Factors Influencing the Stability of Stems Fixed with Impaction Graft in Vitro

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Abstract Mechanical stability of the stem is believed to be an important factor in successful impaction grafting in revision THA. We asked whether particle size, femoral bone deficiencies, stem design, graft composition, and impaction technique influenced the initial stability of the stem in vitro using model femora and human bone particles. Bone particles made with a reciprocating blade-type bone mill contained larger particles with a broader size distribution than those made by a rotating drum-type bone mill and had higher stiffness on compression testing. The stiffness on torsional testing decreased as the degree of proximal-medial segmental deficiencies increased. The stiffness and maximum torque in a stem with a rectangular cross section and wide anteroposterior surface were higher in torsional tests. Adding hydroxyapatite granules to the bone particles increased the torsional stability. To facilitate compact bone particles, we developed a spacer between the guidewire and modified femoral packers. This spacer facilitated compacting bone particles from the middle up to the proximal and the technique increased the amount of impacted bone particles at the middle of the stem and also improved the initial stability of the stem. Stem design and degree of deficiencies influenced stiffness in the torsional test and the addition of hydroxyapatite granules enhanced torsional stiffness.

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Introduction

Impaction grafting of the femur for revision THA was initially developed by Ling et al. [15] and reported by Gie et al. [9] in 1993. This procedure is considered technically demanding, and early failure and complications were reported at the beginning [18]. Recently, high survivorship has been reported in three studies. Halliday et al. [12] reported a survivorship rate of 99.1% at 10 to 11 years and Schreurs et al. [19] reported a survivorship rate of 100% at 8 to 13 years using the Exeter™ stem (Stryker Howmedica, Newbury, UK). Mahoney et al. [16] reported a survivorship rate of 97% at 4.7 years.

Initial mechanical stability of the stem and bioactivity of grafted materials are listed among the key factors for the success of impaction grafting. According to Gokhale et al. [11], most migration and subsidence occur during the first 3 months after surgery. Four variables (age, femoral canal diameter, stem design, and density of the graft at the tip of the stem) affected the subsidence of the stem [11]. It would, therefore, seem that initial mechanical stability is critically important. Other factors such as graft preparation, quality of graft, particle size, graft composition, femoral bone deficiencies, cementing technique, closure of defects, and impaction technique might also influence the initial mechanical stability of the stem.

In clinical situations, impaction grafting is performed using a guidewire, femoral packers, and tamps. It is relatively easy to compact bone particles around the distal part of the stem using available femoral packers and around the proximal part of the stem using tamps, whereas impaction grafting tends to be insufficient in the middle of the stem because of ineffective instruments for the middle part [7]. We therefore developed new instruments and modified the

technique to compact bone particles from the distal part to the proximal part of the stem.

We asked whether five factors influenced the initial mechanical stability of the stem in vitro: (1) bone particle size; (2) selected femoral bone deficiencies; (3) selected stem design; (4) mixture of hydroxyapatite (HA) granules; and (5) selected impaction technique.

Materials and Methods

We investigated the axial and rotational stability of the stem fixed with impaction grafting in vitro. Four different size distributions of bone particles, three grades of proximal medial femoral bone defects, and two types of stems were compared. For graft composition, one of four percentages (0%, 25%, 50%, and 100%) of HA granules was added to bone particles as a bone graft expander. The effects of modifications of impaction techniques were also investigated. To minimize the experimental variations in bone geometry and properties, plastic model femora (Sawbones[®]; Pacific Research Laboratories, Vashon, WA) were used. We prepared six specimens for each of the 15 experimental groups. Power analyses for specified effect sizes of torsional stiffness for each independent variable indicated between four and 20 specimens were required (Appendix 1).

We obtained human femoral heads during primary THA from patients with femoral neck fracture and osteoarthritis. After removing soft tissue and cartilage, we cut the femoral heads equally into four pieces and divided them into four groups at random to minimize heterogeneity among the groups. We prepared four different conditions of bone particles using two types of bone mills, the rotating drum type (Tracer Designs, Inc, Santa Paula, CA) with three kinds of rasps (coarse, medium, and fine) and the reciprocating blade type (Lere Bone Mill; DePuy Orthopaedics, Inc, Warsaw, IN). To determine the size distribution of the bone particles, seven specially designed sieves were made of plastic plates with drilled holes. The size of the drill holes ranged from 2 to 8 mm with 1-mm increments. Thus, the particle sizes were classified into eight grades: larger than 8 mm, 8 to 7 mm, 7 to 6 mm, 6 to 5 mm, 5 to 4 mm, 4 to 3 mm, 3 to 2 mm, and smaller than 2 mm.

Approximately 500 mg of bone particles was first washed in ethanol to remove fat and prevent aggregation and then passed through the sieve from the largest holes. The sieve was manually shaken until there was no further passage of particles. We measured the weight of bone particles remaining on each sieve and calculated the percentage of the particles in each sieve. This procedure was repeated four times for four different conditions. The mean size of bone particles in each group was 2.3 mm (range,

< 2–5 mm) in the fine rotating rasp, 2.6 mm (range, < 2–6 mm) in the medium rotating rasp, 2.5 mm (range, < 2–7 mm) in the coarse rotating rasp, and 2.7 mm (range, < 2 to > 8 mm) in the reciprocating blade. The median size was less than 2 mm in all groups. Compared with the rotating drum mill (coarse, medium, and fine), bone particles prepared by the reciprocating blade mill contained larger bone particles with a broader size distribution (Fig. 1).

We overreamed plastic model femora (six in each group) (Sawbones[®]) up to 15 mm in diameter at the tip of the stem. Impaction grafting was performed exactly like an operative procedure with specially designed instruments. After injection of acrylic bone cement (Osteobond[®]; Zimmer, Inc, Warsaw, IN) using a cement gun, a collarless, polished, and tapered stem (CPT[®]; Zimmer) was inserted and fixed.

We prepared femora with three different grades of bone deficiencies. The first had no medial proximal femoral bone deficiency (Defect (–)), the second was made just below the lesser trochanter (Defect I), and the third was made deficient to 1 cm (Defect II) (Fig. 2). To compare the stem design, two types of polished, tapered stem were prepared (CPT[®] and VerSys[®] CT; Zimmer) (Fig. 3). The stem length was the same, whereas the proximal-lateral part was more bulky in the CPT[®] stem. The cross section of the CPT[®] stem was close to rectangular, whereas that of the VerSys[®] CT was almost round.

Pure crystal HA granules (3–6 mm; Bonfil[®]), which were manufactured by sintering at 1200°C at Sumitomo-Osaka Cement Co Ltd, Chiba, Japan, were added to bone particles by 0%, 25%, 50%, and 100% weight (Fig. 4).

With the conventional technique, impaction grafting is insufficient in the middle of the stem (Fig. 5A) [7]. To overcome these technical difficulties, we developed a spacer between the guidewire and the femoral packers. With the modified technique, bone particles are impacted at

Fig. 1 The size distribution of bone particles in each bone mill shows bone particles prepared with the reciprocating blade bone mill contain larger ($p = 0.001$) bone particles with a broader size distribution.

Fig. 2 We prepared femora with three different grades of proximal bone deficiencies: (1) none (Defect (-)); (2) made just below the lesser trochanter (Defect I); and (3) made deficient to 1 cm (Defect II).

Fig. 3 The collarless, polished, and tapered (CPT[®]) stem (left) and the VerSys[®] CT stem (right) were tested.

the distal part by conventional femoral packers. Then a spacer is inserted through the guidewire and bone particles are compacted around the spacer by modified packers up to the proximal part. This spacer keeps some space around the guidewire and the rest of the femoral canal is filled with impacted bone particles. Finally, bone particles in the middle and proximal parts of the stem are further impacted

by tamps (Fig. 5B). To compare the amount of impacted bone, we impacted bone particles into acrylic model femora (Sawbones[®]) using either the conventional or the modified technique. The model femora were cut at the proximal, middle, and distal levels. We measured the areas of impacted bone and femoral canal and calculated the impacted bone-occupying ratio.

We performed cyclic compression and torsional tests using an Instron[®]-type mechanical tester (Autograph AG-25TD; Shimadzu Co Ltd, Kyoto, Japan). Cyclic loading was applied between 440 and 690 N at a frequency of 0.4 Hz up to 200 cycles. With this test, we calculated stiffness and absorbed energy from the load-displacement curve. Stiffness was defined as the Young's modulus of the loading curve. Absorbed energy was defined as the area surrounded by the loading and unloading curves at a given cyclic compression.

We performed the torsional test with an axial load of 440 N at an angle velocity of 2° per second. Stiffness was defined as the tangent modulus at 14° of the twist angle on the torque-twist curve.

First, we compared four different size distributions of bone particles. Because the bone particles prepared by the reciprocating blade bone mill had the highest stiffness in compression testing in our first experiment, we performed the rest of the examinations using bone particles made by the reciprocating blade bone mill.

Comparisons of particle size, grade of bone deficiencies, and mixture of HA granules were statistically analyzed using analysis of variance, but the Kruskal-Wallis test was applied for the compression test in the grade of bone deficiencies and in the mixture of HA granules because we did not assume normal distributions of the data (Appendix 2). We compared stem design and impaction techniques using the Mann-Whitney U test. We used the SPSS[®] software program (SPSS Inc, Chicago, IL).

Results

The stiffness of the mixture of large and small bone particles from the reciprocating blade mill was higher ($p < 0.03$) than that of smaller particles from the rotating drum mill (coarse, medium, and fine) on the compression test (Fig. 6). Absorbed energy with the reciprocating blade mill was smaller ($p < 0.03$) than that of the rotating drum mill. Stiffness on the torsional test had the same tendency as seen on the compression tests, whereas we observed no differences among bone mills.

Segmental bone deficiencies up to 1 cm below the lesser trochanter did not influence the stiffness in the compression test, whereas stiffness became lower according to the degree of bone deficiency in the torsional test. Stiffness and

Fig. 4 Hydroxyapatite (HA) granules were added to bone particles by 0%, 25%, 50%, and 100% weight.

maximum torque were lower in Defect II ($p < 0.004$) than in Defect (–) (Table 1).

In the compression test, the absorbed energy was higher ($p < 0.02$) in the CPT[®] stem than that in the VerSys[®] CT stem. The stiffness and the maximum torque in the CPT[®] stem were higher ($p < 0.001$) in the torsional test (Table 1).

A mixture of HA granules did not influence the stiffness in the compression test, although the stiffness in the torsional test increased ($p < 0.01$) by adding HA granules (Table 1).

With the conventional technique, impaction grafting was insufficient at the middle of the stem. The modified technique facilitated keeping bone particles in the middle of the stem. The impacted bone-occupying ratio was higher, especially at the middle level ($p = 0.19$), using the modified technique (Fig. 7). The stiffness on the compression test was the same, whereas the stiffness in the torsional test increased ($p < 0.01$) using the modified technique (Table 1).

Discussion

The short-term success of revision arthroplasty with impaction grafting is related to the initial stability of the

construct [3]. The initial stability of the stem should be achievable in a predictable fashion with the use of ideal bone particles and stems and by using a well-organized surgical technique for the optimal compaction of bone particles and cementation. The long-term outcome of impaction grafting depends on whether a lasting bond develops between the graft and the host. Histologic retrieval analysis has confirmed that remodeling does occur with gradual but variable ingrowth [15, 17, 20]. Several studies suggest early and physiologic loading is important for active graft incorporation [21, 23]. Unfortunately, these parameters are not all clearly defined; they interact and affect the initial stability of the stem, as well as the biology and long-term incorporation of the graft. In this study, we investigated certain aspects of the effects of particle size, femoral bone deficiencies, stem design, graft composition, and impaction technique on the initial stability of the stem in vitro. Axial and torsional tests were performed using artificial femora and human bone particles.

One limitation of this study was the absence of intramedullary bleeding; thus, its influence on the impaction of the bone particles and the penetration of the cement was uncertain. The mechanical loading conditions were simplified and muscle loading was ignored. The cyclic loading was applied for a short time in this experiment; thus, we cannot expect the change in mechanical stability of the

Fig. 5A–B (A) A schematic illustration shows the conventional technique. Impaction grafting is insufficient at the middle of the stem. (B) With the modified technique, the spacer keeps some space around the guidewire to facilitate compacting bone particles by modified packers and to impact them by tamps from distal to proximal of the stem.

stem after long-term repetitive loading resulting from daily activity such as walking. A further limitation was our use of plastic model femora instead of cadaver femora, although commercially available artificial bone models have the advantage of minimizing the experimental variations in bone geometry and mechanical properties. On the other hand, bone particles have complex viscoelastic properties that cannot be realized by artificial materials; thus, we used human bone particles. The power analyses (Appendix 1) suggested some of the experiments were underpowered for some specified effect sizes. Finally, the effects of particle size, stem design, and mixture of HA granules on the biologic response from host bone should be investigated for medium- to long-term results.

It is difficult to control the size distribution of bone particles and few studies address optimal particle size. Several studies experimentally investigated the mechanical properties of impacted bone particles [5, 6], but the bone particles were compacted into the cylindrical camber; thus, these conditions are different from those when bone particles are impacted in the femoral canal. In fact, the size distribution of bone particles depends on the type of bone mill. Our data suggest bone particles produced by the reciprocating blade mill included larger bone particles with a broader size distribution and demonstrated superior mechanical properties.

In revision THA, we sometimes encounter combined deficiencies in the femur. Cavitory deficiencies are good

Fig. 6 The stiffness of the reciprocating blade bone mill was higher ($p < 0.03$) than that of the rotating drum bone mill (coarse, medium, and fine) in the compression test.

indications for impaction grafting, whereas segmental deficiencies require reconstruction by a strut graft or metal mesh. The effects of extramedullary augmentation for segmental deficiencies in the proximal-medial region or in the region of the tip of a stem were investigated by others [1, 4]. We investigated the influence of proximal-medial segmental deficiencies without extramedullary augmentation on the stability of the stem fixed with impaction grafting to evaluate the limitation of this technique. The stiffness in the torsional test became lower according to the degree of proximal-medial bone deficiencies.

Originally, impaction grafting was introduced with the ExeterTM stem [9]. The impacted bone graft is subjected to ongoing postoperative deformation, viscoelastic

deformations, and creep [10]. Thus, a stem should result in some additional packing of the graft after cyclic loading. The use of a double-tapered polished stem therefore appears suitable because such a stem can achieve secondary stability after subsidence. Recently, another type of tapered polished stem, such as the CPT[®] stem or the SpectronTM stem (Smith & Nephew Richards, Memphis, TN), and an unpolished stem have also provided good clinical results [14, 16]; however, there are no clear data on a choice for a particular stem. From our results, a stem should have good rotational stability owing to a rectangular cross section and a wide anteroposterior surface in the proximal part.

In impaction grafting for revision THA, morselized bone allografts are usually used. However, allograft presents potential problems with regard to infection, antigenicity, availability, reproducibility, and cost. It is therefore desirable to develop an alternative to allograft. Ceramic materials such as bone graft extenders have been applied to reduce the need for donor bone. Tricalcium phosphate and HA composite granules or HA granules are mixed with bone particles. Mechanical tests suggest tricalcium phosphate/HA granules (size, 2–4 mm) with a 50% mixture to allograft provided higher initial mechanical stability in axial compression testing [2, 22] and impaction grafting using HA granules (size, 0.3–4 mm) with a 50% mixture provided greater rotational stability [8]. Our data suggest the effectiveness for the initial stability of the stem fixed by impaction grafting with HA granules was more obvious with the torsional test. We tried to impact HA granules

Table 1. Summary of results from mechanical tests

Variable	Compression test		Torsional test	
	Stiffness (MN/m)	Absorbed energy (J)	Stiffness (N-m/degrees)	Maximum torque (N-m)
Defect				
Defect (–)	0.73 ± 0.27	0.013 ± 0.012	1.13 ± 0.16	24.3 ± 69.5
Defect I	0.58 ± 0.15	0.013 ± 0.005	0.72 ± 0.18	16.4 ± 67.9
Defect II	0.71 ± 0.25	0.012 ± 0.010	0.32 ± 0.02*	10.1 ± 9.2*
Stem				
CPT [®]	1.80 ± 0.74	0.003 ± 0.003	1.12 ± 0.10	26.9 ± 41.2
VerSys [®] CT	1.22 ± 0.84	0.008 ± 0.003 [†]	0.38 ± 0.02 [‡]	11.2 ± 16.3 [‡]
HA mixture				
HA 0%	0.89 ± 0.20	0.004 ± 0.002	1.00 ± 0.03	25.4 ± 4.7
HA 25%	0.81 ± 0.27	0.006 ± 0.004	1.67 ± 0.23 [§]	30.8 ± 5.7
HA 50%	0.65 ± 0.26	0.005 ± 0.001	1.37 ± 0.04 [§]	29.2 ± 4.6
HA 100%	1.00 ± 0.38	0.004 ± 0.004	2.7 ± 0.04 [§]	30.0 ± 9.2
Technique				
Conventional	0.62 ± 0.11	0.037 ± 0.008	0.74 ± 0.06	24.0 ± 6.1
Modified	0.52 ± 0.10	0.038 ± 0.008	0.94 ± 0.15	29.6 ± 4.3

Values are expressed as mean ± standard deviation; * $p < 0.01$ versus Defect (–); [†] $p < 0.02$ versus CPT[®]; [‡] $p < 0.01$ versus CPT[®]; [§] $p < 0.02$ versus HA 0%; ^{||} $p < 0.01$ versus conventional; HA = hydroxyapatite.

Fig. 7 The impacted bone-occupying ratios at the level of proximal, middle, and distal parts are shown. The ratio was higher ($p = 0.77$ proximally, $p = 0.19$ in the middle, $p = 0.92$ distally) when using the modified technique, especially at the middle level.

alone into the femoral cavity to investigate the effects. The stiffness in the torsional test was slightly higher, whereas it was technically difficult to keep HA granules on the femoral cortex because of the lack of stickiness. We recommend using HA granules with a mixture of bone particles.

Impaction grafting for revision THA is technically demanding, especially for the femur. It is not always easy to compact bone particles from the distal part of the stem up to the proximal part. Some technical modifications were tried to ensure the reproducibility and lower the risk of perioperative fracture [13]. Despite these efforts, graft impaction is reportedly insufficient in Gruen Zones 1, 2, and 6 [7]. Our modified technique facilitated compacting bone particles from distal to proximal. This technique

increased the amount of impacted bone particles at the middle of the stem and also improved the initial mechanical stability of the stem.

We found initial mechanical stability of the stem fixed with impaction grafting was influenced by the size of bone particles, femoral bone deficiencies, implant geometry, the mixture of HA granules, and impaction technique. Larger bone particles with a broad size distribution are suitable for impaction grafting. A mixture of HA granules improved the initial stability of the stem.

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Appendix 1. Effect size and required total sample size in each experiment analyzed by power analysis

Variable	Effect size/Required total sample size	Compression		Torsional	
		Stiffness	Absorbed energy	Stiffness	Maximum torque
Bone particle size (total sample size = 24)	Effect size	0.74	0.70	1.07	Not measured
	Required total sample size	36	40	20	Not measured
Deficiencies (total sample size = 18)	Effect size	0.30	0.05	2.76	0.12
	Required total sample size	174	5634	9	1098
CPT [®] vs VerSys [®] CT (total sample size = 12)	Effect size	0.73	1.67	10.26	0.50
	Required total sample size	100	22	4	210
Mixture of HA (total sample size = 24)	Effect size	0.45	0.28	7.02	0.05
	Required total sample size	92	228	8	6640
Conventional vs modified (total sample size = 12)	Effect size	0.95	0.13	1.75	1.06
	Required total sample size	60	3330	20	50

HA = hydroxyapatite.

Appendix 2. F test for each experiment*

Variable	F, p values/Statistical test used	Compression		Torsional	
		Stiffness	Absorbed energy	Stiffness	Maximum torque
Bone particle size	F(3, 20), p	3.97, 0.02	3.15, 0.05	9.96, 0.0003	Not measured
	Statistical test used	ANOVA	ANOVA	ANOVA	Not measured
Deficiencies	F(2, 16), p	0.76, 0.49	0.08, 0.99	8.95, 0.003	7.8, 0.004
	Statistical test used	Kruskal-Wallis test	Kruskal-Wallis test	ANOVA	ANOVA
CPT [®] versus VerSys [®] CT	F, p	0.77, 0.78	0.78, 0.80	4.68, 0.12	2.53, 0.33
	Statistical test used	Mann-Whitney U test	Mann-Whitney U test	Mann-Whitney U test	Mann-Whitney U test
Mixture of HA	F(3, 20), p	1.04, 0.39	0.53, 0.67	18.01, < 0.0001	0.76, 0.53
	Statistical test used	Kruskal-Wallis test	Kruskal-Wallis test	ANOVA	Kruskal-Wallis test
Conventional versus modified	F, p	1.26, 0.80	0.91, 0.92	0.15, 0.06	2.03, 0.46
	Statistical test used	Mann-Whitney U test	Mann-Whitney U test	Mann-Whitney U test	Mann-Whitney U test

* Nonparametric statistical tests used when $p > 0.05$; ANOVA = analysis of variance; HA = hydroxyapatite.

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