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Behaviour of a 316L stainless steel implant processed by sanding or alumina-coated in the metacarpus bone of sheep

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The behaviour of bone was studied in the presence of two implant materials, a 316L stainless steel with its surface roughened by sanding (type I) and the same steel coated with alumina by plasma-spraying (type II). Twelve nails of types I and II were implanted in the medullary canal of previously fractured metacarpal bones of 12 sheep. Samples were taken from six sheep at 90 days (group A) and 180 days (group B) post-surgery. Clinical examination of the operated sheep as well as radiographic analysis did not show any difference between the two types of implants. Bone ingrowth was studied by optical microscopy and microradiography, by measuring the angle of bone growth around the implants and the minimum distance between the newly formed bone and the implants. Differences between the two types of implants were not statistically significant.

1. Introduction

Biomaterials used in human medicine, dentistry, veterinary surgery and pharmacology are, by definition, in intimate contact with living tissues [1]. The use of porous materials, invaded later by bone cells, increases the area of contact between the implant and the living tissues, and therefore improves the quality of fixation of the implant [2]. Dense alumina has been used as implant in orthopaedic surgery since the late 1960s, the first clinical cases being reported by Boutin in 1971 [3]. Its excellent tolerance, its advantages and limitations have been described elsewhere [1–4]. The sanding of stainless steel roughens its surface and could favour a good bone–implant contact [5]. Functional experiments as well as the control of the colonization of an implant by bone tissue have to be conducted with Haversian bone to keep the biomechanical environment, the size of the implants and the metabolic process close to those in the human body.

The purpose of this work was to study the behaviour of bone tissue in the presence of stainless steel processed by sanding or alumina-coating. For each experimental sheep, one stainless steel nail processed by sanding was implanted in the medullary canal of a previously fractured metacarpus on one side and another steel nail coated with alumina by plasma-spraying was implanted on the other side.

2. Materials and methods

2.1. Animals

Twelve female Ile-de-France adult sheep (mean weight 55 kg) were used for the study. Before surgery the general condition of the sheep was improved by vitamin supplementation (vitamins A, D and E) and by treatment against endoparasites.

2.2. Materials

Twenty-four hollow and split nails in stainless steel 316L (10 cm × 0.6 cm) processed either by sanding (type I) or by alumina-coating using plasma-spraying (Fig. 1) were implanted in sheep according to the design presented in Table I. The roughness obtained by sanding varied between 4 and 40 μm. Alumina granules varied in size between 5 and 45 μm and their chemical composition was 99.3% Al_2O_3, 0.017% SiO_2, 0.011% TiO_2, 0.055% Fe_2O_3, 0.034% CaO, 0.001% MgO and 0.6% Na_2O. This layer was 100 μm thick with a porosity of $< 30\%$.

2.3. Surgical procedure

The sheep were fasted for 24 h before surgery. General anaesthesia was obtained with sodium pentobarbital, under intubation and free breathing. Sheep were placed on their side, the whole limb shaved and disinfected with ether alcohol and iodine. The surgery was performed under clean septic conditions in an operating room. Incision of the skin (30 mm) was performed on the lateral side of the metacarpus, at the level of the diaphysis, followed by incisions of the underlying tissues and periosteum. The osteotomy was performed transversally with an Adam's saw and the implant was placed within the medullary canal by a retrograde procedure. The periosteum and the underlying tissues were sutured with chromic gut (3.0) and the skin with silk (4.0). No drainage was necessary and a cast was placed, allowing the sheep to use their

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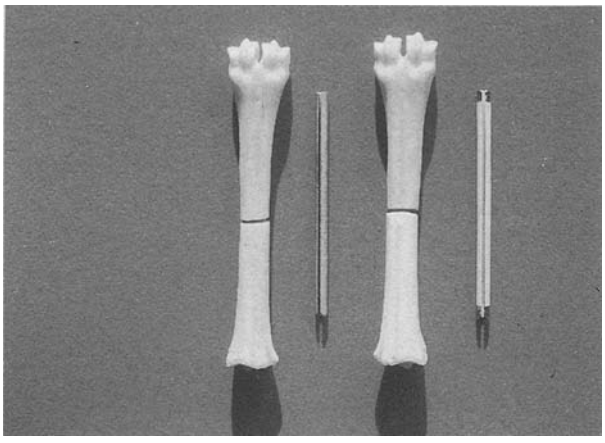

Figure 1 Photograph of the implants: the alumina-coated nail (left) and the stainless steel nail processed by sanding (right).

TABLE I Experimental design

Group		Duration of experiment (days)	No. of sheep	Type of implant
A	A_I	90	6	I
	A_{II}		6	II
B	B_I	180	6	I
	B_{II}		6	II

limb as soon as possible after the surgery. Antibiotics (Oxytetracyclin 150 mg every 24 h, intramuscularly) were given for the following 6 days and the cast was removed at 90 days post-surgery (PS).

2.4. Histology

The experimental sheep were killed at 90 (group A) or 180 days PS (group B). Metacarpal samples including the implants were immediately fixed in 70% alcohol, dehydrated and embedded in methyl methacrylate [6]. Fine transversal sections (60–100 μm) of the metacarpus including the implant were obtained from both the proximal and distal extremities, using a diamond saw. The microscopic preparations were studied radiographically perpendicular to the section and then stained with Giemsa-Red Paragon before observation by optical microscopy. The behaviour of the bone in the presence of both types of implants was judged by measuring from the microradiographs the angle (in degrees) of bone growth around these implants (colonization of the implants) and the minimum distance between the newly formed bone and the nails.

2.5. Data analysis

Data were analysed after computation of the mean, standard deviation and standard error of the mean, using the parametric *t*-test.

3. Results

3.1. Clinical examination

Throughout the experiment the sheep did not show any sign of lameness, fever, local inflammatory reaction or infectious disease. Radiographic examinations showed the presence of a callus as early as 30 days PS, easily visible at 90 days PS and mostly ossified at the level of the periosteum, the cortical and endosteum at 180 days PS. For both types of implants the radiographs were identical and no difference in bone consolidation was observed.

3.2. Histology and microradiography

Study of cross-sections showed an evolution of the bone growth with time: bands of porous bone were observed around the implant at 90 and 180 days PS. These bands gave rise to a fine layer of ossified tissue, irregularly distributed at the surface of the nails and in intimate contact with the nails in some instances. Similarly, the evolution of the fibre tissue with time was noted: fibres of collagen parallel to the bone–nail interface were numerous at 90 days PS and present in limited numbers at 180 days PS. The angle of bone growth around the implants and the minimum distance between the newly formed bone and the implants did not show any statistically significant differences between the two types of implants (Table II).

4. Discussion

The sheep could use their limbs soon after the surgery, which is one of the conditions required to compare the behaviour of the implants in sheep and in humans [1]. The bone growth and its adherence to the skeleton was compared between stainless steel implants processed by sanding and alumina-coated to ascertain the

TABLE II Angle of new bone formation and minimum bone–nail distance in sheep at 90 and 180 days PS

Treatment group	Angle of new bone formation (degrees)	Parametric *t*-test		Minimum bone–nail distance (μm)	Parametric *t*-test	
		Mean	*P*		Mean	*P*
A_I	172.5 ± 42.3	0.8386	0.401	100.8 ± 41.9	0.4045	0.6858
A_{II}	113.3 ± 44.9			107.5 ± 47.1		
B_I	206.8 ± 35.5	1.3628	0.1730	150.0 ± 47.8	0.7338	0.4631
B_{II}	151.7 ± 38.8			204.6 ⊥ 47.4		

Means ± SEM calculated from six replicates.

usefulness of these types of implants in orthopaedic surgery.

The 316L stainless steel is commonly used in surgery for reconstruction or replacement of bones. Therefore, these materials are extremely good candidates for orthopaedic surgery, usually appreciated by surgeons [7–9], even though their use is not always harmless [10]. Ceramics applied to metal supports have been also proposed as implants [2, 11, 19]; the alumina, biocompatible and inert, was used at the tissue–biomaterial interface [10], whereas the metal, rigid but less biocompatible, was responsible for the mechanical support [12]. Sanding of the steel is required before applying the ceramics. The plasma-spraying improves the fusion of the particules of alumina and increases their kinetic energy, resulting in a better adherence between the alumina and the support, and the elimination of gaseous oxidation. The porosity of the coating depends on the plasma-spraying used [10, 13]. Sanding of steel increases the roughness of the implant at its surface.

Previous microscopic examinations of bone have shown the superiority, as far as adherence to the bone is concerned, of the alumina over the smooth steel implant [7, 16]. In this study we did not notice any differences between implants coated with alumina and sanded steel implants. Our results (clinical, radiographic and histological) showed a similar response of the bone appositing each type of implants. The comparative study of the angle of bone growth around the implant did not show any significant differences (t-test: groups A_I–A_{II}, $P = 0.87$; B_I–B_{II}, $P = 0.38$).

Because it is reported that the interaction between the surface of the bone and the implant is a key factor in bone regeneration [14], we explained our results by considering that the sanding treatment of the stainless steel implant did increase its interface with the bone. The importance of the roughness of the steel as well as the long-term biocompatibility of this material, including the toxic effects due to corrosion and some degradation products, need to be investigated before establishing the indications for this type of implant. Although titanium implants processed by sanding do not present any corrosion problem and could easily be used in surgery, problems of biocompatibility under the above conditions need to be studied.

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