Biological evaluation of a zirconia toughened apatitic composite implant[†]

B VAIDHYANATHAN, K ARUN KUMAR^{††},
J N SHETTY^{††} and K J RAO*

Solid State and Structural Chemistry Unit, Indian Institute of Science, Bangalore 560 012, India

^{††} Department of Oral and Maxillofacial Surgery, Government Dental College, Bangalore, India

MS received 15 November 1996

Abstract. A biological study is reported where implants of β -TCP/t-ZrO₂ has been examined in rabbit mandibles. The composite is found to be fully biocompatible and evidence of good osteoconduction and tissue ingress has been noticed.

Keywords. Apatite; bioceramics; implantation studies.

Apatites and related phosphates are known to be very good prosthetic materials for bone repair and replacement (Jarcho *et al* 1976). There have been several reports of the use of apatites as implants in animal studies (Holmes 1978; Reznick *et al* 1989). It has generally been proven that they are highly biocompatible. Implant materials however require to have good mechanical strength besides biocompatibility (Landuyt *et al* 1995). It is also desirable that they encourage tissue growth around the implant and lead to good tissue bonding. In an earlier study we have demonstrated that a zirconia toughened apatitic composite exhibited higher fracture toughness and good *in vitro* biocompatibility (Nagarajan and Rao 1993). The sintered composite had a surface structure which was considered as suitable for tissue growth. But no animal implant studies were performed using these apatitic bodies.

In this communication we report implant studies conducted with this composite in rabbit mandibles. It is demonstrated that the implants are highly biocompatible with no adverse reactions in the surrounding tissue. There is evidence of tissue ingress and good bone bonding with the implant.

The zirconia toughened apatitic composite bodies (hereafter referred to as ZAP-30) were prepared by sintering commercial hydroxyapatite (HAp, 70 mol%) and monoclinic zirconia (m-ZrO₂, 30 mol%) at 1400°C for 2 h. Both HAp and m-ZrO₂ were initially ground together with alcohol and pressed into circular discs. Neither any sintering aid nor external pressure was used during sintering process. It has been established earlier (Nagarajan and Rao 1993) that this process leads to formation of a fine distribution of calcia stabilized tetragonal zirconia (t-ZrO₂) particles in a matrix of β -tricalcium phosphate (β -TCP). The resulting ZAP-30 discs exhibit a remarkable fracture toughness (in the range of 2–3 MPa $\sqrt{m}$). Square pieces (5 mm²) were cut from the disc. The thicknesses of the pellets were uniformly 2 mm. These pieces were used in implant studies. In figure 1a ZAP-30 blocks used in this

[†]Contribution No. 1253 from Solid State and Structural Chemistry Unit

*Author for correspondence

Figure 1. a. ZAP-30 blocks used in the implantation studies and b. scanning electron micrograph of the surface of the ZAP-30 block (prior to implantation).

study are shown while the scanning electron micrograph of the surface of a block is shown in figure 1b. The surface reveals graininess and microporosity is expected to be adequate for tissue bonding.

Figure 2. a. Surgical defect cut in the jaw bone of the rabbit and b. positioning of the ZAP-30 implant.

Ten, 10 months old, healthy, male, New Zealand white rabbits were chosen for the experiments. Through two skin incisions, placed bilaterally, the jaw bone was exposed and using a micromotor, full thickness surgical defects of 5×5 mm square were cut on

Figure 3. Radiograph showing the implant position (after the completion of implantation process).

Table 1. Results of the bio-implant studies of ZAP-30.

Rabbit No.	Weight (in kg) before implantation	Weight (in kg) after implantation	Period of evaluation	Reaction
1.	2.0	2.2	4 weeks	Moderate reaction
2.	2.4	2.6	5 weeks	No reaction
3.	2.9	3.0	6 weeks	No reaction
4.	2.8	3.0	7 weeks	No reaction
5.	2.2	2.9	8 weeks	No reaction
6.	2.5	2.9	9 weeks	No reaction
7.	2.9	3.2	10 weeks	No reaction
8.	2.0	3.0	11 weeks	No reaction
9.	2.25	3.0	12 weeks	No reaction
10.	2.1	3.2	12 weeks	No reaction

either side of the jaw. The ZAP-30 block which has the same dimension was implanted into the defect on one side and the other side was kept empty as the control. The wounds were closed. Figures 2a and b reveal the incisions made in the jaw bone of the rabbit and the positioning of the ZAP-30 block. Figure 3 is the radiograph showing the positioning of the implant after completion of the implantation process.

The rabbits were fed normal diet under laboratory conditions. The animals were sacrificed during the next three months at regular intervals. The implants were

Figure 4. a. Interface of the implant (brown portion) with the neighbouring bone (pink coloured portion) and b. interface between the implant and the muscular tissue.

retrieved along with the surrounding normal bone. The specimens were decalcified with formic acid, sectioned to 5 μ thickness and stained with haematoxylin and eosin and studied under light microscope. The interface of ZAP-30 and surrounding tissue (mainly bone) was examined for necrosis, inflammation, resorption and integration. The tissue reactions and other relevant biological observations are summarized in table 1.

It is evident from table 1 that all animals registered increase in weight before they were sacrificed. There was no observable tissue reaction in these animals. However in only one case of the rabbit sacrificed at the end of just 4 weeks (no. 1 in table 1), a moderate reaction was noticed. Even in this case the rabbit had gained a significant 10% in weight during this period, thereby suggesting that the reaction could be only due to the surgical trauma.

Figure 4a corresponds to the interface of the implant with the neighbouring bone (corresponding to the case of rabbit no. 8). There is very clear evidence of bone–tissue ingress into the ZAP-30 block. This can be taken as good evidence for osteo-conduction and complete biocompatibility. In figure 4b the interface of the implant with the muscular tissue is shown. It is evident that the normal architecture of muscle tissue has been restored around the implant. In one instance (rabbit no. 3 in table 1) we noted spots in the photomicrograph of the tissue region which is indicative of necrosis of the bone tissue. We feel that this could have resulted from the heat generated locally during surgical procedures (bone-cutting).

Thus we find that ZAP-30 implants are fully biocompatible. The tissue reaction to the implant is healthy and there is no evidence of any adverse reactions either with the muscular or boney-tissue at the interfaces. There is clear evidence of osteo-conduction (Arunkumar 1996) and restoration of healthy architecture in the surrounding musculature following implantation. The post implantation response of the rabbits has been normal and they exhibited normal weight increases during these studies. The recovered ZAP-30 implants from the rabbit mandibles have not yet been investigated further to find out whether conversion of TCP to HAp has taken place and whether the structure of t-ZrO₂ has changed. Studies on the fracture toughness of wet samples after implantation have also not been done and work in this direction is in progress.

References

- Arunkumar K 1996 *Biological evaluation of hydroxyapatite–Zirconia composite ceramic: An animal study*, MDS Dissertation, Bangalore University, Bangalore
- Holmes R H 1978 *Plastic and Reconstructive Surgery* **63** 718
- Jarcho M, Bolen C H, Thomas M B, Bobick J, Kay J F and Doremus R H 1976 *J. Mater. Sci.* **11** 2027
- Landuyt P V, Li F, Keustermans J P, Streydio J M, Delannay F and Munting E 1995 *J. Mater. Sci. Mater. Med.* **6** 8
- Nagarajan V S and Rao K J 1993 *J. Mater. Chem.* **3** 43
- Reznick J B, Gilmore W C and Calif T 1989 *Oral Surg. Oral Med. Oral Pathol.* **67** 665