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No biological advantage with a low temperature curing versus a conventional bone cement: an experimental, mechanical and histomorphometrical study in the rabbit tibia

P. MORBERG
Department of Biomaterials/Handicap Research, Department of Orthopedics, Sahlgrenska University Hospital, University of Göteborg, Gothenburg, Sweden and Orthopaedic Research Laboratories, Prince of Wales Hospital, University of New South Wales, Sydney, Australia

C. B. JOHANSSON
Department of Biomaterials/Handicap Research, Sahlgrenska University Hospital, University of Göteborg, Gothenburg, Sweden

H. MALCHAU
Institute for Surgical Sciences, Sahlgrenska University Hospital, University of Göteborg, Gothenburg, Sweden

Both tibial marrow cavities of 12 rabbits were evacuated and filled with curing bone cement. In one of the tibias conventional curing bone cement (Simplex P®) was injected, while the other tibia of the same animal was filled with a low temperature curing bone cement (Boneloc®). Three titanium implants were inserted along the proximal metaphysis of each tibia. Eight weeks after insertion the most distal implant in each tibia was removed while recording the removal torque. The implant was then once again screwed home into its bone bed. The animals were sacrificed 16 weeks after implant insertion. The previously removed implant and another implant in each tibia were then both removed while recording the removal torque. The third implant in each tibia was cut out *en bloc* with surrounding tissue and processed for ground section. We found no statistical differences in the mechanical or the histomorphometric evaluation of implant integration between the two cements, indicating that the low temperature curing bone cement does not result in a significantly different bone response from that of a conventional acrylic cement.

1. Introduction

Histological studies of bone after intramedullary application of polymethylmethacrylate bone cement have demonstrated severe impairment in bone formation [1–4]. These observations have been attributed to a number of factors; thermal injury [5], monomer toxicity [1, 6, 7], high pressure insertion and removal of medullary circulation [4].

To minimize the thermal injury some bone cements with reduced exothermic temperature at polymerization have been introduced [8, 9].

This study was performed to investigate if a low temperature curing bone cement (Boneloc®) disturbs the cortical remodeling activity around implants less than a conventional bone cement (Simplex-P®) after pressurized insertion in the medullary canal.

2. Materials and methods

Twelve adult, lop-eared rabbits, between 9 and 12 months of age were operated on. Anaesthesia was induced with intramuscular injections of Hypnorm® (Mekos) and intraperitoneal injections of Valium® (Roche). Screw-shaped implants were manufactured from commercially pure titanium. The diameter of the threads was 3.7 mm and the top of the implant was square-shaped to fit a specially constructed connector (Fig. 1). The medullary contents of both tibias were, after preparation of the soft tissues, evacuated. Two holes were drilled, one in the proximal part of the bone and one at the distal end of the tibia. Through repeated high-pressure injections of saline into the proximal hole, the marrow contents were removed through the distal hole. Both tibias were then filled with bone cement. In one of the tibias a low-temperature polymerizing bone cement, Boneloc® (Polymers Reconstructive A/S, Farum,

Correspondence to: Per Morberg, Dept. of Biomaterials/Handicap Research, Inst. for Surgical Sciences, Box 412, SE 405 30 Göteborg, Sweden. E-mail: per.morberg@hkf.gu.se

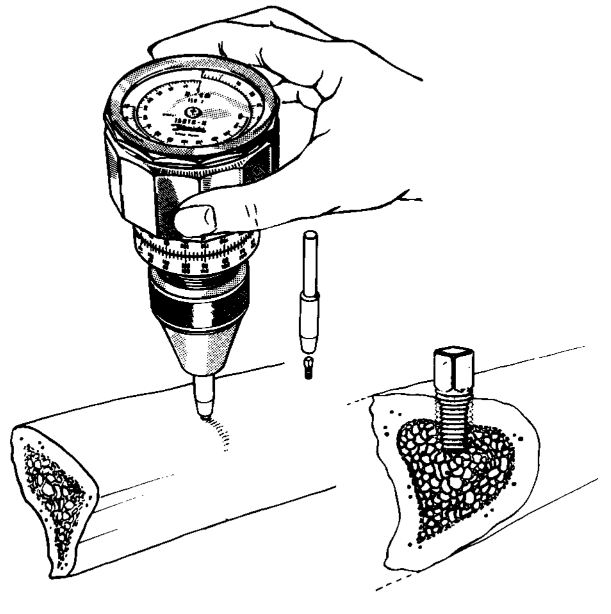

Figure 1 The removal torque screw implant *in situ*. The square-shaped top fits to a specially constructed connector. A torque-gauge instrument with its connector was used to unscrew the implants.

Denmark) was used and a conventional bone cement Simplex® was used in the other tibia. The cement was, after mixing, injected with a cement gun through the proximal hole. When the cement bulged out through the distal hole, manual pressure prevented further leakage and maximal pressure was maintained until polymerization. Two further holes were drilled 5 mm apart and 5 mm distally to the proximal hole. During the drilling procedures, the cortex and bone cement were penetrated with a fine drill, and the holes were gradually enlarged with wider drills using a low rotation speed. The diameters of the holes in the bone cement were enlarged by milling in the bone cement with a fine drill without simultaneous drilling the cortex of the bone. In this way the implants were, after threading the cortex and subsequent insertion, only in contact with the cortex and not with the surrounding bone cement. The implants were screwed home, with an insertion torque of 20 N cm, to a level where there was only one thread seen over the cortical plane. In each proximal tibial methaphysis there were three implants inserted, hereafter called implant 1, 2 and 3 in distal-to-proximal direction. After surgery the animals were allowed immediate full weight bearing.

2.1. Torque measurements

After 8 weeks the soft tissues were again sectioned to expose the top of implant 1. All soft and hard tissues growing on the implant, over the treaded level were carefully removed. After connecting the manometer the screws were removed while recording, with a Tohnichi 15 BTG-N torque instrument. The screws were then reinserted with a insertion torque of 20 N cm, and the soft tissues were sutured. After 16 weeks the soft tissues were again sectioned to expose all implants. With the same procedures as after 8 weeks implant 1 was removed once again and implant 2 was removed for the first time during registration of the removal torque.

2.2. Histological preparations

The animals were sacrificed 16 weeks after insertion and implant 3 was cut out *en bloc* with the surrounding bone tissues. The specimens were dehydrated and embedded in methylmethacrylate plastic. Using the procedure described by Donath and Breuner [10] sections were made through the implants and the surrounding undecalcified bone. After grinding the sections to a thickness of approximately 10 μm they were stained in 1% toluidine blue in a 1% borax solution mixed in proportions 4 to 1 with pyronin-G solution. The interfacial tissue reaction was studied under light microscope. The percentage of bone area inside the thread and bone appositioned to the surface of the metal was calculated for all threads using a computer-based morphometric assessment.

2.3. Statistics

The results were statistically evaluated using the Wilcoxon signed rank test.

3. Results

Two animals died during surgery and another two during the first postoperative 12 h. One animal suffered from a tibial fracture at the distal hole and had to be killed. Post mortem investigation revealed cured bone cement in two venae nutritiae, but no major emboli were observed in the lungs. The remaining animals were all healthy and no signs of any infections were observed in the operated areas.

Most of the implants had some callus formation over the threaded level of the implants. No major differences were observed in this callus formation and the inter-individual differences were greater than the intra-individual ones.

There were no significant differences in removal torques for implants inserted in tibias filled with low-temperature curing versus conventional bone cement. The torque for implant 1 after 8 and 16 weeks and implant 2 after 16 weeks are demonstrated in Table I.

Microscopic investigation revealed soft tissue and bone in the threads and in contact with the implant. Numerous macrophages and some giant cells were observed in areas without direct bone to metal contact.

TABLE I Removal torque (N cm) for c.p. implants 8 (left column, only implant 1) and 16 weeks after insertion in tibias filled with low temperature polymerizing (Boneloc®) and conventional bone cement (Simplex-P®)

	Boneloc®			Simplex-P®		
Animal	Implant 1		Implant 2	Implant 1		Implant 2
1	5	21	19	20	19	28
2	7	3	0	6	0	12
3	15	12	25	17	25	18
4	3	20	0	3	0	0
5	10	0	16	12	18	22
6	10	12	19	12	12	28
7	11	19	37	10	19	38
Mean	8.7	12.4	16.6	11.4	13.3	20.9

TABLE II Percentage of bone in metal contact (BMC) and bone inside the threads (AREA) of implants inserted in tibias filled with Boneloc® and Simplex-P®, respectively

	Boneloc®		Simplex-P®	
Animal	BMC	AREA	BMC	AREA
1	38.6	73.6	40.8	75.5
2	48.3	61.6	28.1	56.9
3	62.6	77.5	70.2	82.1
4	51.4	74.9	50.2	74.5
5	41.7	63.3	26.6	64.1
6	54.7	81.6	58.5	78.6
7	54.6	85.9	67.9	85.6
Mean	50.2	74.1	48.9	73.9

No major qualitative differences were observed around implant inserted in bone containing Simplex P® or Boneloc®. Histomorphometric examination of sections from implant 3 did not reveal any significant difference between the two bone cements regarding bone in direct metal contact (BMC) or the amount of bone inside the threads (AREA). The histomorphometric results are summarized in Table II.

4. Discussion

Boneloc® was developed with the aim of reducing the adverse biological effects associated with cementation of implants. Theoretically, this should be achieved mainly by lower release of monomer and lower polymerization temperature [11].

Less disturbed cortical histology and blood perfusion has been reported in animal experiments after cementation comparing Boneloc® to a conventional cement [9, 12]. Regarding the amount of released monomer, it has been observed that the initial release for Boneloc® is less than for a conventional cement but the oposite has been observed in the long term [13].

Clinically lower temperatures at the bone–cement interface have been registered *in vivo* during total hip arthroplasty with Boneloc® compared to conventional cements [14]. However, it has also been demonstrated that the peak temperature levels at the bone–cement interface of hip arthroplasties do not normally reach temperatures high enough such that the subsequently observed tissue damage could be explained by thermal injury alone [15].

However, even if the temperature rise in the clinical situation is moderate it may still potentiate other tissue-damaging factors [6, 16]. In a recent experimental animal study [17], the authors observed depressed remodeling activity in the inner 2/3 of the cortex by intramedullary inserted bone cement while they were not able to detect any effect of polymerization heat alone. The authors conclude that leakage of hot monomer from bone cement impairs remodeling in the diaphysis while polymerization heat alone did not.

In this study with a method previously demonstrated to be sensitive in detecting remodeling disturbances induced by intramedullary inserted bone cement [18] we were not able to detect any differences between the integration of titanium implants in tibias filled with low-temperature polymerizing and conventional bone cement. Recently, several clinical [19–23] and radiostereometrical [13] studies have demonstrated inferior clinical results after cementation with Boneloc® and the cement has now been withdrawn from clinical use. The clinical relevance of previously observed improved histology after using Boneloc® has been questioned [13].

Our results suggest that the thermal injury is not, even in combination with other tissue damaging factors, a significant factor responsible for the long-term bone tissue injury observed after cementation.

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