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The effect of drilling parameters on bone

Part III *The response to porous hydroxyapatite implants*

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For biocompatibility testing, cylindrical specimens are often inserted into drilled cortical defects. However, little attention has been paid to the drilling conditions. Our previous experience revealed that bone formation in drilled cortial defects was delayed by 5000 r.p.m. drilling due to thermal necrosis around the hole compared with 500 r.p.m., and the use of irrigation was effective in reducing the degree of local ischaemia. Therefore, this experiment was performed to investigate the short- and long-term effects of the drilling conditions on bone response to cylindrical porous hydroxyapatite implants. Two holes were drilled in rabbit tibia diaphysis with two different drilling conditions: 500 r.p.m. with irrigation and 5000 r.p.m. without irrigation. Rabbits were killed at 2 or 12 weeks post-operatively. The bone formation on the hole edge, on the implant surface and within the implant pores was investigated. At 2 weeks post-operatively the area of newly formed bone within the implant pores at 500 r.p.m. was significantly greater, whereas there was no difference at 12 weeks. These results indicate that the drilling conditions affect the short-term bone response to the implants. Therefore, the drilling conditions must be taken into consideration when investigating the early bone response to materials implanted into drilled cortical defects.

1. Introduction

Orthopaedic and dental biomaterials are intended to be implanted into bone. In order to investigate the bone response to these biomaterials, many studies have applied *in vivo* implantation techniques, often by inserting cylindrical specimens into drilled cortical defects. Factors that can influence the bone response to implanted materials are the implantation conditions, the mechanical stability of the implant in the recipient bed, and the implant itself. However, little attention has been paid to the implantation conditions.

Heat production and non-cylindrical drilling are critical problems in drilling bone for implantation. A high temperature causes osteonecrosis around the hole [1, 2], which may deleteriously influence the bone-healing process [3, 4] and the bone response to implanted materials. When a cylindrical specimen is inserted into a non-cylindrical drilled hole, the bone–implant gap introduces another factor of variability in the bone–implant relationship. Therefore, the drilling conditions may affect the bone response to implanted materials.

From the published literature, the drilling conditions have often been studied by *in vitro* temperature measurement [5, 6] or by investigating the initial bone damage [1, 7, 8]. However, bone healing in the drilled hole is also important when investigating the response of bone to implanted materials. Several studies have looked histologically at the bone–healing process in the drilled hole [3, 4, 9], but their aim was mainly to investigate the use of ultraspeed drilling ($>$ 200 000 r.p.m.) and the absence of histomorphometric evaluation has limited the quantification of the studied parameters.

In another experiment [10] we histomorphometrically studied the influence of the drilling conditions on the resultant hole geometry (edge defect), initial bone damage and later healing process by using conditions that were created through three speeds of rotation (200, 500 and 5000 r.p.m.) and the use of irrigation or not. The edge defect and the initial thermal damage did not show a great difference between 200 and 500 r.p.m. The degree of the edge defect was less at 5000 r.p.m. However, the initial thermal damage was greater and the area of newly formed bone in the drilled hole was smaller. On the contrary, 500 r.p.m. drilling, although causing slight initial thermal damage, induced greater new bone formation. Irrigation did not influence bone healing, but reduced the degree of the initial damage.

These results indicated that the drilling conditions affected the bone–healing process in drilled cortical defects without an implant. Therefore, the aim of this

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experiment was to investigate the short- and longer-term effect of the drilling conditions on the bone response to cylindrical implants made of porous hydroxyapatite.

2. Materials and methods

2.1. Implants

Porous hydroxyapatite implants were prepared by Sumitomo Cement Co. (Osaka, Japan). The shape was cylindrical: 3.15 mm outside diameter and 10 mm length (Fig. 1). The porosity was about 40%, with a pore size ranging from 50 to 300 µm. The pores were closed except for the marginal portion, and the interconnections between pores were scarce. They were sterilized by autoclave.

2.2. Drilling conditions

Because of the elasticity of bone, a 3.3 mm diameter semicircular drill (IMZ 514015A, France-Implants, Vincennes, France) was used. The drill was driven by a motor system (AEU-717, Aseptico, Washington, USA), in which the speed of rotation could be adjusted (from 100 to 15 000 r.p.m.). In addition, this system was connected to an irrigation pump. Physiological saline at room temperature (20–22 °C) was used as the irrigation agent and flushed out from the centre of the drill at a flow rate of 60 ml min^{-1} during drilling. Two extreme drilling conditions were selected from our previous experiment [10]: 500 r.p.m. with irrigation was employed as the atraumatic condition, and 5000 r.p.m. without irrigation was employed as the traumatic condition.

2.3. Animal experiments

Six male New Zealand White rabbits, weighing about 3.0 kg, were used. General anaesthesia was induced and maintained by intramuscular injection of Zoletil (Zolazepam + Tiletamine; 20 mg kg^{-1} body weight) and Rompun (Xylazine; 0.2 mg kg^{-1} body weight). The operation was performed under aseptic conditions. Both legs were shaved, cleaned and disinfected. In each hindlimb, a 3 cm longitudinal skin incision was made on the anteromedial surface starting from the distal portion of the tibial tuberosity. The tibia was exposed supraperiosteally. Two holes were drilled in the diaphysis, perpendicular to the cortex, with the previously defined drilling conditions. After drilling, bone debris in all holes was carefully removed by irrigation. The implants were then inserted tightly into the holes in a press-fit manner. Muscles, subcutaneous tissues and skin were closed layer by layer. A sterile dressing was applied. After surgery, all rabbits were kept in individual cages and immediate weight bearing was allowed.

Rabbits were distributed into two groups and killed 2 or 12 weeks after surgery. Tibia were fixed in 10 % buffered formalin, then dehydrated and embedded in methylmethacrylate. Each tibia was cut into two parts, each containing one specimen. Each block was sectioned with a microtome saw, perpendicular to the implant axis, at the middle level of cortical thickness. The sections were ground down to 100 µm and stained with Paragon. Six specimens were available for each group at each implantation time.

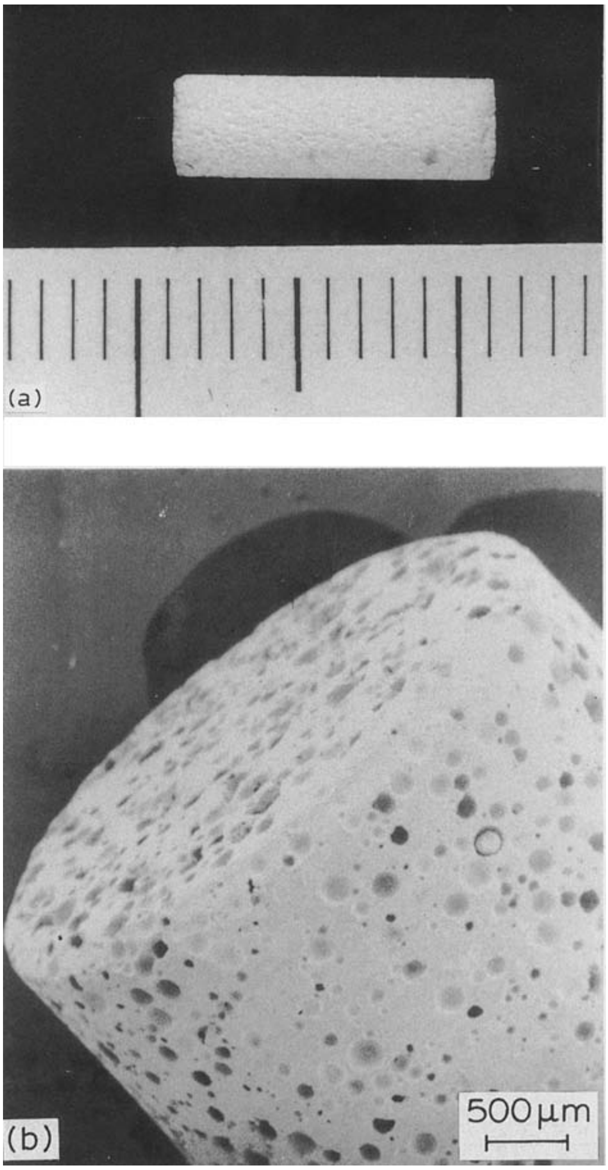

Figure 1 (a) Photograph of a porous hydroxyapatite implant used in this study (taken by Sumitomo Cement Co.) and (b) Scanning electron micrograph.

2.4. Histomorphometry

A microscope connected with an image analyser (CUE-2, Olympus Co., Tokyo, Japan) was used to measure the histomorphometric parameters. The microscope stage was driven by a motor and was controlled by a computer. A magnification of × 100 was used to investigate the specimens, and the measurements were done serially by using this system.

The response of bone to implants was evaluated at three levels: at the hole edge, on the implant surface and within the implant pores. The circumferencial lengths of bone resorption (carved edge, osteoclasts are sometimes observed) and direct bone apposition

TABLE I The length percentage of direct bone formation and bone resorption at the hole edge and bone contact on the implant surface at 2 weeks post-operatively

Drilling conditions	Hole edge		Implant surface
	Bone formation (%)	Bone resorption (%)	Bone contact (%)
500 r.p.m. with irrigation ($n = 6$)	7.7 ± 6.3	9.1 ± 4.6	44.2 ± 17.4
5000 r.p.m. without irrigation ($n = 6$)	7.4 ± 4.4	21.6 ± 17.6	50.6 ± 19.5

Values are means ± standard deviations. No significant differences between two drilling conditions groups.

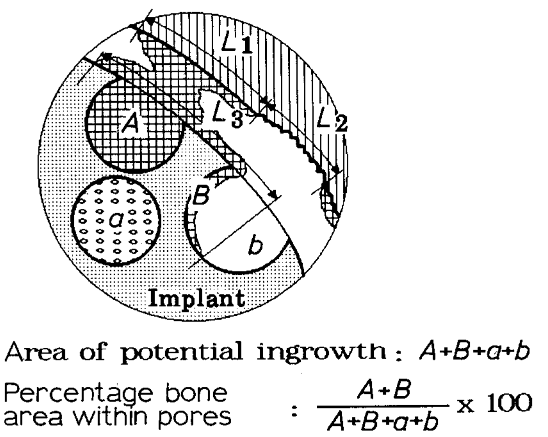

Figure 2 Schematic diagram of the parameters of histomorphometry. L_1, Circumferential length of direct bone formation on the hole edge without resorption; L_2, circumferential length of bone resorption of the hole edge; L_3, length of direct bone contact on the implant surface, including pore wall; A, area of newly formed bone completely filling the pore; B areas of newly formed bone partially occupying the pore; a, pore where only soft tissue is observed. (this area is added to the area of potential ingrowth); and b, no-bone area within partially bony occupied pore.

(new bone forms on the hole edge without resorption) at the bone–implant interface were measured and calculated as percentages of the drilled hole circumference. The length of direct bone contact on the implant surface was measured and calculated as a percentage of the total implant surface length. The area of newly formed bone within the implant pores was measured. As the interconnections between pores were scarce, new bone formation could not be detected at the central portion of the implant 12 weeks post-operatively. Therefore, the total pore area where any cells could be observed was measured as the "area of potential ingrowth". The bone area within the implant pores was calculated as a percentage of the area of potential ingrowth (Fig. 2). Student's paired t-test was implemented throughout the statistical analysis.

3. Results

3.1. 2 weeks

Regardless of the drilling conditions, new bone formation had already occurred at the hole edge, on the implant surface and within the implant pores at 2 weeks post-operatively (Fig. 3). Newly formed bone directly contacted the implant surface and was observed to appose on the hole edge and on the implant surface simultaneously. The percentage of direct bone apposition on the hole edge was identical for the two drilling conditions, whereas the bone resorption was relatively high at 5000 r.p.m. (Table I). The direct bone contact on the implant surface was identical. However, the percentage of the bone formed within the implant pores was significantly higher at 500 r.p.m. ($P < 0.002$; Table II).

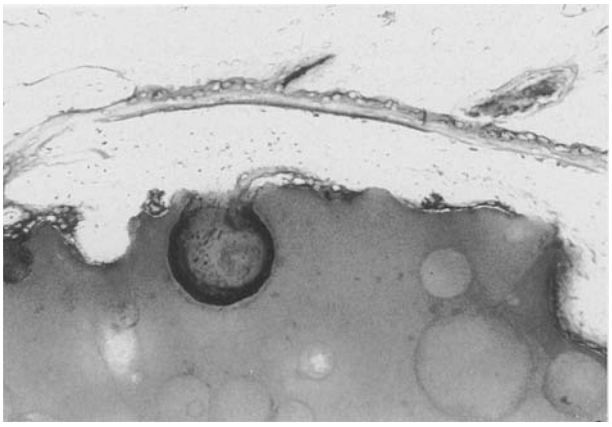

Figure 3 Photomicrograph of a 2 week specimen (Paragon stain, ×44). Newly formed bone seems to appose on the hole edge and on the implant surface simultaneously. It is considered that newly formed bone first covers the implant surface and the hole edge, then bone begins to appose on this bone matrix to form wider trabeculae.

TABLE II The area percentage of newly formed bone within implant pores

Drilling conditions	Implantation time	
	2 weeks	12 weeks
500 r.p.m. with irrigation	38.4 ± 11.0	76.5 ± 16.5
5000 r.p.m. without irrigation	25.5 ± 12.3*	71.4 ± 7.8

Values are means ± standard deviations. The number of specimens was six for each group at each implantation time.
* $P < 0.002$ versus 500 r.p.m. with irrigation.

3.2. 12 weeks

In both groups of rabbits, all implants had been almost totally surrounded by newly formed bone and the hole edge had already been remodelled at 12 weeks post-operatively (Fig. 4), so only the bone area within

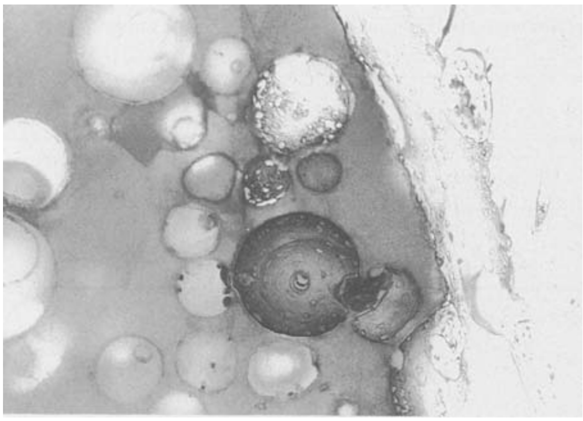

Figure 4 Photomicrograph of a 12 week specimen (Paragon stain, × 44). The implant was totally surrounded by newly formed bone, which also grew into the implant pores as far as the peripheric portion. The hole edge had already been remodelled.

the implant pores was measured. The new bone ingrew as far as the peripheral portion of the implant and the pores at the central were still empty. There was no difference between the two drilling conditions. (Table II).

4. Discussion

A local host-response to an implanted specimen is considered to be a combination of the wound-healing process that takes place after tissue injury and the tissue response to the specimen [11]. If a material is not totally inert, the local host-response is likely to be more intense. The acute phase may be a little more noticeable but, more importantly, the chronic response to the material will be more significant and prolonged. In the case of a non-toxic and non-degradable material, the inflammatory response and the repair process may take place virtually unaffected by the material. With the progress in orthopaedic and dental biomaterials, many kinds of bioactive materials have been developed. These permit early bone formation and direct bone bonding. However, when early bone bonding cannot be achieved for any reason, implant instability will occur and bone bonding cannot be obtained. Therefore, the tissue injury when implanting a specimen may play a more important role in the short-term local response to the implanted specimen than the tissue response to the specimen itself. Accordingly, strict control of the implanting conditions is critical when considering the short-term bone response to implanted materials.

Hydroxyapatite is one of the bioactive materials. Compared with non-bioactive materials (metals or polymers) it allows an optimal response for bone growth and has little effect on the tissue inflammation. Therefore, the local host-response may be considered to depend mainly on the wound-healing process. Moreover, porous implants allow the ingrowth of newly formed bone into the pores and facilitate the quantitative evaluation of the bone reaction. Accordingly, porous hydroxyapatite implants were used in this study.

In our previous experiment [10] the percentage of direct bone apposition on the hole edge 2 weeks following operation was 58.6% at 500 r.p.m. with irrigation and 41.9% at 5000 r.p.m. without irrigation, and bone resorption was 9.2 and 16.4%, respectively. Compared with the present study, the percentage of bone resorption was almost identical for each group, whereas the direct bone apposition on the hole edge with the implant was much lower and there was no difference between the two drilling conditions. When an implant is inserted into a cortical defect and occupies most of the defect, there is less empty space available for bone growth. Therefore, the new bone formation is assumed to be lower than that in the hole without an implant. However, the bone resorption may be assumed not to be influenced by the implant, and it seems to depend on the drilling damage.

At 2 weeks post-operatively the percentage of direct bone contact at the implant surface was identical, whereas the bone area within the implant pores was larger at 500 r.p.m. It is assumed that new bone formation first occurs at the implant surface and progresses along this surface, then bone begins to appose on the existing bone matrix to form wider trabeculae. Thus, new bone formation at 500 r.p.m. is considered to be more advanced, indicating that the drilling conditions affect the short-term bone response to the implanted materials.

Since the hole edge has already been remodelled and any inflammatory cells could not be observed, the bone-repair process and the initial bone response to the specimens may be considered as terminated at 12 weeks post-operatively. The difference at 2 weeks was no longer observed, so the drilling condition did not affect the results of the later response of bone.

Drilling in bone causes a non-specific damage that can shield the specific bone response to implanted materials. Therefore, well-controlled and non-traumatic drilling conditions may allow the difference in early bone response to be demonstrated. These results indicate that the drilling conditions significantly affected the new bone formation in the pores of porous hydroxyapatite implants at 2 weeks post-operatively. Therefore, the drilling conditions must be taken into account for biomaterials testing when implanting specimens into drilled cortical defects.

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