The use of a resorbable augmentation device to secure plating of osteoporotic bones

An in vitro study

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Summary. *Osteotomies in porotic human cadaveric humeri were fixed with metallic plates and screws in 3 experimental groups. In group I, osteotomies of the 3 arbitrarily chosen humeri were plated without reinforcement. The osteotomies of the contralateral 3 humeri were plated after reinforcement with a poly(L-lactide) augmentation device. In group II, osteotomies on one side were plated without reinforcement, but those of the contralateral humeri were plated after reinforcement with methylmethacrylate. In group III, the osteotomies of 3 humeri were plated and reinforced with poly(L-lactide) and in the 3 contralateral humeri were plated after reinforcement with methylmethacrylate. The pullout strength for screws from bones augmented with poly(L-lactide) was identical to those where methylmethacrylate had been used. The bones with poly(L-lactide) augmentation had a higher torsional stiffness than those with methylmethacrylate cement and those which were not reinforced. Resorbable polymeric medullary augmentation devices can be used to enhance plating of osteoporotic bones.*

Résumé. *Des humérus de cadavres humains dont le caractère osteoporotique fût déterminé par tomodynamométrie ont été osteotomisés et ostéosynthésés. Les neufs paires ont été divisées aléatoirement en 3 groupes. Dans le groupe I, l'ostéotomie fût ostéosynthésée à l'aide d'une plaque en T*

sans renforcement. L'humérus controlatéral était renforcé par une barre en polylactate et l'ostéosynthésée fixée à l'aide d'une plaque en T. Dans le groupe II, l'ostéotomie fût ostéosynthésée à l'aide d'une plaque en T sans renforcement. L'humérus controlatéral était renforcé par du méthylméthacrylate et l'ostéosynthésée fixée à l'aide d'une plaque en T. Dans le groupe III, l'ostéotomie fût renforcée par une barre en polylactate et l'ostéosynthésée fixée à l'aide d'une plaque en T. La force d'arrachement des vis insérées dans l'os renforcé par le polylactate était identique à la force d'arrachement des vis insérées dans l'os renforcé par le méthylméthacrylate. Les osteotomies renforcées par la barre en polylactate avaient un moment de torsion supérieur à celles renforcées avec du ciment et aux non renforcées. Les barres en polylactate peuvent potentiellement être utilisées pour le renforcement d'os ostéoporotique.

Introduction

The use of a plate-screw system for the treatment of fractures of fragile porotic bones is often unsatisfactory since the purchase of the screws in the bone is reduced. Hence, oversized implants may be used, or the fracture impacted [1, 12, 21]. Metallic nuts have been applied to the screws at the opposite cortex, but in most cases loosened [18]. Cements, based on methylmethacrylate (PMMA),

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Fig. 1 A–C. Diagram showing the methods of fixation used in the three groups. **A** Osteotomy without reinforcement. **B** Osteotomy with the PLLA augmentation device. **C** Osteotomy reinforced with cement

have also been used to enhance the stability of the fixation, but have the disadvantages of heat production during polymerisation, bone necrosis and release of toxic monomer [2, 5, 11, 19].

More recently ceramic cements which solidify in situ without an increase in temperature and without releasing toxic products have been considered for the treatment of porotic bones. These compounds can, after setting, stabilise the fracture without the use of other fixation devices, or they can enhance the attachment of an implant to bone [6].

Another approach to improving stability would be to use an intramedullary augmentation device produced from resorbable polymers which could produce adequate purchase for the screws [14].

The present study aimed to compare the fixation stability of osteotomies made in human porotic cadaveric bones reinforced with a resorbable medullary polymeric augmentation device or with PMMA cement.

Materials and methods

Medullary augmentation devices (10 × 120 mm) were melt-extruded from poly(L-lactide) (PLLA) [3, 4, 9, 10, 17]. The PMMA used cement was Palacos (Essex Chemie AG, Lucerne).

Nine matched pairs of osteoporotic humeri were selected from a pool of 50 pairs of fresh frozen bones. Each pair was obtained within 48 hours of death. Their osteoporotic state was evaluated with a computed imaging tomograph (Deniscan 1000, Scanco Medical, Zürich) and only bones with a mean density below 1 g/cm³ were used.

The nine pairs were divided randomly into 3 groups (I, II and III) each consisting of 3 pairs. An osteotomy was made on all paired humeri 7 cm from the greater tuberosity and fixed with a 5-hole titanium plate (Synthes 440.15) using an AO technique.

In group I, the osteotomies of 3 arbitrarily selected humeri were plated by a standard procedure (Fig. 1A) and were not reinforced. Those of the contralateral 3 humeri were plated after reinforcement with a PLLA augmentation device (Fig. 1B). A hole was drilled between the surgical neck and the greater tuberosity, and the device inserted into the medullary through it. The plate was then contoured to the bone and holes drilled through the bone and the device. The holes were tapped and screws inserted.

In group II, 3 osteotomies were plated without reinforcement. The 3 contralateral humeri were plated after reinforcing the bone with PMMA (Fig. 1C). The plate was then removed and PMMA injected into the 5 screw holes, but not into the hole in the head of the humerus. Screws were inserted when the cement was almost set (8 to 10 min) and tightened once it was hard.

In group III, 3 osteotomies were plated after reinforcement with a PLLA intramedullary augmentation device and those on the other side were after reinforcing the bone with PMMA.

For mechanical testing, the humeri were sawn through 5 cm below the head, and the proximal and distal ends of each specimen were embedded in PMMA so that they could be gripped by the testing machine. The specimens were moistened with Ringer's solution. A torsion testing machine (Rumul) controlled displacement, axial and torsional loads. Each specimen was maintained at zero axial load and external rotation applied at a rate of 10°/s until failure. The peak torque and torsional stiffness were estimated from load-deformation curves. The machine included 2 universal joints so that the specimen would not bend during testing. The gross observations were made on broken specimens.

After testing in torsion, the last 3 distal screws were removed and the distal end of the plate embedded in PMMA blocks. The remaining 2 proximal screws were slightly loosened so that a clamp could be fitted for pull-out testing. These tests were carried out with an Instron testing machine at a cross-head speed of 5 mm/min. The pull-out force was defined as the maximum force recorded. Comparison of mechanical test data within bone pairs was done by using analysis of variance (The Bonferroni simultaneous confidence intervals of each of the groups were calculated).

When these tests were completed the PLLA augmentation device and PMMA were removed from the bones. The small fragments of the reinforcing materials, within the threads of the screws, were coated with a 15 µm thick gold layer and examined with a Hitachi field emission electron microscope (model S-4100) operating at 2 kV and 10 mA.

Results

The mean bone density of each group was approximately 0.85 g/cm³. The mean cross-sectional area of the humeral diaphysis was about 2.7 cm² and did not differ within the pair from group to group. The enlarged medullary canal which is typical of osteoporotic bones was seen (Fig. 2).

Tables 1, 2 and 3 present the data from the mechanical tests. In group I, there was no statistical difference in the measured peak torque; the

Fig. 2 A, B. Computed tomography of **A** a normal, and **B** an osteoporotic humerus which shows thinning of the cortex and an enlarged medullary canal

torsional stiffness and the pull-out force were statistically higher in the group with the PLLA device than in the group not reinforced (Table 1). In group II, there was no difference in peak torque, but the torsional difference of the reinforced osteotomies was 50% higher than in those not reinforced, but this was not statistically significant. The pull-out force was higher in the bone reinforced with PMMA than in unreinforced bone. In group III, there were no differences in the mechanical properties between the bones reinforced with PLLA or PMMA.

The cracks initiated at the most distal screw during torsional testing were propagated proximally through the screw holes before reaching the osteotomy, so the proximal part of the bone was suitable for pull-out tests. The cement always filled the entire medullary canal (Fig. 3) and remained intact after testing. The PLLA device did not completely fill the canal and was also intact (Fig. 3). The screws pulled out from the PMMA were surrounded by a cement spiral in their threads (Fig. 4A). There was no material attached to the screws which pulled out from the PLLA device.

Table 1. Porotic status and mechanical properties in Group I

	Not reinforced	Poly(L-lactide)	<i>P</i> value*
Bone density (g/cm ³)	0.85 ± 0.03	0.84 ± 0.03	> 0.05
Cross-sectional area (cm ²)	2.51 ± 0.27	2.52 ± 0.26	> 0.05
Peak torque (Nm)	12.67 ± 3.78	27.67 ± 4.2	> 0.05
Torsional Stiffness (Nm/degree)	0.48 ± 0.05	1.03 ± 0.34	< 0.05
Pull-out force (N)	388 ± 40	1462 ± 560	< 0.05

All the values are given as the mean and standard deviation
**P* value as determined by an analysis of variance

Table 2. Porotic status and mechanical properties in Group II

	Not reinforced	PMMA	<i>P</i> value*
Bone density (g/cm ³)	0.83 ± 0.12	0.80 ± 0.11	> 0.05
Cross-sectional area (cm ²)	2.93 ± 0.32	2.94 ± 0.44	> 0.05
Peak torque (Nm)	11.3 ± 2.51	20.3 ± 6.5	> 0.05
Torsional Stiffness (Nm/degree)	0.40 ± 0.07	0.64 ± 0.09	> 0.05
Pull-out force (N)	415 ± 40	1856 ± 560	< 0.05

All the values are given as the mean and standard deviation
**P* value as determined by an analysis of variance

Table 3. Porotic status and mechanical properties in Group III

	Poly(L-lactide)	PMMA	<i>P</i> value*
Bone density (g/cm ³)	0.84 ± 0.12	0.84 ± 0.13	> 0.05
Cross-sectional area (cm ²)	2.76 ± 0.57	2.61 ± 0.56	> 0.05
Peak torque (Nm)	20.3 ± 6.8	22.0 ± 10.0	> 0.05
Torsional Stiffness (Nm/degree)	1.07 ± 0.56	0.78 ± 0.36	> 0.05
Pull-out force (N)	1917 ± 40	1462 ± 560	> 0.05

All the values are given as the mean and standard deviation
**P* value as determined by an analysis of variance

Fig. 3 A–C. Photographs of specimens after failure in torsion showing the typical site of fracture. **A** Osteotomy without reinforcement. **B** Osteotomy reinforced with PLLA showing that the device has not been destroyed during testing. **C** Osteotomy reinforced with PMMA which filled the medullary canal and was intact after testing

The surface of the PLLA device after the screw was pulled out maintained its texture after tapping (Fig. 4B) which is typical for crystalline polymers with high ductility. In contrast the surface of the brittle PMMA had been worn off by the screw thread during the tests, leaving behind debris (Fig. 4C).

Fig. 4. **A** Screws that were pulled out from the PLLA (the thread is filled with cement). **B, C** Scanning electron micrographs after the screws were pulled out of the reinforcing material. **B** The surface of the PLLA reserves its shape. **C** The surface of the PMMA is completely destroyed

Discussion

PMMA combined with internal fixation is an accepted method of treating osteoporotic fractures [2, 8, 12, 15], and mechanical tests have demonstrated good stability of osteotomies reinforced with it [5, 13].

We chose fixation of humeral osteotomies in this study because fractures frequently occur at this site [16, 20]. Spiral fractures are the commonest type, so torsional testing was selected to evaluate the stability of the fixation. Mechanical testing of pairs of long bones allows individual variance to be excluded and long bones on the right and left sides have been reported as having similar mechanical properties [22], which we confirmed in our study. There was no difference in the osteoporotic state or mechanical properties of the paired bones.

The surgical procedure to introduce the PLLA augmentation device into the medullary canal was simple and similar to the technique used to insert humeral nails. The device could also be introduced into the canal through the fracture site. We had no problem fitting the device once drilling was carried out.

The osteotomies with the PLLA device had higher torsional stiffness than those reinforced with PMMA and those that were not reinforced which may be because the PLLA device bridged the osteotomy and the PMMA did not. Two shorter augmentation devices could be used instead of a single one. The pullout strength of screws from bones with the PLLA device was the same as that from bones with PMMA. The pull-out strength of screws from the PLLA device are subject to in vitro degradation which remains constant up to 6 months of ageing [19].

One of the disadvantages of PMMA is that, if there is infection, removal of adherent cement will be difficult and tedious.

Our study has demonstrated the advantages of the PLLA augmentation device, compared with the use of PMMA, in fixing osteotomies in cadaveric bones and the procedure could be used to enhance plating of osteoporotic fractures. Further experimental studies are needed to evaluate other resorbable polymers which have a shorter absorption time than PLLA and other designs of implant which might reduce vascular damage.

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