5.142
	1.2	25035	-6.129	1.2	25260	-5.472				1.2	25282	-5.84
6,2J	**S 1**			**S 2**			**S 3**			**S 4**		
	Start	0	0.0011	Start	0	-0.0007	Start	0	0.001	Start	0	0.0007
	0.2	5000	0.0041	0.2	5000	-0.0107	0.2	5000	0.0018	0.2	5000	-0.0005
	0.4	10000	0.0121	0.4	10000	-0.0119	0.4	10000	-0.005	0.4	10000	-0.0128
	0.6	15000	0.008	0.6	15000	-0.0195	0.6	15000	-0.0189	0.6	15000	-0.0547
	0.8	20000	-0.0247	0.8	20000	-0.0592	0.8	20000	-0.0613	0.8	20000	-0.4983
	1.0	25000	-0.7525	1.0	25000	-0.6424	1.0	25000	-0.6087	1.0	25000	-1.431
	1.2	30000	-1.807	1.2	30000	-1.688	1.2	30000	-1.657	1.2	30000	-2.713
	1.4	35000	-3.392	1.4	35000	-3.283	1.4	35000	-3.153	1.4	35000	-4.416
	1.6	40000	-5.486	1.6	40000	-5.367	1.6	40000	-5.122	1.6	37289	-5.777
	1.8	40163	-5.882	1.8	40469	-5.75	1.8	40592	-5.711			
6,2J	**S 5**			**S 6**								
	Start	0	0.0003	Start	0	-0.001						
	0.2	5000	0.0056	0.2	5000	-0.0102						
	0.4	10000	0.009	0.4	10000	0.0037						
	0.6	15000	-0.0054	0.6	15000	-0.013						
	0.8	20000	-0.2853	0.8	20000	-0.0686						
	1.0	25000	-1.48	1.0	25000	-0.6963						
	1.2	30000	-3.145	1.2	30000	-1.61						
	1.4	35000	-5.277	1.4	35000	-3.089						
	1.6	35294	-5.8	1.6	40000	-5.281						
				1.8	40463	-5.693						
23,35J	**S 1**			**S 2**			**S 3**			**S 4**		
	Start	0	0.0007	Start	0	-0.0016	Start	0	-0.0007	Start	0	-0.0003
	0.2	5000	0.0077	0.2	5000	-0.005	0.2	5000	0.0197	0.2	5000	0.006
	0.4	10000	0.0156	0.4	10000	0.0015	0.4	10000	0.0204	0.4	10000	0.0115
	0.6	15000	0.0197	0.6	15000	-0.0093	0.6	15000	0.0186	0.6	15000	0.0119
	0.8	20000	0.0063	0.8	20000	-0.011	0.8	20000	0.0161	0.8	20000	0.0092
	1.0	25000	-0.1482	1.0	25000	-0.0279	1.0	25000	0.0047	1.0	25000	-0.0086
	1.2	30000	-0.8914	1.2	30000	-0.5376	1.2	30000	-0.0259	1.2	30000	-0.5366
	1.4	35000	-1.882	1.4	35000	-1.226	1.4	35000	-0.6042	1.4	35000	-1.303
	1.6	40000	-3.352	1.6	40000	-2.232	1.6	40000	-1.229	1.6	40000	-2.354
	1.8	45000	-5.587	1.8	45000	-3.809	1.8	45000	-2.174	1.8	45000	-4.232
	2.0	45240	-5.887	2.0	48994	-5.763	2.0	50000	-3.448	2.0	47010	-5.979
							2.2	55000	-5.191			
							2.4	55585	-5.66			
Vol.-mixes 3,1J												
2:1 b/c	**S 1**			**S 2**			**S 3**			**S 4**		
	Start	0	0	Start	0	0.0029	Start	0	-0.0026	Start	0	-0.0019
	0.2	5000	-0.0202	0.2	5000	0.0027	0.2	5000	-0.0078	0.2	5000	-0.0076
	0.4	10000	-0.2526	0.4	10000	-0.0109	0.4	10000	-0.0287	0.4	10000	-0.0067
	0.6	15000	-1.833	0.6	15000	-0.0669	0.6	15000	-1.46	0.6	15000	-0.1229
	0.8	17600	-5.2572	0.8	20000	-1.793	0.8	20000	-5.426	0.8	20000	-2.205
				1.0	23880	-5.335	1.0	20040	-5.96	1.0	21531	-5.846
2:1 b/c	**S 5**											
	Start	0	-0.0015									
	0.2	5000	-0.0196									
	0.4	10000	-0.0303									
	0.6	15000	-0.7065									
	0.8	20000	-3.291									
	1.0	22040	-5.879									

Table 13.12: *Human tube-cone model subsidence, part 2.*

	Force [N]	Cycles	Subs. [mm]	Force [N]	Cycles	Subs. [mm]	Force [N]	Cycles	Subs. [mm]	Force [N]	Cycles	Subs. [mm]
Vol.-mixes 3,1J												
1:1 b/c	**S 1**			**S 2**			**S 3**			**S 4**		
	Start	0	-0.0003	Start	0	0.0001	Start	0	-0.0012	Start	0	-0.0018
	0.2	5000	-0.0006	0.2	5000	-0.0008	0.2	5000	0.0057	0.2	5000	0.0003
	0.4	10000	-0.0126	0.4	10000	-0.0568	0.4	10000	-0.0032	0.4	10000	-0.0045
	0.6	15000	-0.49	0.6	15000	0.0013	0.6	15000	-0.7354	0.6	15000	-0.3584
	0.8	20000	-2.449	0.8	20000	-1.57	0.8	20000	-2.778	0.8	20000	-2.256
	1.0	25000	-5.589	1.0	25000	-4.579	1.0	24851	-5.885	1.0	25000	-5.142
	1.2	25035	-6.129	1.2	25280	-5.472				1.2	25282	-5.8465
1:2 b/c	**S 1**			**S 2**			**S 3**					
	Start	0	0.0009	Start	0	0.004	Start	0	-0.0012			
	0.2	5000	-0.0068	0.2	5000	-0.0021	0.2	5000	-0.004			
	0.4	10000	-0.0103	0.4	10000	0.0033	0.4	10000	-0.0497			
	0.6	15000	-0.5996	0.6	15000	-0.3091	0.6	15000	-0.9228			
	0.8	20000	-2.583	0.8	20000	-1.448	0.8	20000	-2.607			
	1.0	21663	-5.479	1.0	25000	-4.255	1.0	25000	-5.532			
				1.2	27596	-5.943	1.2	25208	-6			
Vol.-mixes 6,2J												
ceramic	**S 1**			**S 2**			**S 3**			**S 4**		
	Start	0	-0.0013	Start	0	-0.0013	Start	0	-0.0005	Start	0	-0.0009
	0.2	5000	0.0021	0.2	5000	-0.0083	0.2	5000	-0.0601	0.2	5000	-0.0085
	0.4	10000	0.0046	0.4	10000	0.0019	0.4	10000	-0.0022	0.4	10000	-0.0072
	0.6	15000	-0.1138	0.6	15000	-0.0115	0.6	15000	-0.0454	0.6	15000	-0.2223
	0.8	20000	-0.6358	0.8	20000	-0.6389	0.8	20000	-0.5392	0.8	20000	-0.8346
	1.0	25000	-1.338	1.0	25000	-1.451	1.0	25000	-1.178	1.0	25000	-1.637
	1.2	30000	-2.113	1.2	30000	-2.344	1.2	30000	-1.853	1.2	30000	-2.448
	1.4	35000	-3.006	1.4	35000	-3.298	1.4	35000	-2.677	1.4	35000	-3.356
	1.6	40000	-4.031	1.6	40000	-4.373	1.6	40000	-3.582	1.6	40000	-4.315
	1.8	45000	-5.012	1.8	45000	-5.468	1.8	45000	-4.428	1.8	45000	-5.358
	2.0	50000	-5.783	2.0	45794	-5.895	2.0	50000	-5.333	2.0	47330	-5.787
							2.2	51384	-5.804			
2:1 b/c	**S 1**			**S 2**			**S 3**					
	Start	0	-0.0006	Start	0	0.0003	Start	0	0			
	0.2	5000	0.0134	0.2	5000	0.0144	0.2	5000	-0.005			
	0.4	10000	0.0233	0.4	10000	0.0065	0.4	10000	-0.0046			
	0.6	15000	0.0139	0.6	15000	-0.0338	0.6	15000	-0.0564			
	0.8	20000	-0.1392	0.8	20000	-1	0.8	20000	-0.1792			
	1.0	25000	-1.299	1.0	25000	-3.526	1.0	25000	-5.112			
	1.2	30000	-3.61	1.2	27741	-6.181	1.2	25240	-5.946			
	1.4	31296	-5.5382									
1:1 b/c	**S 1**			**S 2**			**S 3**			**S 4**		
	Start	0	0.0011	Start	0	-0.0007	Start	0	0.001	Start	0	0.0007
	0.2	5000	0.0041	0.2	5000	-0.0107	0.2	5000	0.0018	0.2	5000	-0.0005
	0.4	10000	0.0121	0.4	10000	-0.0119	0.4	10000	-0.005	0.4	10000	-0.0128
	0.6	15000	0.008	0.6	15000	-0.0195	0.6	15000	-0.0189	0.6	15000	-0.0547
	0.8	20000	-0.0247	0.8	20000	-0.0592	0.8	20000	-0.0613	0.8	20000	-0.4983
	1.0	25000	-0.7525	1.0	25000	-0.6424	1.0	25000	-0.6087	1.0	25000	-1.431
	1.2	30000	-1.807	1.2	30000	-1.688	1.2	30000	-1.657	1.2	30000	-2.713
	1.4	35000	-3.392	1.4	35000	-3.283	1.4	35000	-3.153	1.4	35000	-4.416
	1.6	40000	-5.486	1.6	40000	-5.367	1.6	40000	-5.122	1.6	37289	-5.777
	1.8	40163	-5.882	1.8	40469	-5.75	1.8	40592	-5.711			
1:2 b/c	**S 1**			**S 2**			**S 3**			**S 4**		
	Start	0	0.0003	Start	0	0.0002	Start	0	-0.0167	Start	0	-0.0003
	0.2	5000	0.0056	0.2	5000	0.0107	0.2	5000	-0.0091	0.2	5000	-0.0012
	0.4	10000	0.0094	0.4	10000	0.0174	0.4	10000	-0.0091	0.4	10000	-0.0051
	0.6	15000	0.001	0.6	15000	0.0141	0.6	15000	-0.0205	0.6	15000	-0.3763
	0.8	20000	-0.7384	0.8	20000	-0.4966	0.8	20000	0.5	0.8	20000	-1.168
	1.0	25000	-2.125	1.0	25000	-1.632	1.0	25000	-1.6582	1.0	25000	-2.519
	1.2	30000	-4.606	1.2	30000	-3.561	1.2	30000	-3.5853	1.2	30000	-4.514
	1.4	31481	-5.899	1.4	34662	-5.939	1.4	34660	-5.977	1.4	31663	-5.963

Table 13.13*: Human tube-cone model subsidence, part 3.*

	Force [N]	Cycles	Subs. [mm]	Force [N]	Cycles	Subs. [mm]	Force [N]	Cycles	Subs. [mm]	Force [N]	Cycles	Subs. [mm]
porosity in mix												
0%	**S 1**			**S 2**			**S 3**					
	Start	0	-0.0003	Start	0	0.0169	Start	0	-0.002			
	0.2	5000	0.0083	0.2	5000	0.0019	0.2	5000	0.0031			
	0.4	10000	0.0176	0.4	10000	-0.0019	0.4	10000	0.0052			
	0.6	15000	0.0194	0.6	15000	-0.0163	0.6	15000	0.011			
	0.8	20000	0.0005	0.8	20000	-0.0876	0.8	20000	-0.374			
	1.0	25000	-0.4746	1.0	25000	-0.9074	1.0	25000	-1.468			
	1.2	30000	-1.2450	1.2	30000	-2.1789	1.2	30000	-2.88			
	1.4	35000	-2.4450	1.4	35000	-4.6194	1.4	35000	-5.043			
	1.6	40000	-4.263	1.6	36960	-5.6626	1.6	35912	-5.885			
	1.8	42260	-5.7060									
25%	**S 1**			**S 2**			**S 3**			**S 4**		
	Start	0	0.0011	Start	0	-0.0007	Start	0	0.001	Start	0	0.0007
	0.2	5000	0.0041	0.2	5000	-0.0107	0.2	5000	0.0018	0.2	5000	-0.0005
	0.4	10000	0.0121	0.4	10000	-0.0119	0.4	10000	-0.005	0.4	10000	-0.0128
	0.6	15000	0.0080	0.6	15000	-0.0195	0.6	15000	-0.0189	0.6	15000	-0.0547
	0.8	20000	-0.0247	0.8	20000	-0.0592	0.8	20000	-0.0613	0.8	20000	-0.4983
	1.0	25000	-0.7525	1.0	25000	-0.6424	1.0	25000	-0.6087	1.0	25000	-1.431
	1.2	30000	-1.8070	1.2	30000	-1.688	1.2	30000	-1.657	1.2	30000	-2.713
	1.4	35000	-3.3920	1.4	35000	-3.283	1.4	35000	-3.153	1.4	35000	-4.416
	1.6	40000	-5.4860	1.6	40000	-5.367	1.6	40000	-5.122	1.6	37289	-5.777
	1.8	40163	-5.8820	1.8	40469	-5.75	1.8	40592	-5.711			
	S 5			**S 6**								
	Start	0	0.0003	Start	0	-0.001						
	0.2	5000	0.0056	0.2	5000	-0.0102						
	0.4	10000	0.009	0.4	10000	0.0037						
	0.6	15000	-0.0054	0.6	15000	-0.013						
	0.8	20000	-0.2853	0.8	20000	-0.0686						
	1.0	25000	-1.48	1.0	25000	-0.6963						
	1.2	30000	-3.145	1.2	30000	-1.61						
	1.4	35000	-5.277	1.4	35000	-3.089						
	1.6	35294	-5.8	1.6	40000	-5.281						
				1.8	40463	-5.693						
50%	**S 1**			**S 2**			**S 3**					
	Start	0	-0.0006	Start	0	0.0001	Start	0	0.0007			
	0.2	5000	0.0029	0.2	5000	-0.0012	0.2	5000	0.0016			
	0.4	10000	-0.006	0.4	10000	-0.0148	0.4	10000	0.0083			
	0.6	15000	-0.4587	0.6	15000	-0.3168	0.6	15000	-0.0022			
	0.8	20000	-2.064	0.8	20000	-1.815	0.8	20000	-0.4089			
	1.0	25000	-5.065	1.0	25000	-4.821	1.0	25000	-1.623			
	1.2	25181	-5.638	1.2	25490	-5.927	1.2	30000	-4.01			
							1.4	31126	-5.914			
Tsint in mix												
1050C	**S 1**			**S 2**			**S 3**					
	Start	0	0	Start	0	0.0004	Start	0	-0.0024			
	0.2	5000	0.0081	0.2	5000	0.0098	0.2	5000	0.0045			
	0.4	10000	0.012	0.4	10000	-0.0099	0.4	10000	-0.0166			
	0.6	15000	-0.0023	0.6	15000	-0.4906	0.6	15000	-0.8202			
	0.8	20000	-0.366	0.8	20000	-2.397	0.8	20000	-3.846			
	1.0	25000	-1.592	1.0	21586	-5.869	1.0	20395	-6.076			
	1.2	30000	-3.432									
	1.4	33006	-5.547									
1200C	**S 1**			**S 2**			**S 3**					
	Start	0	0.0008	Start	0	-0.0002	Start	0	0.0008			
	0.2	5000	0.005	0.2	5000	-0.0011	0.2	5000	0.0050			
	0.4	10000	0.0102	0.4	10000	-0.0116	0.4	10000	0.0019			
	0.6	15000	-0.0103	0.6	15000	0.0023	0.6	15000	-0.0301			
	0.8	20000	-0.1967	0.8	20000	-0.0333	0.8	20000	-0.3933			
	1.0	25000	-0.8778	1.0	25000	-0.5897	1.0	25000	-1.4910			
	1.2	30000	-1.7	1.2	30000	-1.432	1.2	30000	-2.9200			
	1.4	35000	-2.868	1.4	35000	-2.69	1.4	35000	-4.7010			
	1.6	40000	-4.795	1.6	40000	-4.367	1.6	36608	-5.9010			
	1.8	42900	-5.868	1.8	45000	-5.838						

Table 13.14: *Human tube-cone model subsidence, part 4.*

	Force [N]	Cycles	Subs. [mm]	Force [N]	Cycles	Subs. [mm]	Force [N]	Cycles	Subs. [mm]	Force [N]	Cycles	Subs. [mm]
size in mix												
1-2mm	**S 1**			**S 2**			**S 3**			**S 4**		
	Start	0	0	Start	0	-0.0005	Start	0	0.0009	Start	0	-0.0036
	0.2	5000	-0.0033	0.2	5000	-0.0083	0.2	5000	-0.0119	0.2	5000	-0.0152
	0.4	10000	0.0034	0.4	10000	-0.0124	0.4	10000	-0.0431	0.4	10000	-0.012
	0.6	15000	-0.0072	0.6	15000	-0.07	0.6	15000	-0.6522	0.6	15000	-0.0398
	0.8	20000	-0.3601	0.8	20000	-0.8317	0.8	20000	-1.945	0.8	20000	-0.6055
	1.0	25000	-1.34	1.0	25000	-2.123	1.0	25000	-3.918	1.0	25000	-1.73
	1.2	30000	-2.796	1.2	30000	-4.09	1.2	26665	-5.692	1.2	30000	-3.423
	1.4	35000	-4.589	1.4	31194	-5.444				1.4	34565	-5.585
	1.6	35793	-5.223									
4-6.3mm	**S 1**			**S 2**			**S 3**					
	Start	0	0.0004	Start	0	-0.0003	Start	0	0.0007			
	0.2	5000	-0.0061	0.2	5000	-0.0029	0.2	5000	0.0019			
	0.4	10000	-0.0228	0.4	10000	-0.0087	0.4	10000	0.015			
	0.6	15000	-0.1087	0.6	15000	-0.0188	0.6	15000	-0.005			
	0.8	20000	-0.8549	0.8	20000	-0.1815	0.8	20000	-0.5714			
	1.0	25000	-1.922	1.0	25000	-1.014	1.0	25000	-1.85			
	1.2	30000	-3.69	1.2	30000	-2.111	1.2	30000	-3.577			
	1.4	35000	-5.59	1.4	35000	-4.476	1.4	33195	-5.774			
				1.6	35531	-5.338						
comp. in mix												
20:80 HA/TCP	**S 1**			**S 2**			**S 3**					
	Start	0	0	Start	0	-0.0003	Start	0	-0.0023			
	0.2	5000	-0.0021	0.2	5000	0.0109	0.2	5000	0.001			
	0.4	10000	-0.0044	0.4	10000	0.0067	0.4	10000	0.0069			
	0.6	15000	-0.0203	0.6	15000	-0.0079	0.6	15000	0.0065			
	0.8	20000	-0.2411	0.8	20000	-0.0833	0.8	20000	-0.1981			
	1.0	25000	-1.215	1.0	25000	-0.9561	1.0	25000	-1.585			
	1.2	30000	-2.901	1.2	30000	-2.402	1.2	30000	-4.374			
	1.4	35000	-5.344	1.4	35000	-5.81	1.4	31155	-5.956			
	1.6	35164	-5.593	1.6	35038	-6.078						
impaction force												
very low	**S 1**											
16*6,5	Start	0	0.0007									
	0.2	5000	0.0044									
	0.4	10000	0.0077									
	0.6	15000	-0.0013									
	0.8	20000	-0.533									
	1.0	25000	-3.112									
	1.2	26219	-5.523									
low	**S 1**			**S 2**			**S 3**					
8*13	Start	0	0.0004	Start	0	0.0001	Start	0	-0.0033			
	0.2	5000	0.0193	0.2	5000	0.0048	0.2	5000	0.0062			
	0.4	10000	0.0242	0.4	10000	0	0.4	10000	-0.0055			
	0.6	15000	0.0002	0.6	15000	-0.0393	0.6	15000	-0.205			
	0.8	20000	-0.6001	0.8	20000	-1.364	0.8	20000	-2.041			
	1.0	25000	-2.807	1.0	25000	-4.143	1.0	25000	-5.198			
	1.2	30000	-5.263	1.2	25808	-5.951	1.2	25057	-5.507			
	1.4	30160	-5.7308									
high	**S 1**			**S 2**			**S 3**					
2*56	Start	0	-0.0006	Start	0	-0.001	Start	0	-0.0031			
	0.2	5000	0.0049	0.2	5000	-0.027	0.2	5000	-0.0135			
	0.4	10000	0.0035	0.4	10000	-0.0233	0.4	10000	-0.0197			
	0.6	15000	0.0022	0.6	15000	-0.0333	0.6	15000	-0.0245			
	0.8	20000	-0.661	0.8	20000	-0.4414	0.8	20000	-0.4482			
	1.0	25000	-2.065	1.0	25000	-1.727	1.0	25000	-1.368			
	1.2	30000	-4.299	1.2	30000	-3.714	1.2	30000	-2.835			
	1.4	31798	-5.927	1.4	33495	-5.747	1.4	35000	-4.889			
							1.6	35947	-5.823			

Table 13.15: *Human tube-cone model subsidence, part 5.*

	Force [N]	Cycles	Subs. [mm]	Force [N]	Cycles	Subs. [mm]	Force [N]	Cycles	Subs. [mm]	Force [N]	Cycles	Subs. [mm]
HA 68% mixes												
2:1 b/c	S 1			S 2			S 3					
	Start	0	0.0005	Start	0	0.0007	Start	0	-0.0017			
	0.2	5000	-0.0007	0.2	5000	-0.0115	0.2	5000	-0.009			
	0.4	10000	-0.0096	0.4	10000	-0.0346	0.4	10000	-0.0259			
	0.6	15000	-0.055	0.6	15000	-0.9748	0.6	15000	-0.6922			
	0.8	20000	-1.679	0.8	20000	-4.716	0.8	20000	-3.817			
	1.0	20990	-5.975	1.0	20146	-5.821	1.0	20154	-5.834			
1:1 b/c	S 1			S 2			S 3					
	Start	0	0.001	Start	0	0.0007	Start	0	0.002			
	0.2	5000	0.001	0.2	5000	0.0026	0.2	5000	0.0119			
	0.4	10000	-0.3715	0.4	10000	-0.0415	0.4	10000	-0.0292			
	0.6	15000	-2.511	0.6	15000	-1.612	0.6	15000	-1.443			
	0.8	16265	-6.01	0.8	20000	-5.895	0.8	20000	-5.906			
				1.0	20043	-6.216	1.0	20042	-6.028			
1:2 b/c	S 1			S 2			S 3					
	Start	0	-0.0012	Start	0	0.0014	Start	0	-0.0002			
	0.2	5000	-0.0161	0.2	5000	-0.0856	0.2	5000	-0.0099			
	0.4	10000	-0.6849	0.4	10000	-1.891	0.4	10000	0.0007			
	0.6	15000	-3.462	0.6	15000	-5.512	0.6	15000	-4.619			
	0.8	15264	-5.788	0.8	15021	-5.659	0.8	15138	-6.007			
1:1 b/c at 23.35												
	S 1											
	Start	0	0.0003									
	0.2	5000	0.0162									
	0.4	10000	0.018									
	0.6	15000	-0.037									
	0.8	20000	-0.746									
	1.0	25000	-2.2									
	1.2	30000	-5.164									
	1.4	30500	-6.095									

Table 13.16: *Human tube-cone model subsidence, part 6.*

List of publications

- **Journal publications:**

1 Grimm B., Miles A.W., Turner I.G. Optimizing a hydroxyapatite/ricalcium-phosphate ceramic as a Bone Graft Extender for impaction grafting. Journal of Materials Science: Materials in Medicine 2001; 12:929-34

2 Grimm B., Miles A.W., Turner I.G. Hydroxyapatite/Tricalcium-Phosphate as a bone graft extender for Impaction Grafting revision hip surgery. J Bone Joint Surg, Orthopaedic Proceedings; Suppl II, 83-B, 190, 2001, 191 *Notes: Presented 5th Congress European Fed. of National Assoc. of Orthopaedics and Traumatology 4.-7.06.2001, Rhodes, Greece*

3 Blom A.W., Grimm B., Miles A.W., Cunningham J.L. Mechanical studies on a ceramic bone graft substitute for use in revision total hip arthroplasty, J Bone Joint Surg, Orthopaedic Proceedings, Suppl II, 83-B, 2001, 204 *Notes: Presented 5th Congress European Fed. of National Assoc. of Orthopaedics and Traumatology 4.-7.06.2001, Rhodes, Greece*

4 Grimm B., Blom A.W., Miles A.W., Turner I.G. *In-Vitro* Endurance Testing of Bone Graft Materials for Impaction Grafting. Key Engineering Materials 2002; 218-220: 375 8

5 Blom A.W, Grimm B., Cunningham J., Miles A.W., Learmonth I.D. *In-Vitro* Testing of BoneSave, a Ceramic Bone Graft Substitute for Use in Impaction Grafting. Key Engineering Materials 2002; 218-220: 417-420

6 Blom A.W., Grimm B., Miles A.W., Cunningham J., Learmonth I.D. Subsidence in impaction grafting. The effect of adding a ceramic bone graft substitute. Journal of Engineering in Medicine Part H Jul 2002; 216 (4): 265-70

7 Gozzard C., Grimm B., Miles A.W., Learmonth I.D. The effect of preparatory technique on the compressive properties of morsellised bone graft. Hip International 2002; 12 (2): 116-8

- **Conference presentations**

8 Grimm B., Sandford G.C., Lee J.R., Miles A.W., Turner I.G. Mechanical properties of morsellised bone graft and synthetic substitutes for Impaction Grafting Total Hip revision, 6th Hawaii World Biomaterials Conference, 15.05.-20.05.2000, Hawaii, USA

9 Grimm B., Miles A.W., Turner I.G. Influence of bone graft parameters on the stability of impaction grafting revision hip arthroplasty, 1st Conf UK Soc for Biomaterials, 7.7.2000, London

10 Grimm B., Miles A.W., Turner I.G. In-vitro analysis of initial mechanical stability of morsellised bone grafts and extenders for Impaction Grafting. 4th Comb. Meeting Orthopaedic Research Soc. of USA, Canada, Europe and Japan, 1-3.06.2001, Rhodes, Greece

11 Grimm B., Miles A.W., Turner I.G. Mechanical Testing of a Hydroxyapatite/Tricalcium-Phosphate ceramic for the Development of a Bone Graft Extender in Impaction Grafting, UKSB Student Conference 2001, Birmingham, U.K.

12 Grimm B., Miles A.W., Turner I.G. Optimising a Hydroxyapatite/Tricalcium-Phosphate ceramic as a Bone Graft Extender for Impaction Grafting. 16th Comb. European Society of Biomaterials Conference, 12.-14.09.2001, London, U.K.

13 Grimm B., Blom A.W., Miles A.W., Turner I.G. In-Vitro Endurance Testing of Bone Graft Materials for Impaction Grafting 14th Int. Symposium on Ceramics in Medicine (Bioceramics 14), November 14–17.2001Palm Springs, USA

14 Blom A.W, Grimm B., Cunningham J., Miles A.W., Learmonth I.D. In-Vitro Testing of BoneSave, a Ceramic Bone Graft Substitute for Use in Impaction Grafting. 14th Int. Symposium on Ceramics in Medicine (Bioceramics 14), November 14–17.2001Palm Springs, USA

15 Grimm B., Gozzard C., Miles A.W., Turner I.G. Compression testing of bone grafts for Impaction Grafting. 48th Annual Meeting Orthop. Res. Soc. 2002, February 2002, Dallas, USA

16 Grimm B., Gozzard C., Miles A.W., Turner I.G. Compression properties of morsellised bone grafts and synthetic alternatives for Impaction Grafting 13th Conference European Society of Biomechanics, 1.-4.9.2002, Wroclaw, Poland

17 Grimm B., Gozzard C., Miles A.W., Turner I.G. Comparing compression properties of bone grafts, ceramic grafts and graft mixes for Impaction Grafting. 17th European Society of Biomaterials Conference, 11.-14.09.2002, Barcelona, Spain

18 Grimm B., Miles A.W., Turner I.G. Measurement of impaction quality and correlation with stability in Impaction Grafting. 49th Annual Meeting Orthop. Res. Soc. 2003, February 2003, New Orleans, USA

1 Journal of Materials Science: Materials in Medicine 12 (2001) 929-934

Optimizing a hydroxyapatite/tricalcium-phosphate ceramic as a Bone Graft Extender for Impaction Grafting

B. GRIMM, A.W. MILES
Dept Mechanical Engineering, University of Bath, Claverton Down, Bath, BA2 7AY

I.G. TURNER
Dept Engineering & Applied Science, University of Bath, Claverton Down, Bath, BA2 7AY

The mechanical properties of morsellised bone allografts and synthetic hydroxapatite/tricalcium-phosphate ceramic extender materials for the use in Impaction Grafting revision hip surgery were investigated using two test methods: a basic compression test and an endurance test in an in-vitro model of an Impaction Grafted femur. Formalin fixed ovine bone graft was identified as mechanically similar to fresh human bone and thus suitable as an experimental material for in-vitro testing. For 1:1 volumetric mixes of bone allograft and synthetic extender, the granular ceramic's properties were varied in porosity, chemical composition, sintering temperature and particle size. Initial mechanical stability, a crucial prerequisite for clinical success in Impaction Grafting, was increased for all bone/extender mixes. A high porosity, tricalcium-phosphate rich ceramic of medium particle size and sintered at high temperatures was recognised as an optimised extender material for Impaction Grafting balancing the mechanical and biological demands. Using the extender without bone graft as a pure replacement is not recommended.

Keywords
Impaction Grafting, bone graft, hydroxapatite/tricalcium-phosphate, graft extender, mechanical properties, endurance testing

Introduction

There has been an increase in the number of total hip joint replacements (THR) performed every year as a consequence of demographic changes. In addition THR is performed increasingly on younger and younger patients with concomitant expectations in respect to their longevity. As a result of the foregoing, there has been an increase in the number of hip replacements presenting for revision. Considering the significantly higher cost of this revision surgery, in comparison to primary THR [1], revision hip replacement has become a considerable financial factor in the health system [2].

The major clinical problem encountered in revision surgery is bone stock loss as a consequence of osteolysis and the surgical factors associated with the removal of the implant. Impaction Grafting revision THR compensates for femoral bone stock loss by compacting morsellised bone allograft into the femoral cavity. The compacted graft creates a new medullary canal for the insertion and cementation of a standard hip prosthesis [3, 4]. It provides initial mechanical stability and over time has the potential to be revascularised, resorbed and replaced by healthy bone. Impaction Grafting has become an increasingly popular revision technique for addressing the problem of bone stock loss.

Limited availability of donor bone [5], risk of infection or rejection, variable graft quality and high cost have lead to the development of synthetic bone graft extenders. For the optimisation of such materials, mechanical evaluation is crucial. Initial mechanical stability is paramount in order to establish a secure position for the implant in both the short and long term. In addition it is important to limit micromotion to a level where the desired graft revascularisation and bone remodelling can take place [6]. An in-vitro model was developed to analyse the effects of different graft properties on initial mechanical stability. The model exposes the bone graft to loading conditions comparable to those, which lead to vertical subsidence, a dominant failure mode in clinical impaction grafting [7]. An ideal property profile of a ceramic as an extender for morsellised bone graft was identified.

Materials and Methods

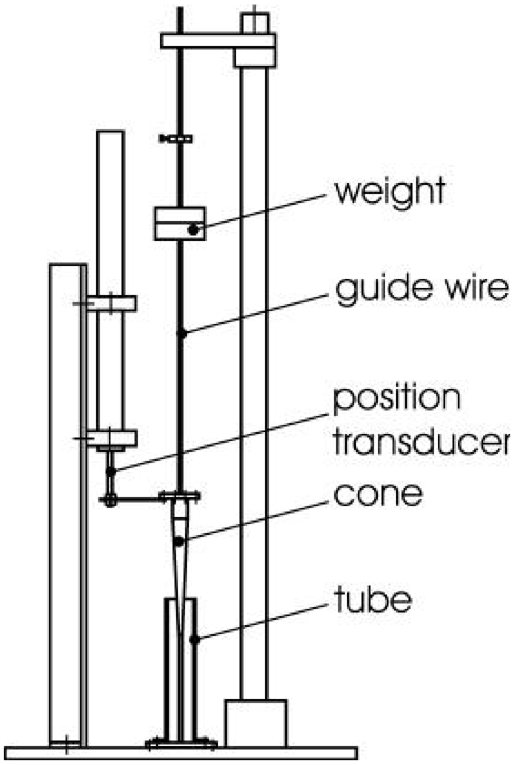
The graft materials investigated were 1:1 volume mixes of bone and synthetic bioceramic. The bone was formalin fixed trabecular bone graft harvested from ovine humeral heads morsellised with a Norfolk bone mill using the coarse blade. The bioceramic was manufactured by TCM Associates Ltd, Neizing, U.K. and comprised granules of a hydroxyapatite/tricalcium-phosphate (HA/TCP) ceramic of different porosity (0%, 25%, 50%), sintering temperature (1050°C, 1150°C, 1200°C) particle size (small 1-2mm, medium 2-4mm, large 4-6.3mm) and composition (HA/TCP ratios 80/20 and 20/80). For comparative purposes, samples comprising pure bone graft as the gold standard in Impaction Grafting were also tested.

(1) A basic quasistatic compression test on $10cm^3$ sample volumes of various bone grafts and synthetic materials was performed using a 20mm diameter die and a hollow cylinder plunger closed with a porous disk on the compacting end to allow

fluid drainage. A compression modulus was derived as the secant gradient of the measured stress-strain curve between a corresponding compression load of 25N, allowing for initial settling of the material, and a 500N peak load. Relaxation behaviour was quantified as the relative drop in stress level two minutes after the plunger stopped its compacting movement. Within that time period most of the relaxation had occurred. This test was designed to compare fundamental properties of different graft materials and thus validate the use of ovine bone graft instead of human bone graft as an experimental material in the in-vitro model.

(2) The Impaction Grafting model used a standardised impaction procedure, a fixed geometry and stiffness of the tube-cone set-up (Fig 1) simulating the femur-stem components and controlled cyclic fatigue mimicking the gait cycle load pattern. The model, derived from the average dimensions of a human femur, comprised a 25mm diameter metal tube and a metal cone of 120mm length with decreasing diameter from 16mm proximally to 5mm distally. The tube was filled with bone graft, this was compacted and the cone driven into the tube with a device called the Impactometer [8, 9] using a dropping weight of a pre-set adjustable height (Fig.1). This allowed impaction energy and momentum to be controlled and reproduced thus eliminating the variability inherent in the manual procedure of clinical Impaction Grafting. Values used were calculated from the mass and geometry of the surgical Impaction Grafting tool kit and the frequency of hammer blows measured interoperatively. These measurements indicated individual hammer blows carried an impaction energy of 1.6 Nm and delivered an impaction momentum of 1.4 Ns.

After impaction the model was mounted in an Instron servohydraulic machine and cyclically block-loaded in compression at peak loads ranging from 0.2 kN to 2.0 kN in 0.2 kN steps for 5000 cycles each and subsidence was recorded. A haversine waveform and a cycling frequency of 2 Hz was used to resemble strain rates similar to the human gait. Subsidence of 5mm or more was regarded as failure.



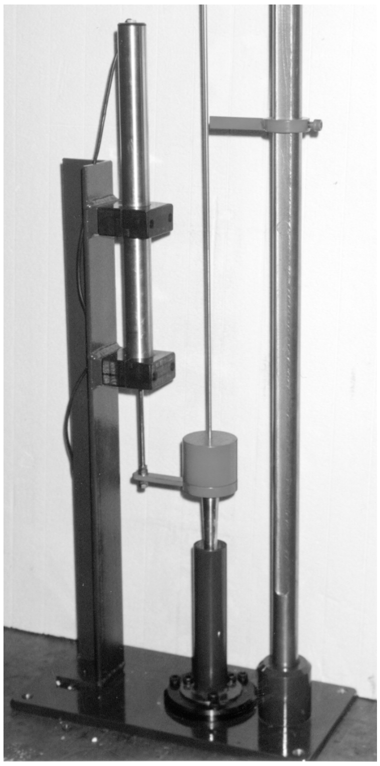


Figure 1 Impaction Grafting model mounted in Impactometer for controlled graft compaction.

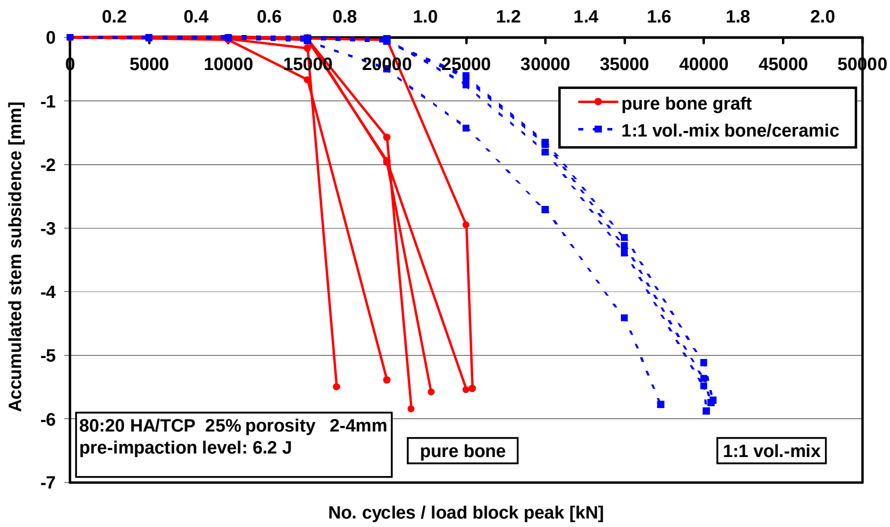


Figure 2 Stem subsidence for pure bone graft and 1:1 vol.-mixes bone/ceramic.

Results

The compression properties of fresh human and both fresh and fixed ovine bone graft were found to be similar with low compression moduli and high relaxation values. The formalin fixed and subsequently washed and air dried ovine graft as used in the in-vitro model described above was found to be about 15% stiffer than fresh human bone graft and showed ca. 10% less relaxation. The synthetic HA/TCP granules were distinctively stiffer and showed significantly less relaxation depending on their manufacturing properties such as sintering temperature, porosity and chemical composition (Table 1).

Bone graft	human	ovine	ovine fixed	HA/TCP
Comp. Modulus [MPa]	3.65	4.22	4.27	11-56
Relaxation [%]	33.5	39.6	30.1	16.8-25.6

TABLE 1: ***Secant compression modulus and relaxation for morsellised bone grafts: Fresh human, fresh and fixed ovine.***

Using the *in-vitro* Impaction Grafting model, adding synthetic HA/TCP granules to natural bone graft significantly improved mechanical stability against cyclic loading subsidence (Fig.2). Compared with pure bone samples, the 1:1 volumetric mix of bone graft and ceramic extender also lead to less variable subsidence and less sudden failure and thus more predictable behaviour (Fig. 2).

Increasing the porosity of the ceramic granules in the graft mixes slightly decreased the mechanical stability of the graft mix at the level of 25% porosity but had a more significant effect at the higher porosity levels of 50% (Fig.3). However, the 1:1 bone/extender graft mix with the high porosity HA/TCP granules still resulted in noticeably higher initial mechanical stability than the pure bone graft samples (Fig.3). Raising the sintering temperature of the HA/TCP from 1050°C to 1150°C increased stability but the effect was less profound at the higher temperatures of 1200°C (Fig.4). Increasing the TCP content of the ceramic by reversing the HA/TCP ratio from 80:20 to 20:80 resulted in a slight drop in the initial mechanical stability (Fig 5). Medium sized 2-4mm ceramic particles in the 1:1 bone/extender graft mix gave the greatest initial mechanical stability when compared to both small (1-2mm) and large (4-6.3mm) granules of a similar nature (Fig.6).

Discussion

Formalin fixed ovine bone is a suitable model for replacing human bone in in-vitro mechanical tests of morsellised grafts, having very similar mechanical properties in compression. The slightly higher stiffness and lower relaxation of the fixed ovine bone graft relative to the gold standard human bone is the result of two effects. Firstly, the chemical fixation process causes polymeric crosslinking, and thus increased rigidity, in the organic components. Secondly, subsequent to fixation, the washing and air drying procedure employed further removes blood, fat, finer particles and tissue in the graft. As a result the ovine graft becomes slightly stiffer and less viscoelastic in comparison to the fresh human bone graft. This in turn compensates for the otherwise slightly lower stiffness and higher relaxation measured for freshly harvested ovine bone which usually contains slightly more fat and other soft tissue when compared to human bone (Table 1).

All HA/TCP granules tested as graft extenders in 1:1 volumetric mixes with bone graft increased initial mechanical stability and are therefore mechanically suited as bone graft extenders for clinical Impaction Grafting. This is as a result of the higher stiffness and lower relaxation values measured for the ceramic particles in comparison to morsellised bone. The ceramic granules are manufactured to exact and reproducible specifications. The manually morsellised bone graft, by nature, showed larger variations in both visual appearance and mechanical properties. As a consequence, graft mixes with a synthetic extender were not only more stable but consistently produced much less variable, more predictable subsidence.

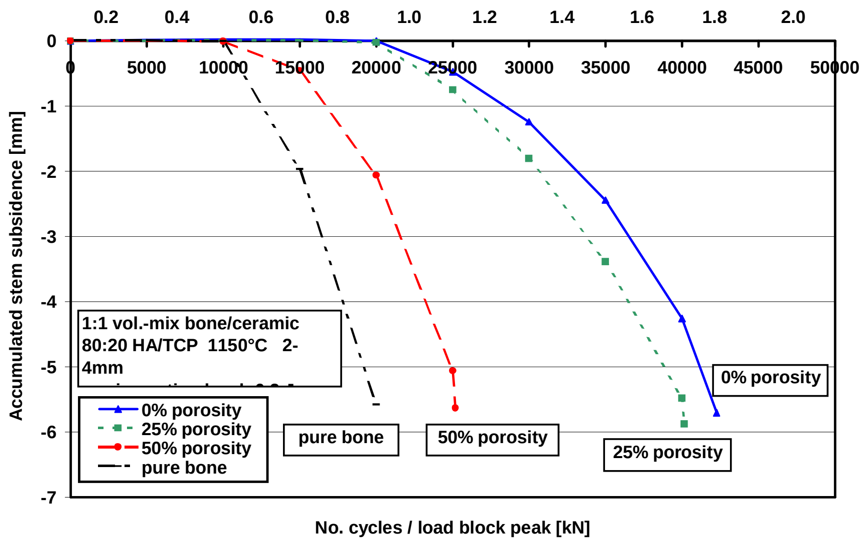


Figure 3 Stem subsidence for pure bone graft and 1:1 vol.-mixes bone/ceramic with varied porosity

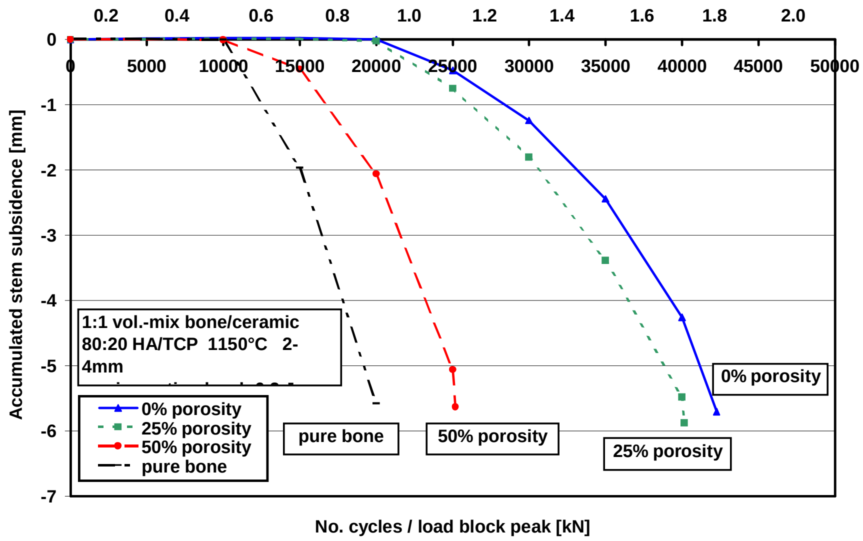


Figure 4 Stem subsidence for 1:1 vol.-mixes bone/ceramic with varied chemical composition

Mechanical stability was reduced as a result of raising both porosity levels and the TCP content of the HA/TCP ceramic. This correlated with the lower stiffness values observed for the pure granular ceramic. The effects must be considered in relation to the specification of an optimal ceramic bone graft extender as it is desirable to increase porosity for improved bone ingrowth or to raise the TCP content for faster in-vivo resorption rates and thus enhanced bone remodelling. Increasing the sintering temperature of the ceramic increased mechanical stability along with its higher stiffness. Therefore high sinterering temperatures could compensate for the stability lost with a highly porous and TCP rich ceramic. Medium sized granules resulted in superior mechanical stability relative to both small and large particles. Large granules do not distribute and rearrange well during impaction and thus compact less efficiently. They also create more void space and can fracture more easily leading to increased subsidence. Due to their large size relative to the gap between stem and endosteal wall, only a few or, in some cases, individual large granules could fill the space leading to high and unevenly distributed stresses in the graft material which could result in fracture and subsequent subsidence. Small particles do not interlock well and, like sand, move more easily relative to one another reducing mechanical stability and thus leading to increased subsidence. Medium sized particles seem to offer a compromise balancing the size dependent effects described and therefore potentially offering maximum stability.

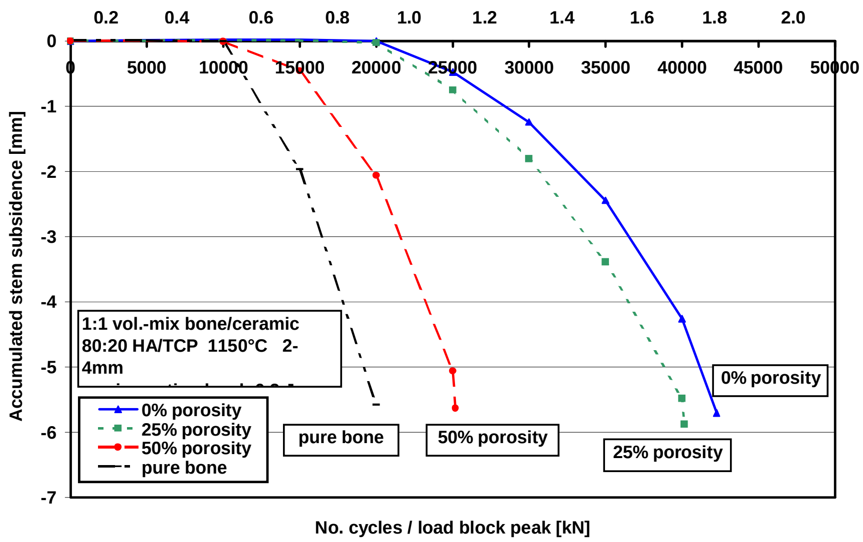


Figure. 5 Stem subsidence for 1:1 vol.-mixes bone/ceramic with varied sintering temperature

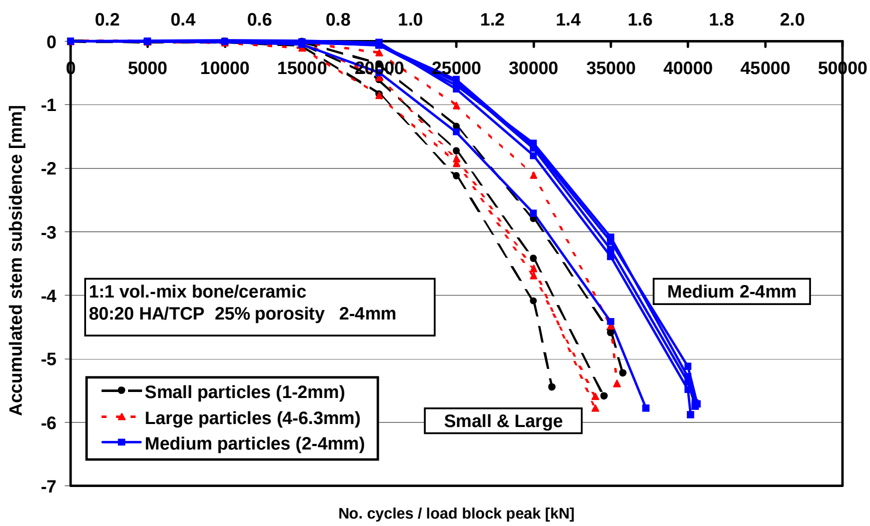


Figure 6 Stem subsidence for 1:1 vol.-mixes bone/ceramic with varied particle size

Conclusions:

HA/TCP ceramic granules were found to be suitable as a bone graft extender for Impaction Grafting THR. A highly porous, TCP-rich ceramic of medium 2-4mm particle size sintered at high temperatures was found to be optimal to meet the biological requirements of bone resorption and mechanical demands of maximum stability. Graft mixes with a synthetic extender promise more consistent clinical results which are less dependent on the user and the donor bone quality. However, pure HA/TCP granules are much stiffer, less viscoelastic and more friable than human bone and therefore cannot entirely mimic the mechanical properties of the gold standard material in Impaction Grafting. As a pure material, ceramic granules in their current form do not have the viscoelastic and cohesive properties of natural bone [8] required for surgical handling and clinical impaction. Used on their own their friable nature could result in the production of potentially damaging wear particles. Consequently HA/TCP granules are recommended as an extender to enhance mechanical stability in a bone graft mix as opposed to a complete alternative to human bone graft.

Acknowledgements:

The research work has been supported by StrykerHowmedicaOsteonics, Staines, U.K.

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Hydroxyapatite/Tricalcium-Phosphate as a bone graft extender for Impaction Grafting revision hip surgery

Grimm B., Miles A.W., Turner I.G.

Purpose:

In Impaction Grafting (IG) revision hip surgery, demand for bone graft has outstripped supply and thus synthetic alternatives need to be investigated. For clinical success initial mechanical stability is most fundamental as it ensures short and long-term implant position and reduces micromotion below limits essential for osteogenesis. A mechanical IG model was developed and the stability of impacted graft mixes investigated.

Materials/Methods:

Pure morsellised trabecular ovine bone graft and a 1:1 vol.-mix thereof with granules of a 80:20 (%-weight) hydroxyapatite/tricalcium-phosphate (HA/TCP) ceramic (50% porosity).

The IG model used a tube and cone of average femur and prosthesis dimensions. The graft mixes were compacted and the cone impacted into the tube using a dropping weight varying impaction levels by controlling potential energy. The specimen were mounted into an Instron servohydraulic machine and cyclically block loaded in compression with increasing peak loads. Subsidence was recorded.

Results:

- With higher impaction energy, mechanical stability increased asymptotically.
- Graft mixes containing HA/TCP showed less subsidence than pure bone samples.
- This difference was highest for low impaction energies.
- Subsidence was less variable and less catastrophic for mixes containing HA/TCP.
- Cone retrieval revealed strong proximal locking.

Conclusions:

- HA/TCP granules as a bone graft extender offer equal or superior mechanical stability.
- Adding HA/TCP:
  - reduces sensitivity to impaction levels and thus surgical variability.
  - increases stability particularly at low impaction levels reducing risk of femoral fracture.
  - promises more predictable clinical results.
- Proximal impaction and femoral integrity is important.

3 J Bone Joint Surg, Orthopaedic Proceedings; Suppl II, 83-B, 203, 2001, 204
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Mechanical studies on a ceramic bone graft substitute for use in revision total hip arthroplasty

Blom A.W., Grimm B., Miles A.W., Cunningham J., Learmonth I.D.

Introduction:

With the rapid rise in the incidence of revision total hip arthroplasty, the demand for allograft bone is increasing dramatically. In addition, allograft has considerable problems with regard to infection, antigenicity, availability, reproducibility and cost. For these reasons, alternatives to allograft are being sought.

Aim:

This study has investigated a porous tricalcium phosphate: hydroxyapatite ceramic for use in impaction grafting of the femur at revision total hip arthroplasty.

We report the findings of an *in-vitro* mechanical study comparing the initial stability of pure allograft, a mixture of 50% allograft and 50% ceramic, and a mixture of 10% allograft and 90% ceramic.

Method:

Impaction grafting was performed in specially constructed model, which was then cyclically loaded in a servohydraulic machine to mimic normally loaded gait cycles. Subsidence of the graft composite was measured.

Results:

The ceramic/allograft mixtures exhibited much greater stability and reproducibility than the pure allograft ($p<0.01$) at the tested loads (200N-800N). The mean subsidence of pure allograft samples was >3.83mm over 20,000 cycles of up to 800N, compared with 0.54mm for 50% allograft/ 50% ceramic, and 0.36mm for 10% allograft/ 90% ceramic samples.

Conclusions:

Mixtures of allograft and ceramic bone graft substitutes have the requisite mechanical stability to be used in impaction grafting of the femur.

The second part of this project is a prospective randomised *in-vivo* study to assess the extent of osseointegration under load and its effect on mechanical stability.

4 Key Engineering Materials 2002; 218-220: 375-8

IN-VITRO ENDURANCE TESTING OF BONE GRAFT MATERIALS FOR IMPACTION GRAFTING

B. Grimm[1], A. W. Blom[2], A.W. Miles[1], I. G. Turner[3]

[1] Dept Mechanical Engineering, University of Bath, Bath BA2 7AY, U.K.
[2] Dept Orthopaedic Surgery, University of Bristol, Bristol BS2 8HW, U.K
[3] Dept Engineering and Applied Science, University of Bath, Bath BA2 7AY, U.K.

Keywords: revision hip arthroplasty, Impaction Grafting, morsellised bone allograft, ceramic graft extender, mechanical model, endurance testing, subsidence

Abstract
Two in-vitro mechanical models and test protocols were developed to analyse the initial mechanical stability of bone graft materials in Impaction Grafting hip revision arthroplasty. Morsellised bone allograft and various mixes with a hydroxyapatite/tricalcium-phosphate (HA-TCP) graft extender were impacted into an ovine and a human geometry model. The samples were cyclically block-loaded in compression and vertical subsidence was recorded. Adding the HA-TCP graft extender to the bone allograft led to reduced subsidence in both models, even at low mixing ratios. Intense impaction was identified as the single most critical factor for achieving initial mechanical stability.

Introduction
The number of revision hip surgeries has been rising and considering the significantly higher cost of this operation in comparison to primary hip replacement [1], revision hip replacement has become a considerable financial factor in the health system [2].

In revision hip arthroplasty bone stock loss is the major problem. Impaction Grafting is a successful revision technique where morsellised allograft bone chips are impacted into the femoral cavity to compensate for the bone stock loss. Thus a new medullary canal for the insertion and cementation of a new prosthesis is created [3, 4]. One of the most influential factors determining clinical success of the operation is the initial mechanical stability of the implant. It ensures short and long-term implant position and reduces micromotion to a level where osteogenesis and bone remodelling can take place [5]. In order to analyse the effects of variations in operative technique and different graft properties on the initial mechanical stability, two standardised in-vitro models and test protocols were developed. They simulate the loading conditions for the bone graft between prosthesis and femoral canal and were used to analyse the influence of compaction energy on stability and how mixing bone graft with a synthetic replacement or extender affects implant performance.

Methods
Two test methods were developed:

(1) Ovine model: Morsellised ovine bone graft was impacted into a metal tube used as a model for the average ovine endosteal geometry. An Impaction Grafting toolkit (StrykerHowmedicaOsteonics) was used comprising a guide wire, slap hammer, various distal impactors and a trial prosthesis. A polished and double-tapered Exeter-type ovine hip stem was cemented into the created canal using PMMA bone cement. The model was mounted in an Instron servohydraulic machine and, at a frequency of 2Hz, cyclically block-loaded in compression at peak loads of 0.2, 0.4, 0.6, 0.8 kN for 5000 cycles each and subsidence was recorded. Subsidence of 5mm or more was regarded as failure.

(2) Human sized tube-cone model: The model was developed to introduce controlled impaction and to eliminate the variability introduced through cementation, thus allowing focus on the influence of graft properties and impaction variables. It consisted of a 25mm diameter metal tube and a metal cone of 120mm length with a diameter of 16mm at the top decreasing to 5mm at the tip. The tube was filled with bone graft, compacted and the cone driven into the tube with a device called the Impactometer [6, 7]: A weight at a preset adjustable height drops along a guide wire and impacts onto a flat disc or the cone the position of which can be monitored. This allows impaction energy and momentum to be controlled and repeated (*Fig.1*).

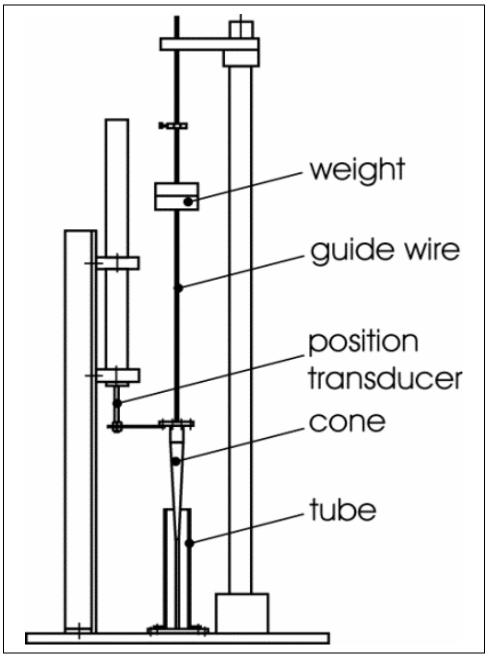

Fig. 1: Controlled impaction with constant impaction energy and monitored cone position using the "Impactometer".

Impaction energy and momentum of the individual hammer blows were set at 1.6Nm and 1.4Ns. This was calculated from the weight of the slap hammer and the hammer speed measured intraoperatively to represent a realistic clinical analogy.

The impaction procedure was a two-stage process with initial graft compaction first using a flat disk and subsequent impaction of the cone into the consolidated graft compacting it further. Total impaction levels were varied by changing the initial compaction energy using the flat disk between 3.1J and 23.3J. This resulted in a total number of 20 to 120 hammer blows required to impact the cone into position.

After impaction the model was mounted in an Instron servohydraulic machine and, at a frequency of 2Hz, cyclically block-loaded in compression at peak loads from 0.2 kN to 2.0 kN in 0.2 kN steps for 5000 cycles each and subsidence was recorded. Subsidence of 5mm or more was regarded as failure.

Materials: The graft materials investigated were volume mixes of morsellised trabecular bone graft harvested from sheep humeral heads and morsellised using a Norwich bone mill, and granules of a hydroxyapatite/tricalcium-phosphate (HA-TCP) ceramic with 25% and 50% porosity sintered at 1150 °C and a 2-4mm particle size (manufactured by TCM Associates Ltd., Neizing, UK) For the ovine model (1) mixing ratios (bone:extender) were pure bone, 1:1 and 1:9; for the human sized model (2) mixing rations were pure bone, 2:1, 1:1 and 1:2.

Results

Adding synthetic HA-TCP granules to natural bone graft increased mechanical stability against cyclic loading subsidence in both the ovine (*Fig.2*) and the human model (*Fig.3*, *Fig.4*). Even relatively small amounts of HA-TCP in a 2:1 graft/ceramic vol.-mix strongly improved stability (*Fig. 3*). The stabilising effect of increasing the ceramic content beyond a 1:1 graft/ceramic ratio decreased but was still noticeable in both experimental models (*Fig.2*, *Fig.3*). The use of a ceramic extender lead to less rapid, more predictable and less variable subsidence (*Fig. 4*). Increasing compaction energy contributed greatly to a higher mechanical stability of the implant (*Fig.5*).

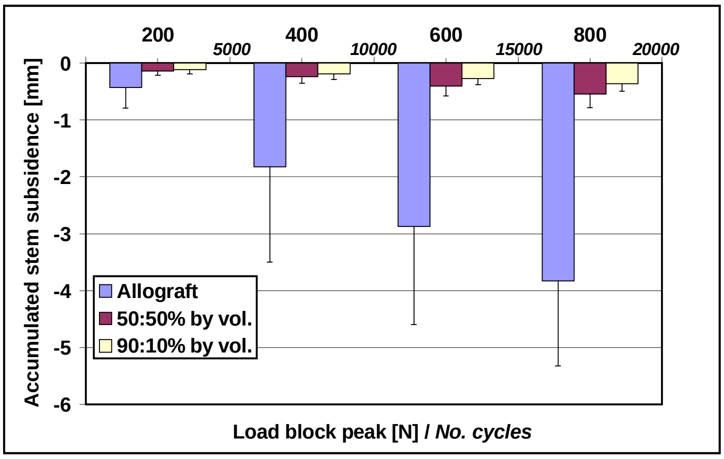

Fig. 2: Stem subsidence in ovine model accumulated during block loading varying graft/extender mixing ratios

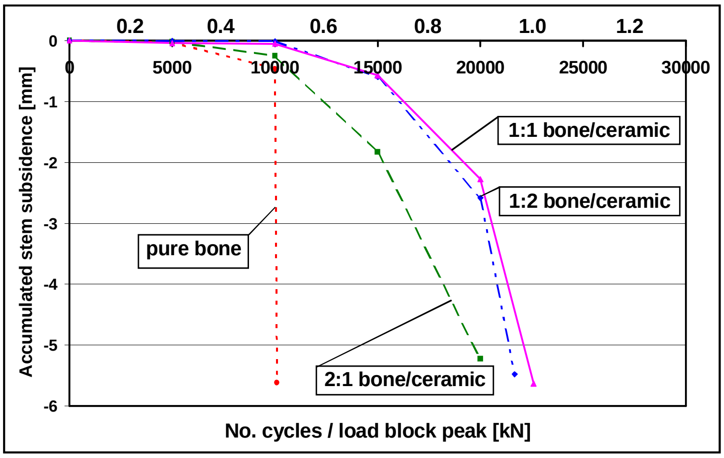

Fig. 3: Stem subsidence in human model accumulated during block loading varying graft/extender mixing ratios (Initial compaction energy 3.1J, ceramic porosity 50%).

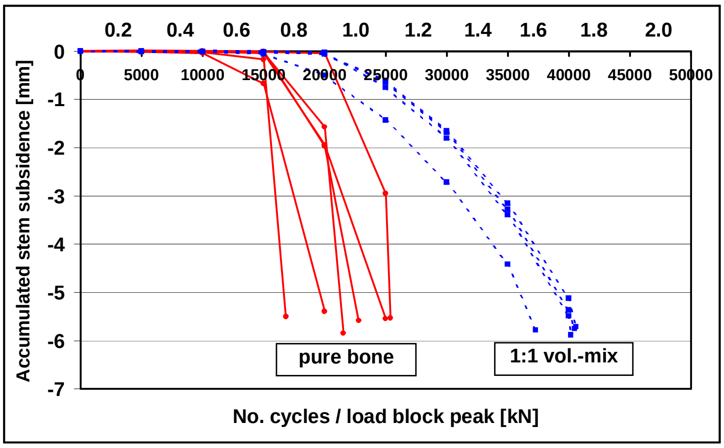

Fig. 4: Stem subsidence in human model accumulated during block loading for pure allograft and a 1:1 graft/ceramic vol.-mix. (Initial compaction energy 6.2J, ceramic porosity 25%).

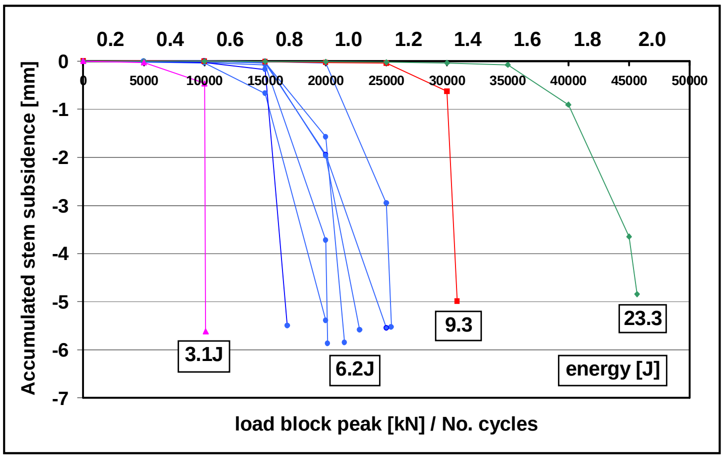

Fig. 5: Stem subsidence in human model during block loading varying compaction energy (pure morsellised bone).

Discussion & Conclusions

Adding TCP/HA particles such as BoneSave of StrykerHowmedicaOsteonics as a bone graft extender led to increased stability and is therefore suited mechanically for clinical application. This effect was shown in both the ovine model using a cemented stem as well as the uncemented tube-cone model resembling the human femoral geometry. This suggests the suitability of both procedures as relevant and efficient mechanical models. In particular the human size tube-cone model shows that cementation and the use of a polished double-tapered stem is not necessarily required for analysing the mechanical stability of graft materials in-vitro. The cone taper provides a wedge geometry which loads the graft in compression and shear comparable to the mechanical situation in-vivo. The tubular canal of the experimental set-up provides the constraining dimensions as found clinically so that size ratios between the diameter of the graft particles and the gap created between implant and femoral canal are identical to the in-vivo situation and thus ensure equivalent load transfer mechanisms.

The less variable and less rapid subsidence of the ceramic mix samples is a result of the controlled ceramic properties versus the variable bone quality due to donor's sex, size and age and different sterilisation, storage and milling procedures. Using HA-TCP granules as a bone graft extender can therefore help making the clinical success of Impaction Grafting less dependent on donor bone quality and surgical procedure.

The large stability improvement observed already for graft mixes with a low ceramic content and the relatively small stability increase measured for raising the ceramic content above 50% of the total volume shows that in clinical application mixing errors or inhomogeneous charging of the femoral cavity due to handling difficulties are not critical. When bone allograft is extended with the synthetic ceramics investigated, increased stability can always be expected.

Volume mixes were chosen in favour of weight mixes anticipating a clinical use where charging the right quantities of bone and extender would be easier to handle by containers than weighing with scales. The difference in granular density between morsellised bone (ca. 0.6 g/cm^3) and ceramic graft (ca. 1.2 g/cm^3) lead to high ceramic contents even at low volume ratios and made homogenous mixing difficult. Thus lower ceramic mixes than the 2:1 bone/ceramic blend need to be investigated.

Higher compaction energies before stem insertion led to a huge increase in stability. This shows that intense graft compaction is the single most influential parameter for achieving mechanical stability clinically. However, the risk of femoral fracture and the higher graft density potentially compromising graft revascularisation must be considered. As adding a synthetic graft increases stability already at low compaction levels, it could help to find an optimum where the necessary compaction energy is at a tolerable maximum while the graft mix still contains sufficient allograft bone for osteogenic activity. Furthermore implant stability achieved with Impaction Grafting could be less dependent on the variable compaction intensities applied by different surgeons. Higher stability at lower impaction levels could also mean that patients previously classified as unsuitable for Impaction Grafting could be included as less impaction force is required for a stable fixation and thus the risk of bone fractures is reduced.

Current experiments will investigate the responsiveness of such allograft/extender mixes to compaction energy and the effects of distal versus proximal compaction and high impact-low frequency versus low impact-high frequency compaction.

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Key Engineering Materials Vols. 218-220 (2002) pp. 417-420

IN-VITRO TESTING OF BONESAVE, A CERAMIC BONE GRAFT SUBSTITUTE FOR USE IN IMPACTION GRAFTING

A. W. Blom[1], B. Grimm[2], J. Cunningham[2], A. W. Miles[2], and I. D. Learmonth[1]

[1] Department of Orthopaedic Surgery, University of Bristol, U.K.

[2] Department of Mechanical Engineering, University of Bath, U.K. Corresponding author: Mr A. W. Blom, 13 Tuscany House, Durdham Park, Bristol BS6 6XA, United Kingdom
Email: blocat@msn.com

Keywords: BoneSave, Bone Graft Substitute, Impaction Grafting, Revision Hip Surgery

Abstract. The incidence of revision total hip arthroplasty is increasing dramatically and the associated demand for allograft bone is likely to exceed the available supply. In addition allograft presents potential problems with regard to infection, antigenicity, availability, reproducibility and cost. It is therefore desirable to develop an alternative to allograft. This study investigated BoneSave, a porous tricalcium-phosphate/hydroxyapatite ceramic for use in impaction grafting of the femur at revision total hip arthroplasty. The findings of an in-vitro mechanical study comparing the initial stability of pure allograft, a volume mixture of 50% allograft and 50% BoneSave, and a volume mixture of 10% allograft and 90% BoneSave are reported. The BoneSave/allograft mixtures exhibit both much greater mechanical stability and reproducibility than the pure allograft ($p<0.05$) at all tested loads (200N- 800N). At high peak loads the high volume (90% by volume) BoneSave mix also provided higher mechanical stability than the medium volume (50% BoneSave/ 50% allograft) mix ($p<0.05$). These results demonstrate that the tested ceramic provides adequate initial stability to be used as a substitute for allograft in impaction grafting of the femur.

Introduction

Over 40,000 total hip replacements, at an estimated cost of £5000 per joint, are performed annually in the U.K. alone. It is predicted that 20% of joint replacements will ultimately fail and thus need revision. The results of total hip revision have often been disappointing. Restoration of bone stock loss remains the greatest challenge to the revision hip surgeon. Early results of revision with impaction grafting of morsellised allograft have been encouraging, although significant early subsidence has been reported in some cases [1]. The morsellised allograft used in impaction grafting is obtained from femoral heads retrieved at primary total hip arthroplasties. Initial stability of the composite is critical for the long term success of impaction grafting. Impaction grafting has improved the results of revisions, but the results are still far from optimal [2,3]

Allograft presents considerable problems with regard to infection, antigenicity, availability, reproducibility and cost [4]. Galea et al [5] estimate that the demand for allograft in the U.K. has already outstripped supply. For these reasons alternatives to allograft are being sought.

This study is designed to determine whether a tricalcium-phosphate/hydroxyapatite ceramic is mechanically suitable as a bone graft extender and can provide sufficient structural stability for revision arthroplasty with impaction grafting to withstand the high loads applied to the proximal femur in-vivo.

Methods

Sample preparation. A synthetic granular porous pure tricalcium-phosphate/hydroxyapatite ceramic (TCP/HA) was manufactured as a bone graft extender according to the specifications shown in Table 1. Allograft was prepared analogous to the procedure in clinical impaction grafting.

Ovine cancellous bone was milled with a Norfolk bone mill (Howmedica, Staines) using the coarse milling blade. Large quantities of such bone graft were prepared prior to testing and then mixed together in order to average out the variability in bone quality and in the manual milling process both uncontrolled variables in clinical impaction grafting.

Three groups of 10 samples were prepared each with a different mixture of allograft and BoneSave for use as an impaction grafting material.

- Group1 consisted of pure allograft.
- Group 2 consisted of 50% allograft and 50% BoneSave by volume
- Group 3 consisted of 10% allograft and 90% BoneSave by volume

A mechanical testing model was developed to reproducibly expose the graft to a stress pattern comparable to that experienced in-vivo. This model consisted of an aluminium tube with the inner dimensions similar to those of an ovine femur. The use of such aluminium tubes provided a standardised testing geometry and mechanical environment for both the impaction grafting process of the morsellised bone plus ceramic mixes and for the subsequent endurance testing of the samples, thus isolating the graft material as the only variable. The higher stiffness of the aluminium tube versus a femur effectively increased the stresses within the graft and allowed for accelerated testing for subsidence.

Standard impaction grafting was performed. Highly polished double tapered femoral stems (Howmedica, Staines) with modular heads were cemented into the graft composite.
Each sample was block loaded in compression with 200N incremental peak load steps for 20,000 haversine cycles at a frequency of 2 Hz in an Instron 8511 hydraulic testing machine (Instron Corporation, Canton, Massachusetts) to a maximum of 800N.
The load was transmitted vertically to the head of the prosthesis via an acetabular connector, which was adjustable for offset. The model enabled accelerated testing and a comparative evaluation of the different bone graft/ceramic samples to be carried out. It was accepted that this compromised quantitative comparison of the results with clinical data but it did allow comparative analysis of relative graft performance to be made.

Subsidence was recorded by applying an averaging algorithm on the position signal acquired from the Instron hydraulic testing machine using HP Vee software (Hewlett Packard).

Table 1 Bone graft extender specifications

Composition: 80% Tricalcium phosphate
20% Hydroxyapatite
Sintering temperature: >1200° C (To achieve optimal hardness)
Crystallinity: high (>80%)
Porosity: 50% by volume
Pore size 300 – 500 microns
Granule size: 2-4 mm

Results

The largest amount of subsidence within each cyclic load block occurred during the early cycles, quantified at about 80% subsidence during the first 500 cycles and 20% for the following 4500 cycles. This behaviour was observed for all samples regardless of graft composition.

The pure allograft samples showed the highest variability in subsidence values leading to the least consistent results. The high BoneSave volume mixes of 50% and 90% showed much more consistent subsidence levels at all loads.

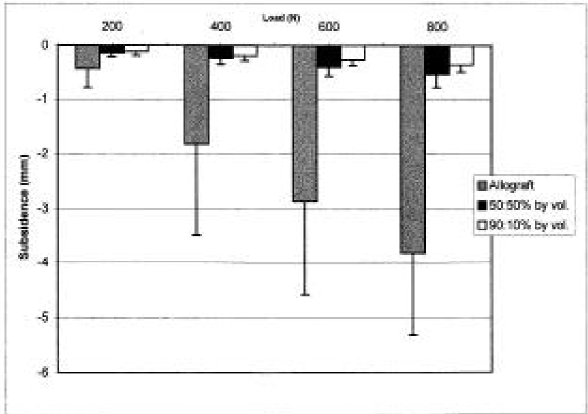

Table 2: Analysis of statistical difference with the single tailed unpaired Student's t-test

	200 N	400 N	600 N	800 N
50:50 VS PURE ALLOGRAFT	P<0.025	P<0.01	P<0.005	P<0.005
90:10 VS PURE ALLOGRAFT	P<0.005	P<0.005	P<0.005	P<0.005
90:10 VS 50:50	NOT SIGNIFICANT	NOT SIGNIFICANT	P<0.05	P<0.05

Discussion

In-vitro tests of impaction grafting can only assess the initial stability of the composite. However, significant subsidence reported in-vivo in the literature occurred within three months.[1] It would therefore seem that initial stability is critically important.

There are many factors that effect the subsidence of allograft in-vivo. These include graft preparation, quality of graft, particle morphology and size, impaction techniques, graft composition, post-operative loading, the host's immune response and the host/ graft interface. This study focused on the influence of graft composition by isolating the intrinsic mechanical graft properties as the only variable.

The qualitative course of subsidence over the number of cycles was independent from graft composition and peak load. The largest amount of subsidence occurred in the early stage of loading the samples, suggesting that cyclical loading at first generates a further degree of impaction. This

was followed by a slow exponential decay, which became asymptotic towards the end of the block loading sequence and this to some extent, replicates the clinical scenario.

Adding BoneSave to the morsellised allograft bone chips as a bone graft extender significantly increased the samples' resistance to subsidence in the comparison of both mixes of allograft/ceramic against pure allograft. This demonstrates the potential of TCP/HA extender mixes to provide higher initial mechanical stability than pure allograft when used clinically. The high mechanical stability recorded for the large synthetic volume graft mixes suggests that the stabilising effect of osseointegration, necessary for the long-term success of pure allografts, might be less crucial when using an optimised bone graft extender. At the same time the increased initial stability would allow earlier and higher load bearing of the patients postoperatively and thus might even stimulate osteogenesis.

Pure bone allograft does not provide reproducibility, despite the efforts to reduce the variability inherent in a manually harvested and prepared biological material by mixing several morsellised heads together. The pure allograft samples showed the highest standard deviation in subsidence leading to the least predictable results. In contrast the samples with high extender volume mixes of 50% and 90% showed much more consistent subsidence levels at all loads. In the clinical environment there is great variability in quality of allograft due to donors' health, sex, size and age, different sterilisation methods and storage procedures. Adding BoneSave would reduce bone graft variability. Since graft variability is perceived as a reason for the different results achieved in impaction grafting at hip revision, adding TCP/HA ceramic granules of controllable properties could improve the success rate by providing a more mechanically consistent graft material.

Subsidence of allograft as measured in this model is higher than in the in-vivo setting. This is due to differences between the model and the in-vivo setting (such as the absence of osseointegration, and different moduli of elasticity). As such the model is more demanding than the in-vivo setting, but has the advantage of isolating graft composition as the only variable.

The second part of this project will be an in-vivo ovine study to assess the extent of osseointegration of different allograft compositions, and its effect on mechanical stability.

Acknowledgements

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Subsidence in impaction grafting. The effect of adding a ceramic bone graft substitute.

AUTHORS:
Blom A.W., Grimm B., Miles A.W., Cunningham J., Learmonth I.D.

ABSTRACT
The incidence of revision total hip arthroplasty is increasing dramatically and the associated demand for allograft bone is likely to exceed the available supply. In addition allograft presents potential problems with regard to infection, antigenicity, availability, reproducibility and cost.

It is therefore desirable to develop an alternative to allograft. This study investigated BoneSave, a porous tricalcium-phosphate/hydroxyapatite ceramic for use in impaction grafting of the femur at revision total hip arthroplasty.
The findings of an in-vitro mechanical study comparing the initial stability of pure allograft, a volume mixture of 50% allograft and 50% BoneSave, and a volume mixture of 10% allograft and 90% BoneSave are reported.

The BoneSave/allograft mixtures exhibit both much greater mechanical stability and reproducibility than the pure allograft ($p<0.05$) at all tested loads (200N- 800N). At high peak loads the high volume (90% by volume) BoneSave mix also provided higher mechanical stability than the medium volume (50% BoneSave/ 50% allograft) mix ($p<0.05$).

These results demonstrate that the tested ceramic provides adequate initial stability to be used as a substitute for allograft in impaction grafting of the femur.

INTRODUCTION
Over 40 000 total hip replacements, at an estimated cost of £5000 per joint, are performed annually in the U.K. alone. It is predicted that 20% of joint replacements will ultimately fail and thus need revision. The results of total hip revision have often been disappointing. Restoration of bone stock loss remains the greatest challenge to the revision hip surgeon. Early results of revision with impaction grafting of morsellised allograft have been encouraging, although significant early subsidence has been reported in some cases[1]. The morsellised allograft used in impaction grafting is obtained from femoral heads retrieved at primary total hip arthroplasties. Initial stability of the composite is critical for the long term success of impaction grafting. Impaction grafting has improved the results of revisions, but the results are still far from optimal[2,3].

Allograft presents considerable problems with regard to infection, antigenicity, availability, reproducibility and cost[4]. Galea et al[5] estimate that the demand for allograft in the U.K. has already outstripped supply. A number of alternatives to allograft have been investigated. These include xenografts, various ceramics such as hydroxyapatite and other calcium-phosphates, coral, bamboo and reinforced collagen matrices[6,7,8]. Ongoing studies at the University of Bristol are investigating the use of bovine xenografts and glass-ionomer ceramics in in-vitro and in-vivo (ovine) models. The work reported here is part of an ongoing ovine study into allograft substitutes for use in impaction grafting.

Initial results have identified certain shortcomings with both xenografts and glass-ionomers. Xenografts osseo-integrate less well than allograft, and as with allograft, have variability in particle size, particle morphology and impaction properties. They also have potential problems of infection and antigenicity[9].

Glass-ionomers are non-compressible and, as they are non-porous, allow only peripheral osseo-integration with no effective osseo-conduction within the ceramic particles. Tsuruga et al[10] and Kuhne et al[11] have shown that a pore size of approximately 300-400 micrometers in ceramics will allow optimal osseo-conduction.
Hydroxyapatite and tricalcium-phosphate ceramics have been shown to osseointegrate[12,13], but concerns have been raised as to their ability to maintain their structural integrity under load . A harder, tricalcium-phosphate/hydroxyapatite ceramic with a porosity of approximately 400 micrometers mean

diameter has been developed using a higher sintering temperature. This study is designed to determine whether such a tricalcium-phosphate/hydroxyapatite ceramic is mechanically suitable as a bone graft extender and can provide sufficient structural stability for revision arthroplasty with impaction grafting to withstand the high loads applied to the proximal femur in-vivo.

MATERIALS AND METHOD

Sample preparation

A synthetic granular porous pure tricalcium-phosphate/hydroxyapatite ceramic (TCP/HA) was manufactured as a bone graft extender according to the specifications shown in Table 1. Allograft was prepared analogous to the procedure in clinical impaction grafting. Sheep humeral heads were milled with a Norfolk bone mill (Howmedica, Staines) using the coarse milling blade. Humeral heads were used in lieu of femoral heads, as they are larger with a higher proportion of cancellous bone. Large quantities of such bone graft were prepared prior to testing and then mixed together in order to average out the variability in bone quality and in the manual milling process both uncontrolled variables in clinical impaction grafting. Allograft particle size was analysed using a Pulnix TM 520 camera mounted on a height adjustable rig. Samples were spread on a light box and Optimas 6.1 image analysis software was used to assimilate the data and evaluate the images on a computer. (graph 1).

Composition:	80% Tricalcium phosphate 20% Hydroxyapatite
Sintering temperature:	>1200o C (To achieve optimal hardness)
Crystallinity:	high (>80%)
Porosity:	50% by volume
Pore size	300 – 500 microns
Granule size:	2-4 mm

Table 1 Bone graft extender specifications

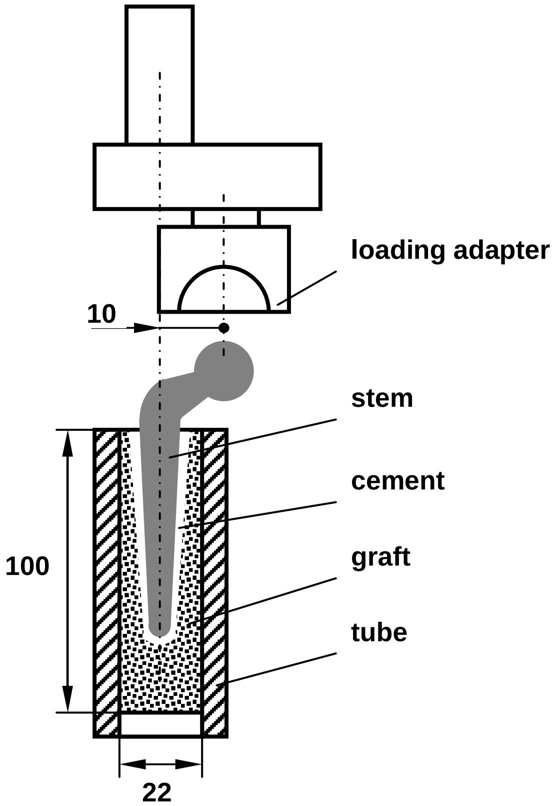
Three groups of 10 samples were prepared each with a different mixture of allograft and BoneSave for use as an impaction grafting material.

- Group1 consisted of pure allograft.
- Group 2 consisted of 50% allograft and 50% BoneSave by volume
- Group 3 consisted of 10% allograft and 90% BoneSave by volume

Pure allograft (Group 1) was used as the gold standard and chosen as the reference against which the two mixes were compared. A pure BoneSave group was not chosen as the opposite extreme because mechanically a small amount of bone “additive” allows cohesion and adhesion of the otherwise loose mix which is crucial for surgical handling. Biologically the bone adds osteoinductive potential to the otherwise only bioactive and osteoconductive ceramic. A 90% BoneSave and 10% allograft volumetric mix was chosen as the extreme (Group 3). The 50% allograft and 50% BoneSave volumetric mix (Group 2) marks an intermediary between Group 1 (pure allograft) and Group 3 (high content BoneSave) so that the effects of adding different quantities of BoneSave to the allograft could be examined.

A mechanical testing model was developed to reproducibly expose the graft to a stress pattern comparable to that experienced in-vivo. Twenty sheep femurs were measured to ascertain the inner dimensions of the proximal femur. The morphology was found to resemble a cylindrical tube with a mean diameter of 22mm (range: 17mm-27mm). Tubes were therefore constructed out of aluminium to mimic a sheep femur with an inner diameter of 22mm. The use of such aluminium tubes provided a standardised testing geometry and mechanical environment for both the impaction grafting process of the morsellised bone plus ceramic mixes and for the subsequent endurance testing of the samples, thus isolating the graft material as the only variable. The higher stiffness of the aluminium tube versus a femur effectively increased the stresses within the graft and allowed for accelerated testing for subsidence.

Standard impaction grafting was performed using specially manufactured sheep impaction instruments (Howmedica, Staines). All samples were impacted until no further impaction was possible and the phantom could only be removed with extreme difficulty. Highly polished double tapered sheep femoral stems (Howmedica, Staines) with modular heads were cemented into the graft composite. Samples were left to cure for 24 hours at a constant temperature of 22 degrees C.



Picture 1: Sketch of experimental set-up

<u>Testing</u>

Force plate analysis performed on thirty skeletally mature Welsh Mountain sheep showed that they generated ground reaction forces peaking at between 250N and 400N when walking. Each sample was block loaded in compression with 200N incremental peak load steps for 20,000 haversine cycles at a frequency of 2 Hz in an Instron 8511 hydraulic testing machine (Instron Corporation, Canton, Massachusetts) as follows.

200N load for 5,000 cycles
400N load for 5,000 cycles
600N load for 5,000 cycles
800N load for 5,000 cycles

The load was transmitted vertically to the head of the prosthesis via an acetabular connector, which was adjustable for offset (see picture 1). The model enabled accelerated testing and a comparative evaluation of the different bone graft/ceramic samples to be carried out. It was accepted that this compromised quantitative comparison of the results with clinical data but it did allow comparative analysis of relative graft performance to be made.

The cycle frequency of 2 Hz mimics the gait speed of walking sheep and therefore modelled comparable conditions for the graft mixes in terms of visco-elastic damping associated with normal gait. Subsidence was recorded by applying an averaging algorithm on the position signal acquired from the Instron hydraulic testing machine using HP Vee software (Hewlett Packard). The end point for each test was defined as completion of 20,000 cycles or subsidence greater than 5mm.

RESULTS

These are illustrated in graph 3: Subsidence versus Load.

	200 N	400 N	600 N	800 N
50:50 VS PURE ALLOGRAFT	P<0.025	P<0.01	P<0.005	P<0.005
90:10 VS PURE ALLOGRAFT	P<0.005	P<0.005	P<0.005	P<0.005
90:10 VS 50:50	NOT SIGNIFICANT	NOT SIGNIFICANT	P<0.05	P<0.05

Table 2: Analysis of statistical difference with the single tailed unpaired Student's t-test

All samples survived the initial 5000 cycles of vertical loading at 200N with less than 1.5mm total subsidence. The least subsidence (0.02mm) was recorded for a 90:10 volume mix of extender and sheep bone allograft whilst the most (1.28mm) was encountered with a pure allograft sample.

After application of the 400N loading three out of the pure allograft samples had visibly subsided, to 3.10mm, 4.50mm and 4.32mm. The other pure allograft specimens all subsided to less than 3mm. All samples impacted with either 50 %volume or 90 %volume BoneSave showed very low total subsidence of a few tenths of a millimetre (average 0.25mm) peaking at 0.50mm for a 50:50 BoneSave/allograft sample.

At 600N and at 800N four of the ten pure allograft samples catastrophically failed with the femoral head touching the tube. For these specimens a maximum subsidence of 5mm was recorded. Subsidence of more than 2mm was only encountered with the pure allograft samples.

All samples impacted with an allograft-BoneSave mixture survived even the 800N load block without approaching the failure criteria. The highest total subsidence after 20,000 cycles of block loading occurred for a specimen with a 50:50 volume mix, which subsidised a total of 1.04mm. On average the high volume synthetic extender mixes (90:10 BoneSave/allograft) subsided significantly less than the 50:50 group.

The largest amount of subsidence within each cyclic load block occurred during the early cycles, quantified at about 80% subsidence during the first 500 cycles and 20% for the following 4500 cycles (see Graph 2). This behaviour was observed for all samples regardless of graft composition.

The pure allograft samples showed the highest variability in subsidence values leading to the least consistent results. The high BoneSave volume mixes of 50% and 90% showed much more consistent subsidence levels at all loads.

After stopping the cyclic loading at each step relaxation of up to 0.1mm was observed regardless of graft composition (See Graph 2).

DISCUSSION

In-vitro tests of impaction grafting can only assess the initial stability of the composite. However, significant subsidence reported in-vivo in the literature occurred within three months.1 It would therefore seem that initial stability is critically important.

There are many factors that effect the subsidence of allograft in-vivo. These include graft preparation, quality of graft, particle morphology and size, impaction techniques, graft composition, post-operative loading, the host's immune response and the host/ graft interface. This study focused on the influence of graft composition by isolating the intrinsic mechanical graft properties as the only variable.

The qualitative course of subsidence over the number of cycles was independent from graft composition and peak load. The largest amount of subsidence occurred in the early stage of loading the samples, suggesting that cyclical loading at first generates a further degree of impaction. This was followed by a slow exponential decay which became assymptotic towards the end of the block loading sequence and this to some extent, replicates the clinical scenario.

Adding TCP/HA granules to the morsellised allograft bone chips as a bone graft extender significantly increased the samples' resistance to subsidence in the comparison of both mixes of allograft/ceramic against pure allograft. This demonstrates the potential of TCP/HA extender mixes to provide higher initial mechanical stability than pure allograft when used clinically. The high mechanical stability recorded for the large synthetic volume graft mixes suggests that the stabilising effect of osseointegration, necessary for the long-term success of pure allografts, might be less crucial when using an optimised bone graft extender. At the same time the increased initial stability would allow earlier and higher load bearing of the patients postoperatively and thus might even stimulate osteogenesis.

Pure bone allograft does not provide reproducibility, despite the efforts to reduce the variability inherent in a manually harvested and prepared biological material by mixing several morsellised heads together. The pure allograft samples showed the highest standard deviation in subsidence leading to the least predictable results. In contrast the samples with high extender volume mixes of 50% and 90% showed much more consistent subsidence levels at all loads. In the clinical environment there is great variability in quality of allograft due to donors' health, sex, size and age, different sterilisation methods and storage procedures. Adding the TCP/HA graft extender would reduce bone graft variability. Since graft variability is perceived as a reason for the different results achieved in impaction grafting at hip revision, adding TCP/HA ceramic granules of controllable properties could improve the success rate by providing a more mechanically consistent graft material.
Subsidence of allograft as measured in this model is higher than in the in-vivo setting. This is due to differences between the model and the in-vivo setting (such as the absence of osseointegration, and different moduli of elasticity). As such the model is more demanding than the in-vivo setting, but has the advantage of isolating graft composition as the only variable.

The second part of this project will be an in-vivo ovine study to assess the extent of osseointegration of different allograft compositions, and its effect on mechanical stability.

ACKNOWLEDGEMENTS

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The effect of preparatory technique on the compressive properties of morsellised bone graft.

Gozzard C[1], Grimm B[2], Miles AW[2], Learmonth ID[1].
(1-Dept of Orthopaedic Surgery, University of Bristol, 2-Dept of Mechanical Engineering, University of Bath)

Introduction:

Surgical technique is an important factor in determining outcome following impaction grafting. The mechanical properties of the morsellised graft may also alter the behaviour of the impacted graft, both during and after impaction. Several methods are currently employed to prepare morsellised bone graft prior to impaction. The aim of this study is to determine what effect different preparation methods have on the mechanical compressive properties of morsellised bone graft. As demand for human bone for impaction grafting outstrips supply, availability of human bone for research purposes is limited. This study also investigates the compressive properties of ovine bone with a view to determining its suitability for use in impaction grafting research.

Materials and Method:

Six methods of preparing human morsellised bone graft were tested (see table 1).

Human bone graft		
fresh from mill	frozen and thawed	washed and towel dried
Fixed with formaline	irradiated at 2.5 MRad	irradiated at 5 MRad

Table 1. Methods of preparation of human morsellised bone graft.

To reduce the effects of mechanical variability between femoral heads, morsellised bone graft from four femoral heads was mixed prior to mechanical testing.
Three methods of preparing ovine morsellised bone graft were tested (see table 2).

Ovine bone graft		
fresh from the mill	washed and towel dried	fixed with formaline

Table 2. Methods of preparation of ovine morsellised bone graft.

Ovine humeral head morsellised graft samples were also combined prior to compression testing.
Compression testing of morsellised bone graft was performed using a die-plunger. The die consisted of a hollow tube of 20mm diameter which was capped by a porous disc. The porous disc enabled the escape of fluid from the samples during compression. The plunger consisted of a 20mmm diameter hollow cylinder. The starting volume of each morsellised bone sample was $10cm^3$. The die-plunger was positioned in a materials testing machine. Each sample was tested to a compressive load of 500N. Following compression to 500N, the fall in relaxation force was recorded over a two minute period. Each morsellised bone graft sample was tested six times. Load-displacement data were recorded. Stress-strain curves and a secant compression modulus was calculated for each bone graft sample. Percentage relaxation of the bone graft was recorded over a two minute period. Statistical analysis on all data was performed using the unpaired student t-test.

Results:

Compression moduli resulting from each method of bone graft preparation are shown in figure 1. The stiffness of human bone graft varied from 3.65-3.87MPa according to the method of graft preparation. Only the difference between fresh and irradiated human graft was statistically significant ($p_{2.5MRad}=0.038$, $p_{5MRad}=0.02$). Ovine morsellised bone graft was stiffer than human (3.93-4.27MPa). The stiffness of fresh ovine bone graft was 16% greater than fresh human graft ($p<0.0001$). Washing and drying ovine bone graft reduced the secant modulus by 7% ($p=0.004$). The effect of bone graft preparation on force relaxation is shown in figure 2. For human graft, increased relaxation was noted for all groups ($p<0.035$) except formaline fixation ($p=0.0527$). Washing and drying and formaline fixation reduced relaxation in the ovine groups ($p<0.0001$).

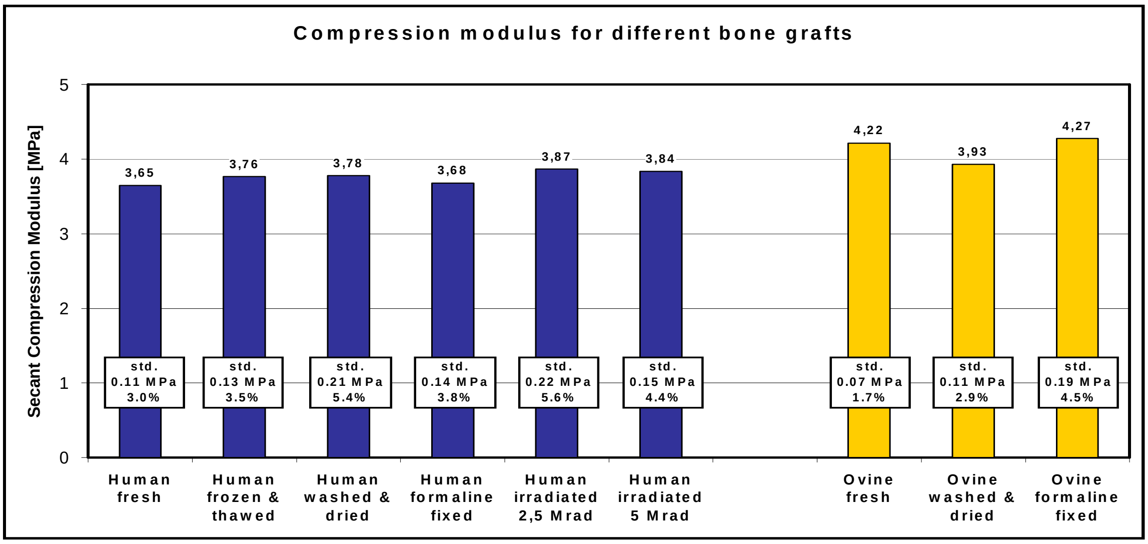

Figure 1. Compression moduli for different graft materials.

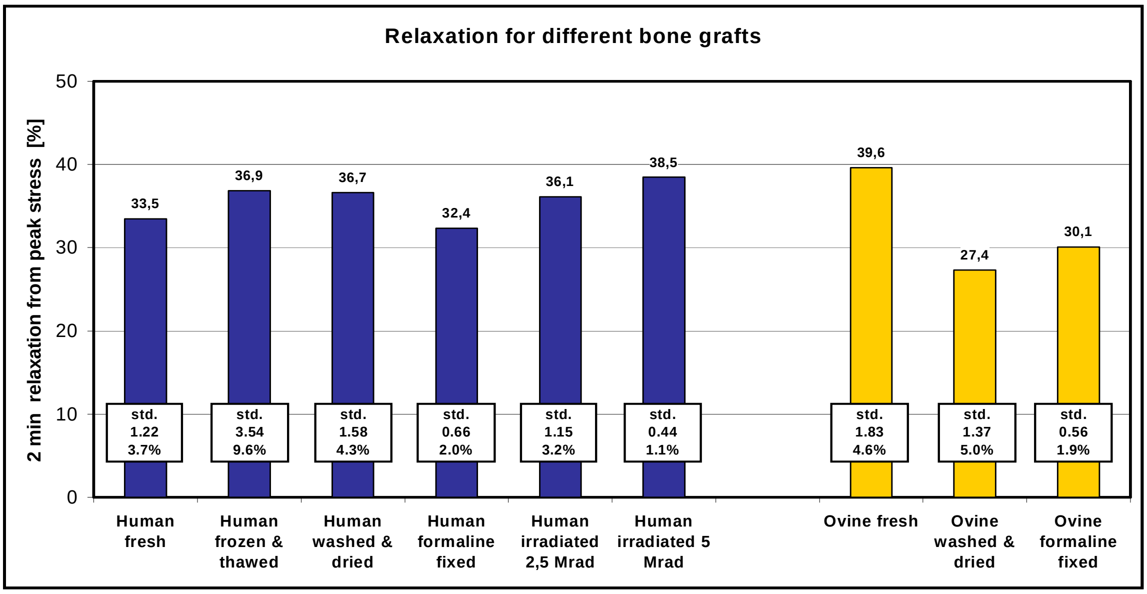

Figure 2. Force relaxation for different graft materials.

Discussion:

Different methods of preparing morsellised human bone graft had little effect on the stiffness of the graft material. Relaxation behaviour was more susceptible to graft treatment. Methods of graft preparation may affect the viscoelastic organic properties of human bone graft to a greater extent than the mineral content.

The compressive behaviour of ovine bone graft was comparable to human bone graft. The higher stiffness of ovine bone may be explained by the donor source - ovine humeral heads were obtained from young, healthy sheep as opposed to human femoral heads from osteoporotic elderly patients. The sensitivity of ovine bone graft to preparation method may reflect a higher organic content. The use of ovine bone as a substitute for human bone during in-vitro research appears justified.

8 6th World Biomaterials Conference, 15.05.-20.05.2000, Hawaii

Mechanical properties of morsellised bone graft and synthetic substitutes for Impaction Grafting Total Hip Revision Arthroplasty.

Grimm B.; Sandford G.C., Lee J.R., Miles A.W., Turner I.G.
Department of Mechanical Engineering and Department of Materials Science and Engineering, University of Bath, Claverton Down, Bath

Introduction: Impaction grafting has become an increasingly popular technique in revision total hip arthroplasty. Morsellised allograft bone chips are impacted into the femoral cavity creating a new medullary canal for the insertion and cementation of a new prosthesis[1]. One of the most important factors determining clinical success of the operation is the initial mechanical stability of the implant. This ensures short and long-term implant position and reduces micromotion to a level where osteogenesis and bone remodelling can take place[2]. The growing popularity of impaction grafting has led to a situation where demand for bone graft outstrips supply[3]. This has made the development and mechanical analysis of synthetic grafts as a bone replacement or extender an urgent issue. This paper reports on the development of mechanical testing protocols for evaluating synthetic bone graft materials.

Materials and Methods: Two test methods have been developed:

(1) The first method was based on techniques used in civil engineering soil mechanics where shear strength is a fundamental factor for the mechanical stability of particulate aggregates. As an analogy the Mohr-Coulomb failure criterion has been applied to bone grafts and the shear properties - cohesion *c* and angle of shearing resistance ϕ determined[4]. In this study experiments were carried out using a shear box consisting of two 60mm by 60mm cuboids filled with graft and sheared against each other along their separating plane similar to the set-up described by Brewster *et al*[5]. The materials investigated were; pure morsellised trabecular bone graft harvested from sheep femoral and humeral heads, a 50:50 and a 10:90 volume mix of this bone graft and granules of a 80% tricalcium phosphate and 20% hydroxyapatite ceramic with 50% porosity sintered at 1150 °C. In addition the shear properties of a 50:50 mix with no impaction and with impaction forces of 490N and 710N were compared.

(2) A model simulating loading conditions for the bone graft between prosthesis and femoral canal has been developed. It consisted of a 25mm diameter metal tube and a metal cone of 120mm length with decreasing diameter from 16mm at the top to 5mm at the end. The tube was filled with bone graft and the cone driven into the tube with a dropping weight. Impaction energy, number of hammer blows and set per hammer blow could thus be controlled (Impactometer). After impaction the model was mounted in an Instron servohydraulic machine and cyclically block-loaded in compression at peak loads of 0.2, 0.4, 0.8 and 1.2 kN for 5000 cycles each and subsidence was recorded. Subsidence of 5mm or more was regarded as failure. The material investigated was the same 50:50 mix as above varying the HA-TCP ceramic's particle size through sieving - fine (1-2mm), medium (2-4mm) and coarse (>4mm) particles.

Results: Adding synthetic HA-TCP granules to natural bone graft increased the angle of shear resistance and therefore the shear strength of the graft. The cohesion at the same time decreased, as a result of the lower fat content in the mixes (Fig.1). Higher impaction forces increased the shear strength of the graft (Fig. 2). Graft mixes containing fine HA-TCP particles caused significantly less subsidence than mixes with coarse particles, which all failed at 1.2 kN peak load (Fig. 3).

Discussion: HA-TCP ceramic particles as an alternative or an extender for morsellised bone graft have a higher shear strength than bone graft and therefore are mechanically suited to clinical application. The higher the synthetic component in the mix, the higher the shear strength. Further work needs to be done to investigate whether the reduction in cohesion associated with the use of synthetic grafts affects initial stability and surgical handling (Impactomter and cyclic loading tests). Compaction with higher forces also contributed to higher shear strength emphasising the importance of intense graft impaction in the clinical situation. Clinically however, the risk of femoral fracture and the higher graft density compromising graft revascularisation needs to be balanced against this improvement. Mixing bone graft with fine HA-TCP particles results in a higher stability and a greater resistance to subsidence than mixing with coarse particles. This may have been the result of better impaction which was achieved with smaller, and therefore more mobile, particles. The theory of soil mechanics suggests a particular particle size distribution to give optimum shear strength. Current experiments will investigate the influence of particle size mixes, particle morphology, porosity, cohesion and particle friability on shear properties and cyclic stability of synthetic bone graft for clinical use in impaction grafting.

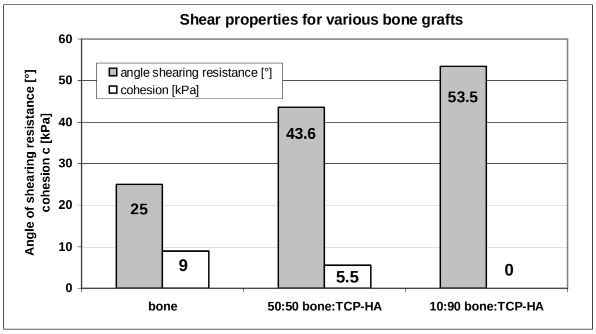

Fig. 1: ***Shear properties for various bone grafts.***

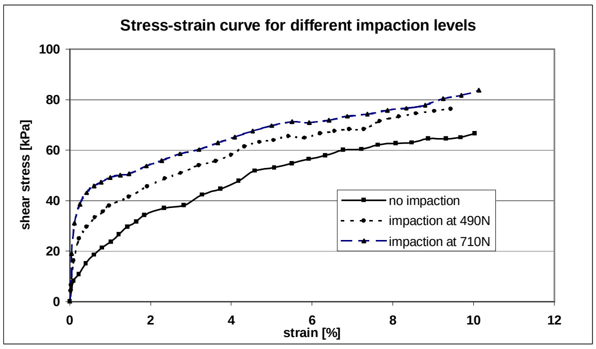

Fig. 2: ***Stress-strain curve for different impaction levels.***

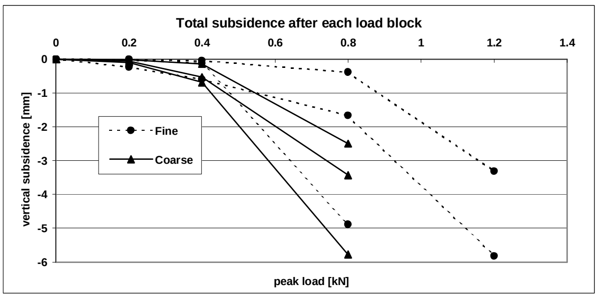

Fig. 3: ***Subsidence of fine and coarse graft after cyclic loading.***

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Influence of bone graft parameters on the stability of impaction grafting revision hip arthroplasty

Grimm B.; Miles A.W., Turner I.G.

Department of Mechanical Engineering and Department of Materials Science and Engineering, University of Bath, Claverton Down, Bath BA2 7AY, United Kingdom

Introduction: In Impaction grafting morsellised allograft bone chips are impacted into the femoral cavity creating a new medullary canal for the insertion and cementation of a new prosthesis[1]. One of the most important factors determining clinical success is the initial mechanical stability of the implant. This ensures short and long-term implant position and reduces micromotion to a level where osteogenesis and bone remodelling can take place[2]. Demand for bone graft has outstriped supply[3] urging the development of synthetic grafts as a bone replacement or extender.

Materials and Methods: Two test methods have been developed: (1) Shear strength is a fundamental factor for the mechanical stability of particulate aggregates. Cohesion c and angle of shearing resistance φ were determined[4] using a shear box consisting of two 60mm by 60mm cuboids filled with graft sheared against each other along their separating plane[5]. Materials investigated: Pure morsellised trabecular ovine bone graft, a 50:50 and a 10:90 volume mix of such bone graft and granules of a 80% tricalcium phosphate and 20% hydroxyapatite ceramic with 50% porosity sintered at 1150 °C. In addition the shear properties of a 1:1 b/c mix with different impaction forces (0-710N) were compared.

(2) A model simulating loading conditions for the bone graft between prosthesis and femoral canal has been developed. A 25mm diameter tube was filled with bone graft and the 120mm cone driven into the tube with a dropping weight. Impaction energy, No. of hammer blows and set per hammer blow could thus be controlled (Impactometer). After impaction the model was mounted in an Instron servohydraulic machine and cyclically block-loaded in compression at peak loads of 0.2, 0.4, 0.8 and 1.2 kN for 5000 cycles each and subsidence was recorded. Subsidence of 5mm or more was regarded as failure. The material investigated was the same 1:1 b/c mix as above varying the HA-TCP ceramic's particle size through sieving - fine (1-2mm), medium (2-4mm) and coarse (>4mm) particles.

Results: Adding synthetic HA-TCP granules to natural bone graft increased the angle of shear resistance and therefore the shear strength of the graft. The cohesion at the same time decreased, as a result of the lower fat content in the mixes (Tab.1). Higher impaction energies significantly increased the stability of bone graft (Fig. 1). Most graft mixes containing fine HA-TCP particles failed earlier than mixes with coarse particles (Fig. 2).

Conclusions: HA-TCP ceramic particles as an alternative or an extender for morsellised bone graft have a higher shear strength than bone graft and therefore are mechanically suited to clinical application. The higher the synthetic component in the mix, the higher the shear strength. Compaction with higher energies had the strongest effect on initial mechanical stability emphasising the importance of intense graft impaction in the clinical situation. Mixing bone graft with fine HA-TCP particles results in a higher stability and a greater resistance to subsidence than mixing with coarse particles. This may have been the result of better impaction which was achieved with smaller, and therefore more mobile, particles. Current experiments will investigate the influence of particle size mixes, particle morphology, porosity, cohesion and particle friability on shear properties and cyclic stability of synthetic bone graft for clinical use in impaction grafting.

	Cohesion c [kPa]	**Shear angle φ [°]**
Bone	25	9
1:1 bone/ceramic mix	43.6	5.5
1:9 bone/ceramic mix	53.5	0

Tab. 1: ***Shear properties for various bone grafts.***

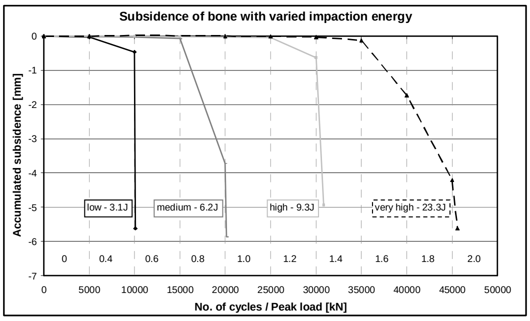

Fig. 1: ***Stress-strain curve for different impaction levels.***

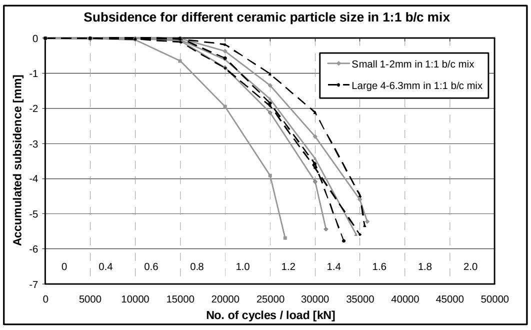

Fig. 2: ***Subsidence of fine and coarse graft after cyclic loading.***

References: **1.** Gie *et al.*, J Bone Joint Surg [Br] 1993; 75-B (1):14-21; **2.** Schreurs *et al.*, Acta Orthop Scand 1994, 65 (3): 267-275; **3.** Galea *et al.*, J Bone Joint Surg [Br] 1998; 80-B (4):595-9 **4.** Craig, Soil Mechanics, 6th Ed., Chapman & Hall, 1997 **5.** Brewster *et al.*, J Bone Joint Surg [Br] 1999; 81-B (1):118-24.

Acknowledgements: The research work has been supported by Stryker Howmedica Osteonics Corp., Staines, U.K.

10 4th Comb. Meeting Orth. Res. Soc. of USA, Canada, Europe Japan, 1.-3.06.2001, Rhodes

In-vitro analysis of initial mechanical stability of morsellised bone grafts and extenders for Impaction Grafting.

Grimm B.; Miles A.W., Turner I.G.

Department of Mechanical Engineering and Department of Materials Science and Engineering, University of Bath, Claverton Down, Bath BA2 7AY, United Kingdom

Introduction: In revision hip arthroplasty bone stock loss is a fundamental problem. Impaction Grafting is a surgical method which compensates the bone stock loss by compacting morsellised bone allograft into the femoral cavity and thus creating a new medullary canal which allows a standard hip prosthesis to be cemented. In order to assure a firm short and long term implant position and to limit micromotion to a level where the desired revascularisation of the graft and bone remodelling can take place, initial mechanical stability is paramount. An in-vitro model and test protocol was developed to analyse the effects of operative technique and different graft materials on initial mechanical stability. The model exposes the bone graft to comparable loading conditions which lead to vertical subsidence as the dominant failure mode in clinical impaction grafting. Variations in graft preparation, impaction levels and different materials can thus be compared against bone allograft as the gold standard.

Materials and Methods: The model used a standardised impaction procedure and a fixed geometry and stiffness for the tube-cone/femur-stem model. Derived from a human femur, it comprised a 25mm diameter metal tube and a metal cone of 120mm length with decreasing diameter from 16mm proximally to 5mm distally. The tube was filled with bone graft, the graft compacted and the cone driven into the tube with a device called the Impactometer. A weight of a preset adjustable height dropped along a guide wire and impacted a flat disc (pre-impaction, distal impactor) and the cone (phantom prosthesis), the positions were monitored at both stages. This allowed impaction energy to be controlled and repeated. Cement was not used to eliminate the variability introduced by cementation to allow focus on the influences of graft properties and impaction variables. After impaction the model was mounted in an Instron servohydraulic machine and cyclically block-loaded in compression at peak loads from 0.2 kN to 2.0 kN in 0.2 kN steps for 5000 cycles each and subsidence was recorded. Subsidence of 5mm or more was regarded as failure.

Materials: The graft materials investigated were volume mixes of pure morsellised trabecular bone graft harvested from sheep femoral and humeral heads and granules of a tricalcium-phosphate/hydroxyapatite ceramic of different porosity (0%, 25%, 50%), sintering temperature (1050°C, 1150°C, 1200°C) at a constant particle size a 2-4mm. Mixing ratios (bone:ceramic extender) were pure bone, 2:1, 1:1 and 1:2.

Results: Adding synthetic HA/TCP granules to natural bone graft increased mechanical stability against cyclic loading subsidence (Fig.1). Even at low ceramic volumes (b:c=2:1) a strong improvement was discovered. Adding the ceramic also lead to less variable and thus more predictable behaviour (Fig.1). Higher impaction levels increased mechanical stability for pure bone grafts as well as for bone/ceramic mixes (Fig.2). It was observed that the strengthening effect of adding HA/TCP granules was the greatest at low impaction levels. Only at very high impaction levels could pure bone grafts match the mechanical performance of the ceramic mixes. Increasing porosity of the ceramic granules decreased mechanical stability only slightly for medium pore levels but significantly at higher values (Fig.3). However a highly porous ceramic mix is still as mechanically stable as a pure bone graft (Fig.1, Fig.3). Raising the sintering temperature of the HA/TCP in the graft mix up to 1150°C increases stability but had less effect at higher temperatures (Fig.4).

Discussion: Adding HA/TCP granules as a bone graft extender led to increased initial stability, less variability in graft performance and less sensitivity to impaction levels when compared to pure allografts. Therefore the HA/TCP particles investigated are mechanically suitable for clinical application. For all ceramic parameters and all mixing ratios tested the surgeon can expect mechanical performance superior or at least on par with pure bone graft. The controlled ceramic properties take out the variability of Impaction Grafting inherent in morsellised allograft. The significant stability increase of synthetic mixes already at low impaction levels, promises that the risk of femoral fracture due to excessive impaction could be reduced. The decrease in mechanical stability for the high porosity ceramics, desirable for bone ingrowth, could be compensated by a higher sintering temperature.

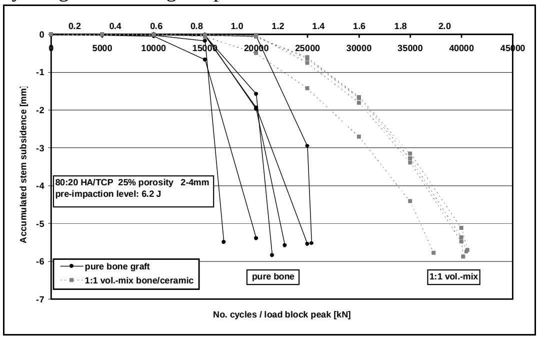

Fig.1: ***Stem subsidence: Pure bone and 1:1 vol.-mix bone:ceramic.***

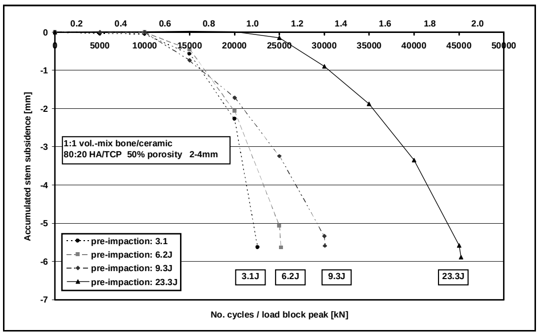

Fig.2: ***Stem subsidence for different impaction levels.***

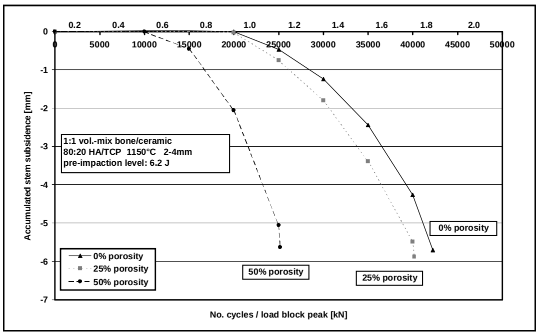

Fig.3: ***Stem subsidence for different ceramic porosities in a graft mix.***

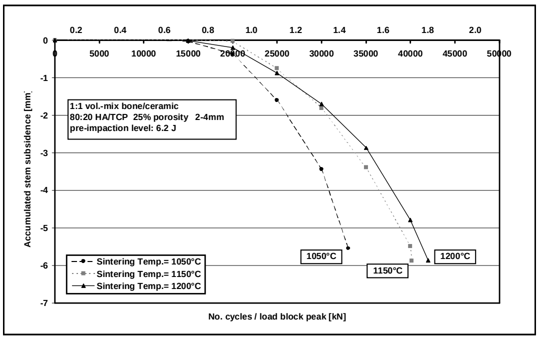

Fig.4:***Stem subsidence for different ceramic T_{sinter} in a graft mix.***

References:

1. Gie *et al.*, J Bone Joint Surg [Br] 1993; 75-B (1):14-21

2. Schreurs *et al.*, Acta Orthop Scand 1994, 65 (3): 267-275

3. Grimm *et al.*, World Biomat Conf 2000, Transaction Vol.2: 564

11 UK Soc Biomaterials Student Conference 2001, 19.07.2001, Birmingham U.K.

Mechanical Testing of a Hydroxyapatite/Tricalcium-Phosphate ceramic for the Development of a Bone Graft Extender in Impaction Grafting

Grimm B.; Miles A.W., Turner I.G.

Dept Mechanical Engineering and Dept Materials Science and Engineering, University of Bath, Bath BA2 7AY, UK

Introduction: Impaction Grafting addresses the major problem in revision hip arthroplasty: bone stock loss. Morsellised allograft bone chips are impacted into the femoral cavity creating a new medullary canal for the cementation of a new prosthesis[1]. Demand for bone graft has outstriped supply[2] creating the need for synthetic graft replacements or extenders. The development of such synthetic grafts has to consider biological aspects of biocompatibility and osteogenicity and mechanical factors such as the initial stability of the implant. It ensures short and long-term implant position and reduces micromotion to a level where osteogenesis and bone remodelling can take place[3].

Materials and Methods: The graft materials investigated were 1:1 vol.-mixes of pure morsellised trabecular bone graft harvested from sheep humeral heads and a synthetic graft manufactured by TCM Associates, U.K. for Stryker-Howmedica-Osteonics, U.K. with the following properties: 2-4mm granules of a tricalcium-phosphate/hydroxyapatite (HA/TCP) ceramic of different porosity (0%, 25%, 50%), sintering temperature (1050°C, 1150°C, 1200°C) and chemical composition (HA/TCP ratios 20:80, 80:20).

A model simulating loading conditions for the bone graft between prosthesis and femoral canal has been developed. A 25mm diameter tube was filled with bone graft and a 120mm cone driven into the tube with a dropping weight. Impaction energy, No. of hammer blows and set per hammer blow could thus be controlled (Impactometer[4]). After impaction the model was mounted in an Instron servohydraulic machine and cyclically block-loaded in compression at peak loads of 0.2, 0.4, 0.8 and 1.2 kN for 5000 cycles each and subsidence was recorded. Subsidence of 5mm or more was regarded as failure.

Results: All graft mixes containing the synthetic HA/TCP granules showed increased initial mechanical stability compared to pure bone. Higher porosity of the ceramic granules decreased stability slightly at 25% porosity but substantially at 50% (Fig.1). Raising the sintering temperature of the ceramic improved stability with declining effect nearing the degradation temperature (Fig. 2). The high hydroxyapatite ceramic mixes were more stable than the high tricalcium-phosphate samples (Fig.3).

Conclusions: Ceramics of all parameter variations tested are mechanically suited as bone graft extenders for Impaction Grafting. Regarding mechanical requirements, a non-porous ceramic with a high hydroxyapatite content is preferable. Biologically however maximum porosity is needed for bone ingrowth and a high tricalcium-phosphate ceramic is superior to a high hydroxyapatite ceramic as it resorbs faster and thus accelerates the clinically desired bone incorporation and subsequent remodelling process. The stability sacrificed and can partially be compensated by a high sintering temperature. The compromise identified between mechanical and biological requirements has led to the optimal ceramic configuration chosen by Stryker-Howmedica-Osteonics as their commercial bone graft extender BoneSave.

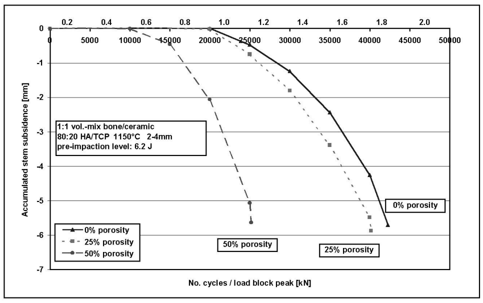

Fig. 1: Stem subsidence varying ceramic porosities.

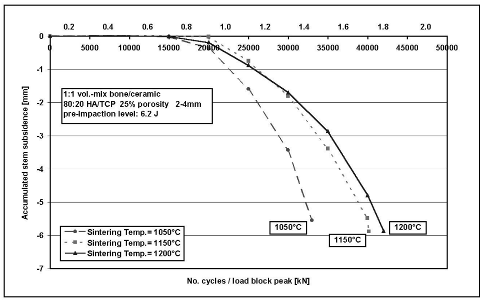

Fig. 2: Stem subsidence varying T_{sinter} of ceramic.

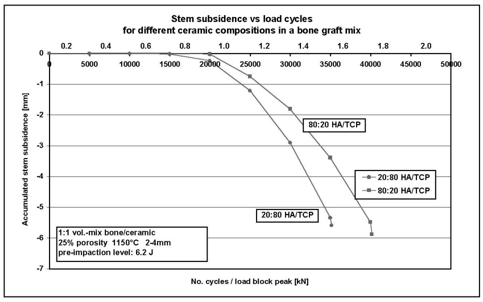

Fig. 3: ***Stem subsidence varying ceramic HA/TCP ratio.***

References: 1. Gie *et al.*, J B J S [Br] 1993; 75-B (1):14-21
2. Galea *et al.*, Acta Orthop Scand 1994, 65 (3): 267-275
3. Schreurs *et al.*, Acta Orthop Scand 1994, 65 (3): 267-275
4. Grimm *et al.*, World Biomat Conf 2000, Transaction Vol.2: 564

12 16th European Society of Biomaterials Comb. Conference, 12.-14.09.2001, London, U.K.

Optimising a Hydroxyapatite/Tricalcium-Phosphate ceramic as a Bone Graft Extender for Impaction Grafting

B. Grimm[1], A.W. Miles[1], I.G. Turner[2]
[1]Dept Mechanical Engineering, University of Bath, Claverton Down, Bath, BA2 7AY
[2]Dept Engineering and Applied Science, University of Bath, Claverton Down, Bath, BA2 7AY

Introduction: In Impaction Grafting revision THR femoral bone stock loss is compensated by compacting morsellised bone allograft into the femoral cavity. The compacted graft creates a new medullary canal for the cementation of a standard hip prosthesis[1]. Insufficient availability of donor bone, risk of infection or rejection and variable graft quality have lead to the development of synthetic bone graft extenders. For the optimisation of such materials, mechanical evaluation is crucial. In order to assure a firm short and long term implant position and to limit micromotion to a level where the desired graft revascularisation and bone remodelling can take place[2], initial mechanical stability is paramount. An in-vitro model was developed to analyse the effects of different graft properties on initial mechanical stability. The model exposes the bone graft to comparable loading conditions which lead to vertical subsidence as the dominant failure mode in clinical impaction grafting. An ideal property profile of a ceramic as an extender for morsellised bone graft was identified.

Materials and Methods: (1) A basic quasistatic compression test on 10cm^3 sample volumes was performed in a 20mm diameter die to derive a compression modulus and compare the relaxation behaviour of individual graft materials. (2) Above model used a standardised impaction procedure and a fixed geometry and stiffness for the tube-cone/femur-stem model. Derived from a human femur, it comprised a 25mm diameter metal tube and a metal cone of 120mm length with decreasing diameter from 16mm proximally to 5mm distally. The tube was filled with bone graft, the graft compacted and the cone driven into the tube with a device called the Impactometer[3] using a dropping weight of a pre-set adjustable height. This allowed impaction energy to be controlled and repeated. After impaction the model was mounted in an Instron servohydraulic machine and cyclically block-loaded in compression at peak loads from 0.2 kN to 2.0 kN in 0.2 kN steps for 5000 cycles each and subsidence was recorded. Subsidence of 5mm or more was regarded as failure. Materials: The graft materials investigated were 1:1 volume mixes of formaline fixed morsellised trabecular bone graft harvested from ovine humeral heads and granules of a hydroxyapatite/tricalcium-phosphate ceramic of different porosity (0%, 25%, 50%), sintering temperature (1050°C, 1150°C, 1200°C) particle size (small 1-2mm, medium 2-4mm, large 4-6.3mm) and composition (HA/TCP ratios 80/20 and 20/80)

Results: Compression properties of dry human, fresh and fixed ovine bone graft is similar with low compression moduli and high relaxation values. The synthetic HA/TCP granules are distinctively stiffer and show less relaxation depending on their manufactured properties (Tab.1). Adding synthetic HA/TCP granules to natural bone graft improved mechanical stability against cyclic loading subsidence (Fig.1). Increasing porosity of the ceramic granules decreased mechanical stability of the graft mix only slightly for medium pore levels but significantly at higher values (Fig.1). Raising the sintering temperature of the HA/TCP up to 1150°C increased stability but had less effect at higher temperatures (Fig.2). Increasing the TCP content of the ceramic by reversing the HA/TCP ratio from 80:20 to 20:80, stability dropped slightly (Fig 3). Medium ceramic particles were most stable when compared to both small and large granules of similar stability (Fig.4).

Discussion: Ovine bone is a suitable model for replacing human bone in in-vitro mechanical tests of morsellised grafts. The HA/TCP granules tested increase stability and thus are mechanically suited as bone graft extenders for impaction grafting. Varying porosity levels and the TCP content of the HA/TCP ceramic affects stability. The effects must be considered when porosity is increased for improved bone ingrowth or the TCP content is raised for higher in-vivo resorption rates and thus enhanced bone remodelling. The lost stability can partially be compensated by higher sintering temperatures. Medium sized granules give the best mechanical stability. Large granules do not distribute well and create more void space and thus fracture more easily. Small ones do not interlock well and like sand move more easily. All this gives way to increased subsidence.

bone graft	human	ovine	ovine fixed	HA/TCP
Comp. modulus [MPa]	6.75	7.03	Ø 7.75	11-56
Relaxation [%]	32.8	40.0	30.3	16.8-25.6

Tab. 1: *Secant compression modulus and relaxation for morsellised bone grafts: Dried human, fresh and fixed ovine.*

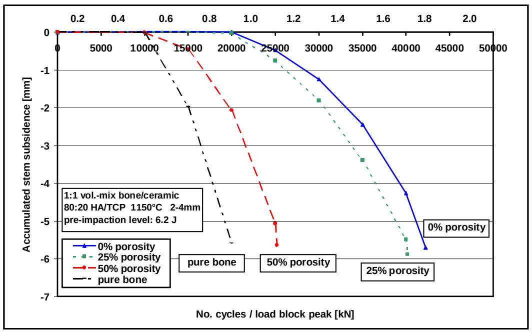

Fig. 1: ***Stem subsidence varying ceramic porosity in a bone graft mix.***

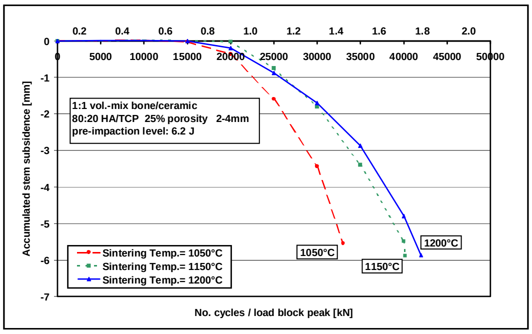

Fig. 2: ***Stem subsidence varying T_{sinter} of ceramic in a bone graft mix.***

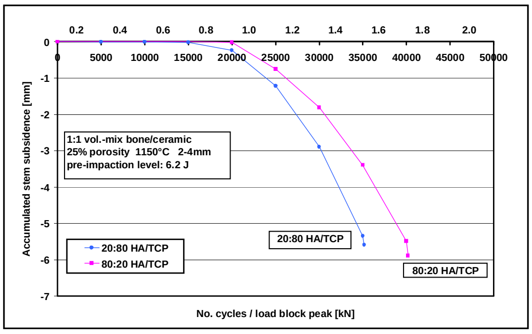

Fig. 3: ***Stem subsidence varying ceramic HA/TCP ratio in a graft mix.***

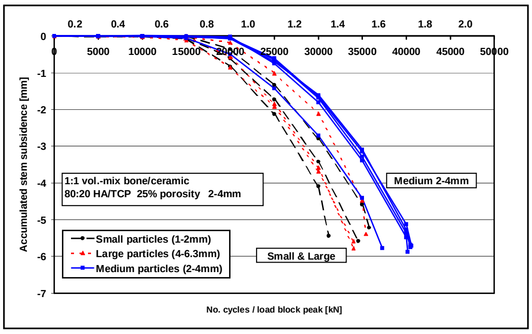

Fig. 4: ***Stem subsidence varying ceramic particle size in a graft mix.***

References: . Gie *et al.*, J Bone Joint Surg [Br] 1993; 75-B (1):14-21
2. Schreurs *et al.*, Acta Orthop Scand 1994, 65 (3): 267-275
3. Grimm *et al.*, World Biomat Conf 2000, Transaction Vol.2: 564

13 14th Int. Symp Ceramics in Medicine (Bioceramics 14), 14–17.11.2001, Palm Springs, USA

In-Vitro Endurance Testing of bone Graft materials for impaction grafting

B. Grimm,[1] A. W. Blom,[2] and A.W. Miles,[3] I. G. Turner,[4]

[1, 3] Dept Mechanical Engineering, University of Bath, U.K., [2] Dept Orthopaedic Surgery, University of Bristol, U.K.,.[4] Dept Engineering and Applied Science, University of Bath, U.K.

INTRODUCTION: In Impaction Grafting morsellised allograft bone chips are impacted into the femoral cavity to compensate for the bone stock loss associated with revision hip arthroplasty. Thus a new medullary canal for the insertion and cementation of a new prosthesis is created[1]. One of the most influential factors determining clinical success of the operation is the initial mechanical stability of the implant. It ensures short and long-term implant position and reduces micromotion to a level where osteogenesis and bone remodelling can take place[2]. In order to analyse the effects of variations in operative technique and different graft properties on the initial mechanical stability, two standardised in-vitro models and test protocols were developed. They simulate the loading conditions for the bone graft between prosthesis and femoral canal and were used to analyse the influence of compaction energy on stability and how mixing bone graft with a synthetic replacement or extender affects implant performance.

METHODS: Two test methods have been developed:

(1) *Ovine model:* Morsellised ovine bone graft was impacted into a metal tube as a model for the average ovine endosteal geometry. An Impaction Grafting toolkit (StrykerHowmedicaOsteonics) was used comprising a guide wire, slap hammer, various distal impactors and a trial prosthesis. An polished and double-tapered Exeter-type ovine hip stem was cemented into the created canal using PMMA bone cement. The model was mounted in an Instron servohydraulic machine and cyclically block-loaded in compression at peak loads of 0.2, 0.4, 0.6, 0.8 kN for 5000 cycles each and subsidence was recorded. Subsidence of 5mm or more was regarded as failure.

(2) *Human sized tube-cone model:* The model was developed to introduce controlled impaction and to eliminate the variability introduced through cementation, thus allowing focus on the influence of graft properties and impaction variables. It consisted of a 25mm diameter metal tube and a metal cone of 120mm length with decreasing diameter from 16mm at the top to 5mm at the end. The tube was filled with bone graft, compacted and the cone driven into the tube with a device called the *Impactometer*[3]. A weight of a preset adjustable height drops along a guide wire and impacts a cone of which the position can be monitored. This allows impaction energy and momentum to be controlled and repeated. After impaction the model was mounted in an Instron servohydraulic machine and cyclically block-loaded in compression at peak loads from 0.2 kN to 2.0 kN in 0.2 kN steps for 5000 cycles each and subsidence was recorded. Subsidence of 5mm or more was regarded as failure.

Materials: The graft materials investigated were volume mixes of pure morsellised trabecular bone graft harvested from sheep humeral heads and granules of a tricalcium-phosphate/hydroxyapatite ceramic with 50% porosity sintered at 1150 °C and a 2-4mm particle size. For model *(1)* mixing ratios (bone:extender) were pure bone, 1:1 and 1:9; for model *(2)* mixing rations were pure bone, 2:1, 1:1 and 1:2.

RESULTS: Adding synthetic HA-TCP granules to natural bone graft even in small amounts increased mechanical stability against cyclic loading subsidence in both the ovine (*Fig.1*) and the human model (*Fig.2*). The ceramic extender leads to less rapid, more predictable and less variable subsidence. Increasing compaction energy contributes greatly to a higher mechanical stability of the implant (*Fig.3*).

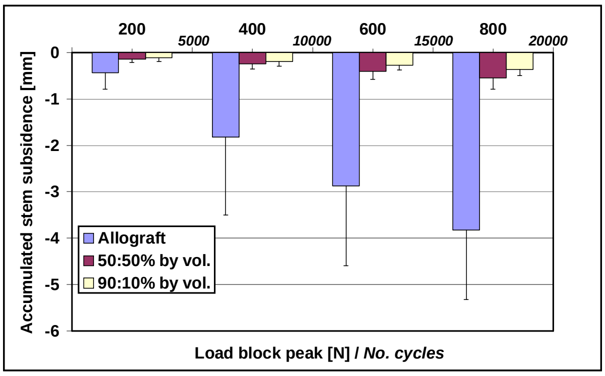

Fig. 1: *Stem subsidence in ovine model accumulated during block loading varying graft/extender mixing ratios.*

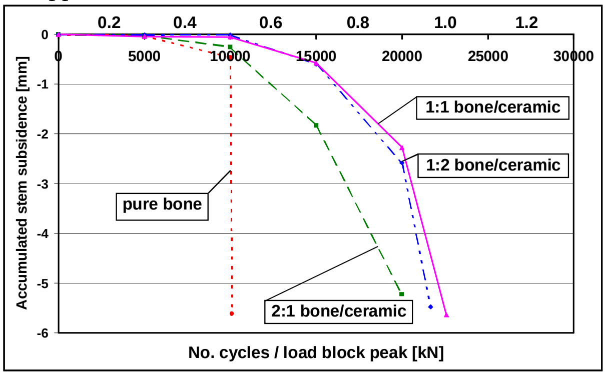

Fig. 2: *Stem subsidence in human model accumulated during block loading varying graft/extender mixing ratios*

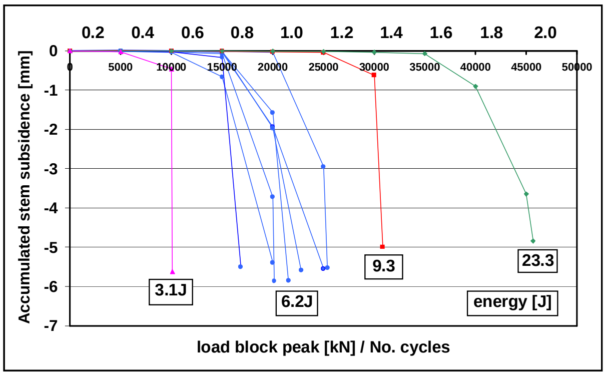

Fig. 3: *Stem subsidence in human model during block loading varying compaction energy (pure morsellised bone).*

DISCUSSION & CONCLUSIONS: Adding TCP/HA particles such as BoneSave of StrykerHowmedicaOsteonics as a bone graft extender led to increased stability and is therefore suited mechanically for clinical application. This effect was shown in both the ovine model using a cemented stem as well as the uncemented tube-cone model resembling the human femoral geometry. This suggests the suitability of both procedures as relevant and efficient mechanical models. In particular the human size tube-cone model shows that cementation and the use of a polished double-tapered stem is not necessarily required for analysing the mechanical stability of graft materials in-vitro.

The less variable subsidence and less rapid subsidence of the ceramic mix samples is a result of the controlled ceramic properties versus the variable bone quality due to donor's sex, size and age and different sterilisation, storage and milling procedures. Using TCP/HA granules such as BoneSave as a bone graft extender can therefore help making the clinical success of Impaction Grafting less dependent on donor bone quality and surgical procedure.

Volume mixes were chosen in favour of weight mixes anticipating a clinical use where charging the right quantities of bone and extender would be easier to handle by containers than weighing with scales. The difference in granular density between morsellised bone (ca. 0.6 g/cm^3) and ceramic graft (ca. 1.2 g/cm^3) lead to high ceramic contents even at low volume ratios and made homogenous mixing difficult. Lower ceramic mixes thus need to be investigated.

Higher compaction energies before stem insertion led to an enormous increase in stability. This shows that intense graft compaction is the single most influential parameter for achieving mechanical stability clinically. However, the risk of femoral fracture and the higher graft density potentially compromising graft revascularisation must be considered. As adding a synthetic graft increases stability already at low compaction levels, it could help to find an optimum where the necessary compaction energy is at a tolerable maximum while the graft mix still contains sufficient allograft bone for osteogenic activity. Furthermore implant stability achieved with Impaction Grafting could be less dependent on the variable compaction intensities applied by different surgeons.

Current experiments will investigate the responsiveness of such allograft/extender mixes to compaction energy and the effects of distal versus proximal compaction and high impact-low frequency versus low impact-high frequency compaction.

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[1] Gie et al., *J Bone Joint Surg [*Br] 1993; 75-B (1):14-21

[2] Schreurs et al., *Acta Orthop Scand* 1994, 65 (3): 267-275

[3] Grimm et al., *World Biomat Conf* 2000, Transaction Vol.2: 564

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15 48th Annual Meeting Orthop. Res. Soc. 2002, February 2002, Dallas, USA

Compression testing of bone grafts for Impaction Grafting

Grimm B.[1]; Gozzard C[2]., Miles A.W[1]., Turner I.G[3].

[1]Dept Mech Eng, University of Bath, Bath, U.K., [2]Dept Orthop Surgery, University of Bristol, Bristol, U.K., [3]Dept Applied Science & Eng University of Bath, Bath, U.K,

Introduction: In Impaction Grafting morsellised human allograft bone chips are impacted into the femoral cavity compensating for the bone stock loss associated with revision hip arthroplasty. The compacted graft acts as a mechanically stable and biologically active matrix and forms a new medullary canal for the insertion and cementation of a new prosthesis. One of the most influential factors determining clinical success of the operation is the initial mechanical stability of the implant. As the bone graft in Impaction Grafting is predominantly loaded in compression and shear, a basic compression test has been configured to analyse fundamental mechanical properties of different bone grafts with regard to their suitability for Impaction Grafting. It has been suggested that different graft preparation, sterilisation and storage methods not only affect the biological but also the mechanical properties of bone grafts. The effect on compression stiffness and relaxation was investigated in this study. As demand for human allograft for Impaction Grafting has outstripped supply and in-vitro testing of Impaction Grafting techniques requires large graft quantities, the compression properties of more easily and cheaply available xenografts were studied to establish equivalency for in-vitro experimentation.

Materials and Methods: Materials investigated were human cancellous allograft bone chips harvested from femoral heads and morsellised with a Norwich type bone mill. Preparation, sterilisation and storage methods of the grafts were altered and the following categories were tested:

Human bone graft		
fresh from mill	frozen and thawed	washed and towel dried
formaline fixed	irradiated at 2.5 MRad	irradiated at 5 MRad

Tab. 1: ***Groups of differently treated human bone graft tested.***

Four femoral heads per group were prepared at once and the bone chips mixed to compensate for varying qualities between individual samples. A dose of 2.5 MRad was chosen as it represents a common dose used in bone banks. For comparison ovine bone chips were produced from humeral heads and tested as well as two samples of a granular hydroxyapatite/tricalcium-phosphate synthetic bone graft sintered at 1150 °C and sieved to a 2-4mm particle size by TCM Associates, U.K.

Ovine bone graft		
fresh from the mill	washed and towel dried	formaline fixed
Synthetic bone graft: 80:20 hydroxyapatite/tricalcium-phosphate		
no porosity (0%)	high porosity (50%)	

Tab. 2: ***Groups of differently treated ovine and synthetic graft tested.***

A die-plunger compression test was performed using a 20mm diameter die and a 20 mm diameter hollow cylinder as a plunger. The cylinder was closed with a porous disc on the compressing end to allow liquid penetration. Sample volumes of 10cm^3 were compressed quasistatically at a crosshead speed of 0.05mm/s up to a peak load of 500N and a stress-strain curve was recorded. The crosshead was then stopped and the decline in reaction force was recorded for 2 min as relaxation.

The behaviour under compression loading was quantified by calculating a compression modulus from the slope of the secant between the strains recorded at 25N to discard effects of settling in and the peak load of 500N. Relaxation was determined as the drop in reaction force two minutes after reaching the peak force expressed as a percentage value thereof. Although relaxation continued beyond this time span, its exponential decline towards an assymptotic value allowed characteristic differentiation. Six samples per group were tested and unpaired student t-tests were performed on the data.

Results: The average stiffness values for differently treated human bone grafts ranged from 3.65MPa for graft fresh from the mill to 3.87MPa for graft irradiated at 2.5MRad. Standard deviation for all groups was below 6% of the mean (Fig. 1). Only the difference between the stiffness of fresh and both irradiated grafts were statistically significant ($p_{2.5MRad}$=0.038 and p_{5MRad}=0.02). Ovine bone graft was stiffer with modulus averages ranging from 3.93MPa to 4.27 MPa. Stiffness for fresh ovine graft was 16% higher than human graft ($p<0.0001$). Washing and drying ovine graft reduced the modulus by 7% (p=0.004). Both synthetic grafts were much stiffer than bone with modulus values of 7.38MPa for the porous and 20.98MPa for the non-porous ceramic. The average relaxation values for differently treated human grafts ranged from 32.4% for fixed bone to 38.5% for bone irradiated at 5MRad and 33.5% for fresh human bone. Standard deviation for all groups was below 9.6% of the mean (Fig.2). Differences of treated versus fresh graft were all statistically significant ($p<0.035$).except for formaline fixation (p_{Fixed}=0.0527). Fresh ovine bone showed significantly higher relaxation than fresh human graft ($p<0.0001$) and both washing & drying and fixation reduced relaxation by ca. one quarter ($p<0.0001$). Both synthetic grafts showed less relaxation than bone with 22.75% for the porous and 19.18% for the non-porous ceramic.

Discussion: Using the common techniques for preparation, sterilisation and storage of human bone grafts had small or no significant effect on its stiffness, however relaxation behaviour was affected in particular by irradiation. The effect of treatment methods mainly on relaxation but not on stiffness suggests that predominantly the viscoelastic organic tissue but not the bone mineral is affected but the organic phase is removed (washing & drying), crosslinked (fixing) or denatured (irradiating). Clinically this might result in a different impaction feel for the surgeon as recoil is increased.

Ovine bone showed comparable compression behaviour and thus seems to be a suitable bone graft for in-vitro mechanical testing. As ovine bone is harvested from young and healthy sheep its higher stiffness versus human bone from old and osteoporotic donors can be explained. Its higher sensitivity to treatment methods suggests a higher organic content than human bone. The synthetic grafts do not mimic human graft in its compressive behaviour, but the higher stiffness and lower relaxation promise mechanically more stable Impaction Grafting.

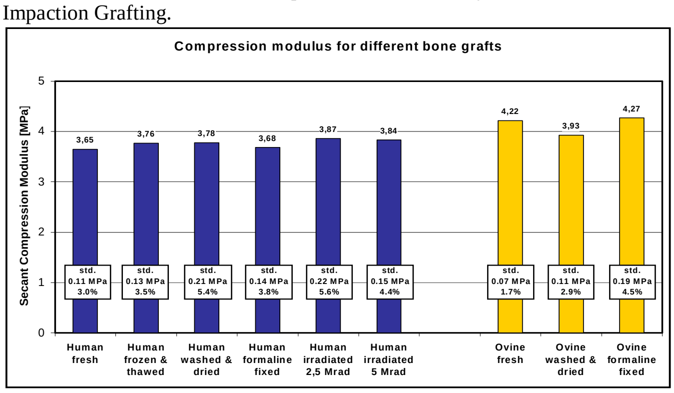

Fig. 1: ***Compression moduli for different graft materials.***

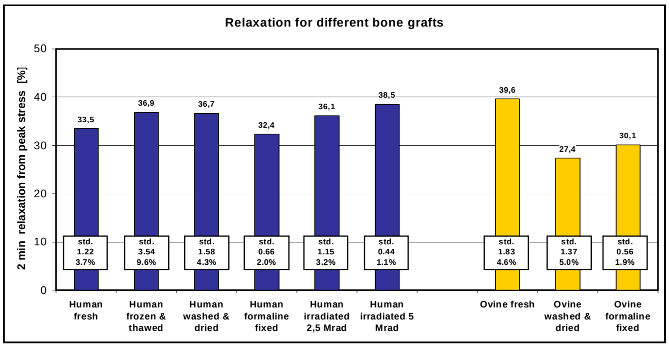

Fig. 2: ***Relaxation as percentage of peak stress for different graft materials..***

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Compression properties of morsellised bone grafts and synthetic alternatives for Impaction Grafting

Grimm B., Gozzard C., Miles A.W., Turner I.G.

[1]Department of Mechanical Engineering, University of Bath, Bath, U.K.; [2]Department of Orthopaedic Surgery, University of Bristol, Bristol, U.K.; [3]Department of Engineering and Applied Science, University of Bath, Bath, U.K.

Introduction

Impaction Grafting is a popular surgical technique for revision hip where bone stock loss is a major problem. Morsellised human allograft bone chips are impacted into the femoral cavity to compensate for the bone stock loss. The compacted graft serves as a mechanically stable and biologically active matrix and forms a new medullary canal for the insertion and cementation of a new prosthesis[1]. One of the most influential factors determining clinical success of the operation is the initial mechanical stability of the implant[2]. As the bone graft in Impaction Grafting is predominantly loaded in compression and shear, a basic compression test has been configured to analyse fundamental mechanical properties of different bone grafts with regard to their suitability for clinical Impaction Grafting or as experimental grafts for Impaction Grafting research.. It has been suggested that different graft preparation, sterilisation and storage methods not only affect the biological but also the mechanical properties of bone grafts[3]. The effect on compression stiffness and relaxation was investigated in this study. Human bone graft as the gold standard is compared with a synthetic ceramic graft extender As demand for human allograft for Impaction Grafting has outstripped supply and in-vitro testing of Impaction Grafting techniques requires large graft quantities, the compression properties of more easily and cheaply available xenografts were also studied to establish equivalency for in-vitro experimentation.

Materials and Methods

Materials investigated were human cancellous allograft bone chips harvested from femoral heads and morsellised with a Norwich type bone mill. Preparation, sterilisation and storage methods of the grafts were altered and the following categories were tested:

Human bone graft		
Fresh from mill	Frozen and thawed	Washed and towel dried
Formaline fixed	Irradiated at 2.5 MRad	Irradiated at 5 MRad

Table. 1: Different human bone graft preparation and storage methods tested.

Ovine bone graft		
Fresh from mill	frozen and thawed	Formaline fixed
Synthetic bone graft: *80:20 hydroxyapatite/tri-calcium-phosphate*		
No porosity 0%	High porosity 50%	

Table. 2: Different human bone graft preparation and storage methods tested.

In order to eliminate the variability inherent with human femoral heads received from donors of different age, size, sex and health, the morsellised graft from four femoral heads was mixed prior to testing each parameter set from *Table 1.* The irradiation dose of 2.5 MRad represents a dose commonly used by bone banks. Ovine bone chips were morsellised from humeral heads, preparation varied according to *Table 2* and tested for comparison. Also two samples of a granular hydroxyapatite/tricalcium-phosphate synthetic bone graft extender sintered at 1150 °C and sieved to a 2-4mm particle size by TCM Associates, U.K was analysed.

A compression test was performed using a 20mm diameter die and a 20 mm diameter hollow cylinder capped by a disk on one end as a plunger[4]. The disc was highly porous to allow liquid penetration of negligible resistance. Individual samples were charged with volumes of $10cm^3$ and compressed quasistatically at a crosshead speed of 0.05mm/s. The stress-strain curve was recorded. When the peak load of 500N was reached the crosshead was stopped and relaxation was observed by measuring the declining reaction force for a 2 min period.

The compression properties were analysed by deriving a secant compression modulus and a percentage relaxation as shown in *Fig. 1.* The slope of a straight line between the strains recorded at 25N discarding settling effects and the peak load of 500N was defined as a compression modulus. Relaxation was calculated as the relative drop of the reaction force in percent two minutes after loading was stopped at the peak load of 500N. The reaction force declined exponentially towards an asymptotic value so that despite continuing relaxation a characteristic differentiation was possible after a two minute period. Six samples per group were tested and for statistical analysis unpaired student t-tests were performed on the data.

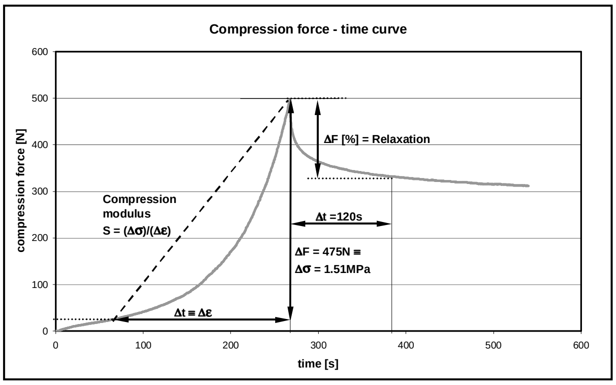

Fig. 1: Calculation of compression modulus and relaxation.

Results

Fig. 1 shows the typical force vs. time signal recorded for a human or an ovine bone graft. After an initial settling, the compression force rose exponentially to the preset peak force and after the crosshead had stopped the reaction force dropped exponentially towards an asymptotic value. This observation was qualitatively identical for all human and ovine bone grafts tested (*Fig. 2*). Quantitative differences were the result of horizontally or vertically skewed signal curves.

Fig. 2 compares the force-strain curve from all samples of the gold standard fresh human bone graft with fresh ovine bone graft, an easily accessible experimental graft. Additionally the force-strain signals of the two synthetic ceramic graft extenders with 0% and 50% porosity are displayed. Human bone graft showed the lowest stiffness with ovine bone graft being ca. 15% stiffer and slightly less variable.

Both ceramic extender materials proved qualitatively and quantitatively to be very different from human and ovine bone graft. The compression stress-strain curve resembled a straight line as a first approximation when compared to the exponential curves of the wet and viscous bone grafts. On a more detailed scale, the stress-strain curves of the ceramics revealed sudden drops and steep rises resulting in a jagged profile to the curve. The highly porous ceramic showed this behaviour at a higher frequency and intensity. Stiffness values for the highly porous ceramic were twice as high as for fresh human graft and more than five times higher for the non-porous material.

Fig. 3 displays the secant compression moduli recorded for the differently treated human and ovine grafts. The average stiffness values for various human bone grafts ranged from 3.65MPa for graft fresh from the mill to 3.87MPa for graft irradiated at 2.5MRad. Standard deviation for all groups varied between 1.7% and 5.6% of the average. Irradiating the human graft at 2.5MRad or 5MRad resulted in stiffness which was 5-6% higher when compared with fresh human graft. This difference in stiffness was the only statictically significant one within the human graft groups ($p_{2.5MRad}$=0.038 and p_{5MRad}=0.02). For formaline fixation, washing & towel drying and frozen & thawed human graft no statistically significant differences in stiffness were recorded.

Ovine bone graft was stiffer with modulus averages ranging from 3.93MPa for washed and dried graft to 4.27 MPa for formaline fixed graft. Stiffness for fresh ovine graft was 16% higher than human graft ($p<0.0001$). Washing and drying ovine graft reduced the modulus by 7% ($p=0.004$). Both synthetic grafts were much stiffer than bone with modulus values of 7.38MPa for the highly porous and 20.98MPa for the non-porous ceramic.

The average relaxation values for differently prepared human grafts ranged from 32.4% for fixed bone to 38.5% for bone irradiated at 5Mrad. Fresh human bone relaxed 33.5% in 2min. Standard deviation for all groups was between 1.1% and 9.6% of the mean (*Fig. 4*). Differences of treated versus fresh graft were all statistically significant ($p<0.035$).except for formaline fixation (p_{Fixed}=0.0527). Fresh ovine bone showed significantly higher relaxation than fresh human graft ($p<0.0001$). Washing & drying and fixation reduced relaxation ($p<0.0001$). Both synthetic grafts showed less relaxation than bone with 22.75% for the porous and 19.18% for the non-porous ceramic.

Large variations in liquid volumes escaping through the porous disk were observed for the fresh and the irradiated human bone grafts when compared to the washed or fixed human grafts as well as the ovine grafts.

Discussion

The clinically applied techniques for preparation, sterilisation and storage of human bone grafts had small or no significant effect on stiffness. However relaxation was affected, in particular by irradiation. The fact that mainly relaxation but not stiffness is sensitive to different treatment methods suggests that predominantly the viscoelastic organic tissue but not the bone mineral is affected. The organic phase is removed (washing & drying), crosslinked (fixing) or denatured (irradiating). Clinically this might result in a different impaction feel for the surgeon as recoil is increased.

The compression properties of ovine bone were qualitatively and quantitatively similar to human graft. Consequently it seems suitable as an experimental graft for mechanical in-vitro research. The higher stiffness of ovine bone might be a reflection that it is harvested from young and healthy sheep and not from old and osteoporotic donors which are most often the source of human bone graft. The higher sensitivity of ovine bone to preparations methods suggests a higher organic content than human bone. Although washing and drying the human graft did not lead to a significant change in stiffness and relaxation it did reduce the high liquid volumes which had escaped from fresh and irradiated samples. Under dynamic clinical impaction where there is no sufficient time or permeability for effective liquid escape, washing and dry-ing could enhance stability by allowing efficient compaction.

The synthetic grafts do not mimic human graft in stiffness and relaxation. However the higher stiffness and lower relaxation promise a mechanically more stable Impaction Grafting when the ceramic used as an extender but not on its own.

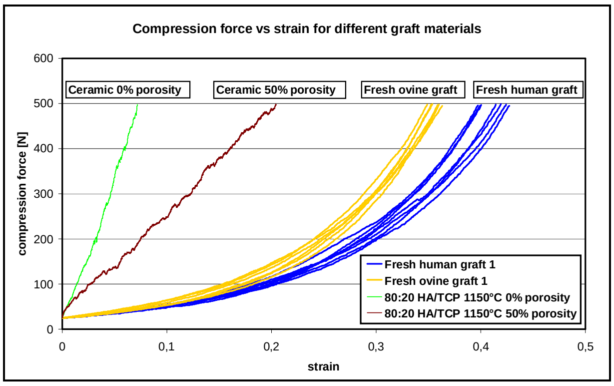

Fig. 2: Force-strain curves for bone and ceramic graft substitutes.

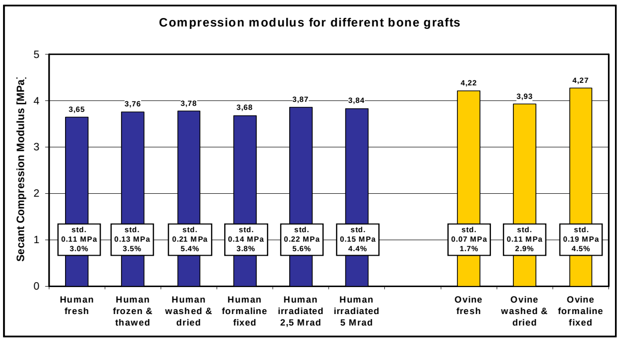

Fig. 3: Compression moduli for different graft materials.

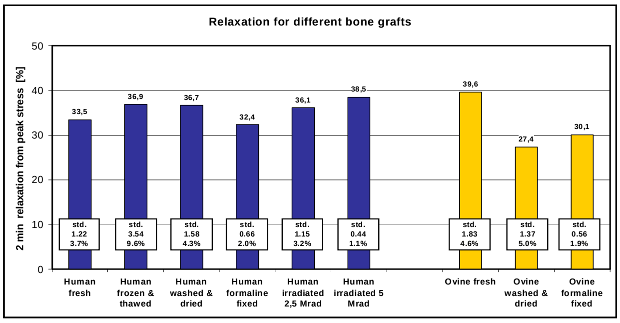

Fig. 4: Relaxation for different graft materials.

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COMPARING COMPRESSION PROPERTIES OF BONE GRAFTS, CERAMIC GRAFTS AND GRAFT MIXES FOR IMPACTION GRAFTING

Grimm B[1], Gozzard C[2], Miles A W[1], Turner I G[3]

[1]University of Bath, Dept Mechanical Engineering, Bath BA2 7AY, U.K.; e-mail: B.Grimm@bath.ac.uk
[2]University of Bristol, Dept of Orthopaedic Surgery, Bristol, U.K.
[3]University of Bath, Dept Applied Science and Engineering, Bath BA2 7AY, U.K

Introduction

In Impaction Grafting hip revision arthroplasty bone stock loss is compensated by impacting morsellised bone grafts into the femoral cavity creating a mechanically stable and biologically active matrix for the fixation of a new implant. Initial mechanical stability of the graft is a crucial factor for clinical success[1, 2]. As the bone graft is predominantly loaded in shear and compression, a basic compression test was performed to compare fundamental mechanical properties of bone, synthetic grafts and graft mixes.

Materials and Methods

Materials tested were human bone graft as the gold standard, ovine and bovine bone grafts as easily reproducible xenografts for in-vitro experiments and a 80:20 hydroxyapatite/tri-calcium-phosphate ceramic with its sintering temperature, porosity and size varied from the standard configuration (1150°C, 25%, 2-4mm) as found in table I. Also tested were volume mixes of ovine graft and the standard HA/TCP ceramic. Bone grafts were morsellised using either a Norwich or a Howex bone mill.

Table I: Graft materials tested.

bone grafts	ceramic grafts	bone/ceramic
Human Norwich, Howex mill	Size: 1-2, 2-4, 4-6.3mm	1:2 b/c vol.-mix
Fixed ovine Norwich mill	Porosity: 0%, 25%, 50%	1:1 b/c vol.-mix
Bovine Howex mill	T_{sint}: 1050, 1150, 1200°C	2:1 b/c vol.-mix

A compression test was performed using a 20mm diameter die and a 20 mm diameter hollow plunger capped by a porous disk to allow liquid penetration. Individual samples of 10cm^3 volume were compressed quasi-statically at a crosshead speed of 2mm/min. The stress-strain curve was recorded. At a peak load of 500N the crosshead was stopped and relaxation was determined as the relative drop of the reaction force over a 2min period. Stiffness was defined as a secant compression modulus derived from the slope of a straight line between the strains recorded at 25N discarding settling effects and the peak load of 500N[3].

Results

Compression moduli for bone grafts ranged between 3.65MPa (human Norwich) and 4.91MPa (bovine Howex). Human bone graft prepared with a Howex mill (4.14MPa) and fixed ovine graft morsellised with a Norwich mill (4.27MPa) scored nearly equal values of no statistically significant difference. Relaxation values for all bone grafts ranged closely between 30.1% (ovine) and 33.5% (Human Norwich). Depending on porosity, size or T_{sint}, compression moduli of the ceramics reached values between 7.98MPa (50% porosity) and 29.27MPa (0% porosity). The modulus decreased with larger particle size and lower T_{sint}. However relaxation values were not affected by the ceramic configurations with values mainly below 20%, significantly lower than for bone. Graft mixes combined properties of both the bone and ceramic phase. Compression stiffness increased with a rising ceramic content from 5.27MPa (2:1 b/c mix) to 6.99MPa (1:2 b/c mix). Also relaxation lay between the bone and ceramic values ranging from 26.7% (1:2 b/c) to 29.0% (1:1 b/c).

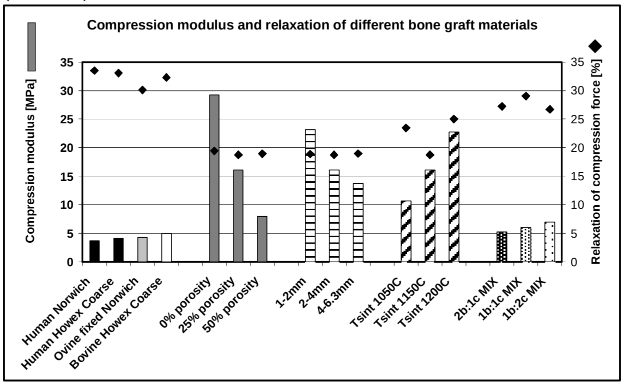

Figure1: Modulus and relaxation for different grafts.

Discussion and Conclusions

Bone preparation methods such as the bone mill type used influence graft stiffness and possibly clinical stability. Ovine bone is similar to human graft and can be used as an experimental graft. Bovine bone is up to 35% stiffer than human graft and thus less suited. Ceramic grafts are much stiffer with less relaxation than bone grafts and in pure form seem not suitable as a full bone replacement. However as an extender in a graft mix ceramics can increase the compression modulus while the ability to compact the graft well enough is maintained. The correlations shown between ceramic properties or mixing ratios and the compression behaviour allow graft mixes to be fine tuned as clinically desired. In combination with their controlled reproducibility ceramics can be recommended as graft extenders for Impaction Grafting.

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18 49th Annual Meeting Orthop. Res. Soc. 2003, February 2003, New Orleans, USA

MEASUREMENT OF IMPACTION QUALITY AND CORRELATION WITH STABILITY IN IMPACTION GRAFTING

+*Grimm, B; *Miles, A W; **Turner I G;
+*University of Bath, Dept Mech Eng Bath, United Kingdom

INTRODUCTION: The surgical technique Impaction Grafting addresses the bone stock loss associated with hip revisions by impacting morsellised human allograft bone chips into the femoral cavity. The compacted graft forms a new medullary canal for the fixation of a new prosthesis. It provides mechanical stability and serves as a biologically active matrix for bone stock regeneration[1]. The successful clinical outcome is influenced by the initial mechanical stability of the graft which strongly correlates with the quality of the impaction of the graft[2]. Too strong an impaction presents risks of fractures in the femoral bone and too weak an impaction may result in excessive subsidence leading to failure. The level of impaction may also influence potential for revascularisation of the graft. In the assessment of the impaction quality the surgeon can only rely on "feeling" or experience. This study investigates if the set of the hammer blows can be used as a more objective reference to predict sufficient impaction and stability.

Demand for human allograft suitable for Impaction Grafting has outstripped supply[3] and thus synthetic graft extenders such as calcium-phosphate based ceramics have been successfully tested in-vitro[4]. This study investigates if the clinical use of these synthetic materials in graft mixes affects the impaction feel and the stability associated with a specific impaction level.

MATERIALS AND METHODS: A tube and cone system was used to model the human femur and stem conditions in-vitro. The model consisted of a 25mm diameter metal tube and a metal cone of 120mm length with decreasing diameter from 16mm proximally to 5mm distally. The tube was filled with graft, the graft pre-compacted with a flat disk and the cone driven into the tube with a device called the Impactometer[3]. A weight of a preset adjustable height drops along a guide wire onto the disk or cone allowing impaction momentum and energy to be controlled and repeated. The position of the disk and cone was monitored during impaction and the set per hammer was measured.

After impaction the model was mounted in an Instron servo-hydraulic machine and cyclically block-loaded in compression at peak loads increasing from 0.2 in 0.2 kN steps of 5000 cycles each until failure at a maximum subsidence of 6mm. Pre-impaction energy was varied between 3.1J (low), 6.2J (medium), 9.3J (high) and 23.3J (very high) to represent a wide range of total impaction quality. The drop height of the hammer was varied between 65mm, 130mm and 260mm to vary impaction force while keeping the pre-impaction energy constant.

Materials: Pure human morsellised trabecular bone graft was tested as the gold standard. Ovine graft harvested from sheep humeral heads was tested as an in-vitro experimental graft[6]. Volume mixes of ovine graft and granules of various tricalcium-phosphate/hydroxyapatite ceramics were analysed. Mixing ratios were 2:1, 1:1 and 1:2 . For 1:1 bone/ceramic mixes the parameters of the synthetic extender were varied in chemical composition (HA:TCP: 100:0, 20:80, 50:50, 80:20), in porosity (0%, 25%, 50%, 67%), particle size (1-2mm, 2-4mm, 4-6.3mm) and sintering temperature (1050°C, 1150°C, 1200°C).

RESULTS: *Fig. 1* shows the accumulated set during cone impaction of three characteristic sample groups which recorded distinctively different number of cycles to failure and required significantly different numbers of hammer blows for full cone insertion. However, as with all other graft configurations tested, the set accumulated over the number of hammer blows increased exponentially in all cases as the nearly straight lines against a logarithmic axis show. The slope of the lines and thus the exponent of the functional relationship between accumulated set and number of blows indicate a relationship between impaction set and graft stability for the three extreme graft configurations shown here. However it was not sensitive enough to significantly resolve a correlation for samples of less distinctive properties.

Fig. 2 shows the set of the final hammer blow as a function of stability given as the number of cycles to failure for the total range of graft materials tested. For all pure bone grafts (human and ovine) and for all graft/ceramic mixes there is a clear correlation between the set of the final hammer blow and the mechanical stability against cyclic compression loading. With number of cycles to failure during block loading as a scale for stability there is an exponential relationship between set and stability. With decreasing set the stability increases exponentially. Within the scatter of results this correlation is similar for pure bone grafts and mixes and thus appears to be independent of the graft material. The scatter of values recorded for bone samples appears slightly higher than for the graft/ceramic mixes and this correlates with the scatter of stability values recorded. For different hammer drop heights and thus different impaction peak forces the data points outside the standard trend curve indicate that for different hammer forces the set-stability function must be shifted towards a higher set per final blow for larger drop heights and vice versa.

DISCUSSION: The current subjective surgical assessment of impaction quality as a measure of stability by "manually sensed hammer response" could be objectively replaced by a measurement of set per hammer blow. A set measurement sensor could be integrated into the surgical impaction hammer and guide wire system providing the basis of a tool for intra-operative assessment of impaction quality and stability. Absolute values for recommended final set values could be calibrated with the help of Sawbone® composite bone model experiments. However as the manual hammer force is not controlled, an average set over a range of the final hammer blows needs to be taken or in the long term, the hammer force needs to be calibrated as well. In this manner some of the variability associated with the surgical impaction process could be significantly reduced leading to a more predictable and reliable outcome. As the set-stability correlation is constant for bone grafts and for graft mixes, surgeons using such an instrumented feedback system may be able to rely on this form of assessment even when ceramic graft extenders are being used. Assuming set per blow as the major component of the manually sensed feedback of a surgeon during impaction, even the use of ceramic graft extenders may not affect this crucial subjective judgment of impaction quality.

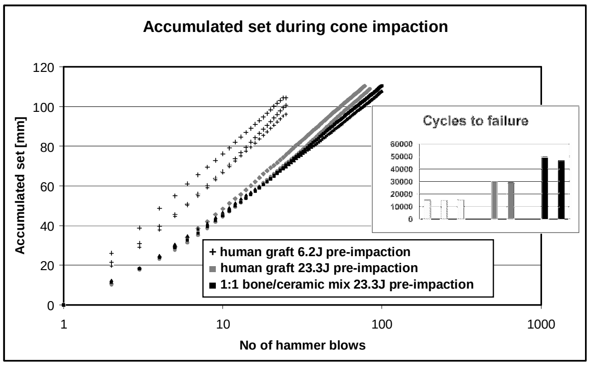

Fig. 1: ***Set during cone impaction for different graft materials.***

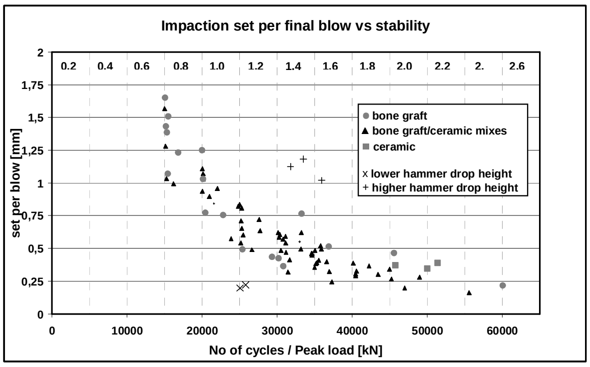

Fig. 2: ***Correlation between final impaction set and stability.***

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AFFILIATED INSTITUTIONS FOR CO-AUTHORS:
**University of Bath, Dept Eng & Appl. Science Bath, United Kingdom