

Biodegradable implants for orthodontic anchorage.

A preliminary biomechanical study

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SUMMARY The use of endosseous implants as temporary orthodontic anchoring elements has good results in many clinical applications. The development of a new orthodontic implant anchorage system comprising an implant produced of biodegradable polylactide with a metal superstructure is described. The presented bioresorbable implant anchor for orthodontics system (BIOS) implant is designed to provide orthodontic anchoring functions in adolescents and adult patients, and to then be resorbed without a foreign body reaction or signs of clinical inflammation.

Shear strength and maximum vertical strength have been measured in biomechanical *in vitro* tests. BIOS fixtures can be loaded with horizontal shearing forces of 50 N with a mean deflection of 0.26 ± 0.13 mm and mean vertical removal forces of 155 ± 80 N.

Clinical studies are currently being undertaken to evaluate clinical practicability and biocompatibility of the BIOS implants.

Introduction

One problem frequently occurring in the therapy of dental and skeletal dysgnathias is an adequate stationary anchorage to absorb reactive forces and moments. As a rule, the anchorage preparation is directed primarily towards the biological anchorage quality of the teeth. In many cases, however, mechanical anchorage aids are needed, irrespective of the orthodontist's skill, because the periodontal ligament offers inadequate anchorage potential (Diedrich, 1990; Wehrbein 1993). A distinction is made here between intra- and extra-oral appliances.

The best-known intra-oral appliances are palatal or lingual bars, the Nance holding arch and intermaxillary elastics, but often by using these appliances, loss of anchorage leads to undesirable side-effects such as protrusion of the incisors, extrusion and tipping of the teeth, and negative influence on the occlusal plane (Fuhrmann *et al.*, 1994).

The most frequently used extra-oral anchorage, headgear, is subject to negative criticism regardless of its undisputed range of applications, as acceptance problems on the part of patients may result in poor compliance, jeopardising the overall success of orthodontic therapy (Diedrich, 1993).

A further problem arises especially among adult patients. A reduced dentition, advanced attachment loss or the absence of entire anchorage-relevant tooth groups often forces the orthodontist to fall back on therapeutic alternatives which then prevent the individual therapeutic objective from being attained.

In the last few years, alloplastic implants have been the subject of numerous studies on the biomechanical aspects of anchorage (Brånemark *et al.*, 1977; Gray *et al.*, 1983; Ödman *et al.*, 1988; Turley *et al.*, 1988; Roberts *et al.*, 1989, 1990; Haanaes *et al.*, 1991).

Wehrbein and Diedrich (1993) stated that endosseous titanium implants are suitable as anchoring units for long-term orthodontic treatment. Furthermore, the applied force may induce marginal bone appositions adjacent to the implants and so lead to better stability of the fixtures.

This suggests that implants can also be used in principle as anchorage elements for complex orthodontic tooth movements. However, if the alloplastic implant is solely used for anchorage purposes, it has to be removed in a secondary operation at the conclusion of orthodontic treatment. The ideal solution would thus be a stable positioned implant which could assume a stationary anchorage function for an adequate

period but could then be readily removed or, preferably resorbed within the tissues.

This objective was the basis for the development of the bioresorbable implant anchor for orthodontics system (BIOS) which is presented in this paper. Implants made of biodegradable polylactide alpha-polyester and adapted to the respective range of indications are used as anchorage in the osseous jaw. They should retain the required stability for a period of 9–12 months and are then degraded, with no trace of residual material and without a significant foreign-body reaction (Kronenthal, 1975). Present investigations with resorbable implants in other medical fields showed histological findings with an encapsulation of the implants by bony tissue with sometimes interposition of a thin layer of fibrous tissue (Vert *et al.*, 1992). The degradation process is illustrated in Figure 1.

Prior to clinical application, the aim of this

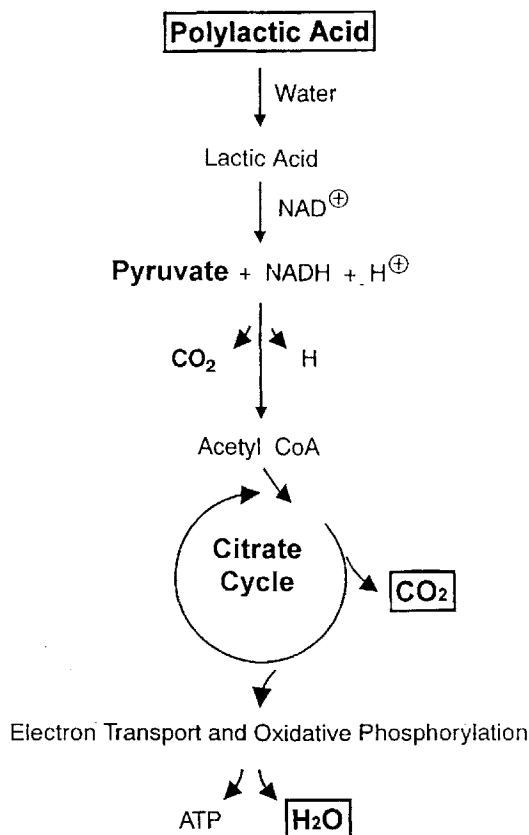


Figure 1 Diagram showing the degradation of polylactid.

study was to prove the biomechanical properties of the BIOS implants.

Material and biomechanical test methods

The newly developed BIOS implant comprises a biodegradable implant body and a variable metal abutment as a superstructure (Fig. 2). The metal abutment is anchored by means of a metrically-standardized internal thread (size M2) located in the plastic implant. The technological innovation of this development is, however, in the biodegradable poly LDL lactide copolymer (90/10 per cent) implant body. This copolymer has been in use for some considerable time as an osteosynthetic material in traumatological applications (Claes *et al.*, 1992; Helling *et al.*, 1992).

The resorbable implant body was produced by injection moulding and sterilized using ethylene oxide. The dimensions and design of the biodegradable implant with respect to the external thread were derived from an ITI-Bonefit® screw implant (Straumann, Waldenburg, Switzerland) with a fixture length of 6 mm. This has the advantage of reducing the number of instruments required for implantation, as BIOS-implants can thus be inserted with conventional instruments, making use of well-tried surgical techniques.

The implants were screwed into delrin block polymerisate test pieces into which threads had previously been cut with the Bonefit® instruments, according to the clinical procedure.

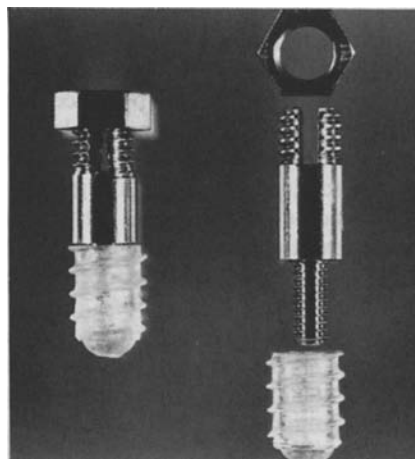


Figure 2 BIOS implant system comprising (i) resorbable implant body and (ii) metal abutment with fixation screw.



Figure 3 Zwick 1454 tensile test machine.

Shear strength and maximum vertical displacement to failure forces were measured in a Zwick 1454 tensile test machine (Zwick, Germany) under ambient conditions (Fig. 3).

Ten BIOS implants were tested in each series of measurements, with a reference group formed from Bonefit® implants of the same number and with identical dimensions.

Statistical analysis

The Kruskal–Wallis test with a significance level of $P < 0.05$ was used to analyse the data.

Results

Shear strength tests

Table 1 provides a summary of shear strength data for different force application. The implant deflections were generally small, even though

Table 1 Shear strength data. Deflection (in mm) of the measured implants for different horizontal forces.

Implant type	Horizontal force (N)				
	2	14	26	38	50
Bonefit Implant 1	0.000	0.000	0.015	0.035	0.070
Bonefit Implant 2	0.000	0.000	0.018	0.035	0.070
Bonefit Implant 3	0.000	0.000	0.018	0.035	0.070
Bonefit Implant 4	0.000	0.000	0.015	0.030	0.065
Bonefit Implant 5	0.000	0.000	0.018	0.035	0.070
Bonefit Implant 6	0.000	0.000	0.020	0.040	0.080
Bonefit Implant 7	0.000	0.000	0.017	0.032	0.060
Bonefit Implant 8	0.000	0.000	0.020	0.038	0.070
Bonefit Implant 9	0.000	0.000	0.019	0.035	0.070
Bonefit Implant 10	0.000	0.000	0.018	0.038	0.070
BIOS Implant 1	0.000	0.090	0.210	0.300	0.580
BIOS Implant 2	0.000	0.070	0.150	0.220	0.310
BIOS Implant 3	0.000	0.015	0.038	0.060	0.250
BIOS Implant 4	0.000	0.015	0.080	0.150	0.250
BIOS Implant 5	0.000	0.018	0.027	0.050	0.080
BIOS Implant 6	0.000	0.020	0.040	0.070	0.110
BIOS Implant 7	0.000	0.040	0.090	0.170	0.300
BIOS Implant 8	0.000	0.040	0.060	0.120	0.200
BIOS Implant 9	0.000	0.030	0.040	0.080	0.200
BIOS Implant 10	0.000	0.050	0.080	0.180	0.320

BIOS = bioresorbable implant anchor for orthodontics system.

significantly different data could be measured between the two implant systems.

Under a load of up to a maximum force of 50 N, engaging perpendicularly at a height of 3 mm with the metal abutment (equivalent to the ultimate clinical force application), the following values were measured:

The Bonefit® statistical analysis implants underwent a deflection up to 0.07 ± 0.01 mm, with a maximum value of 0.08 mm. The values measured at the BIOS implants were up to $0.26 \text{ mm} \pm 0.13 \text{ mm}$ with a maximum deflection of 0.58 mm. Shearing-off or material fracture was not observed in any of the implants.

Vertical forces tests

The results of the measurement are given in Table 2. The Bonefit® implants can be loaded with vertical forces of up to 422 ± 21 N with a maximum value of 460 N before the external thread was torn out from the test piece. The BIOS fixtures attained mean values of 155 ± 80 N with a maximum value of 244 N.

In contrast to the Bonefit® implants, the metal superstructure was invariably torn out of the internal thread of the implant body.

Table 2 Maximum vertical force data.

Implant type	Maximum force (N)
Bonefit Implant 1	420.0
Bonefit Implant 2	410.0
Bonefit Implant 3	420.0
Bonefit Implant 4	430.0
Bonefit Implant 5	450.0
Bonefit Implant 6	410.0
Bonefit Implant 7	390.0
Bonefit Implant 8	430.0
Bonefit Implant 9	460.0
Bonefit Implant 10	400.0
BIOS Implant 1	60.0
BIOS Implant 2	208.0
BIOS Implant 3	10.0
BIOS Implant 4	123.0
BIOS Implant 5	213.0
BIOS Implant 6	244.0
BIOS Implant 7	212.0
BIOS Implant 8	198.0
BIOS Implant 9	78.0
BIOS Implant 10	201.0

BIOS = bioresorbable implant anchor for orthodontics system.

Discussion

The experiments were designed as preclinical biomechanical tests of these new biodegradable implants.

The test results show that, in the newly developed BIOS implants, the limiting element in intercepting reactive forces is invariably the connection between the internal thread of the resorbable implant and the metal abutment.

Although the mechanical test data obtained are significantly lower in the BIOS implant group, the loading capacity of the BIOS implant was found to be adequate for clinical application in orthodontics, because in orthodontic tooth movement forces of this size are not required.

Encouraged from the *in vitro* results and the experiences with this polymer in other medical fields, the behaviour in therapeutic use of the newly developed fixtures is now currently being tested in a clinical pilot study. Possible implantation areas suitable for purely orthodontic anchorage are the alveolar part of the maxilla or mandible, the retromolar region and the median palate (Fig. 4).

Triaca *et al.* (1992) and Wehrbein (1994) described the anterior palatal region as an implantation site for orthodontic anchorage in the maxilla. This could be a new possibility in

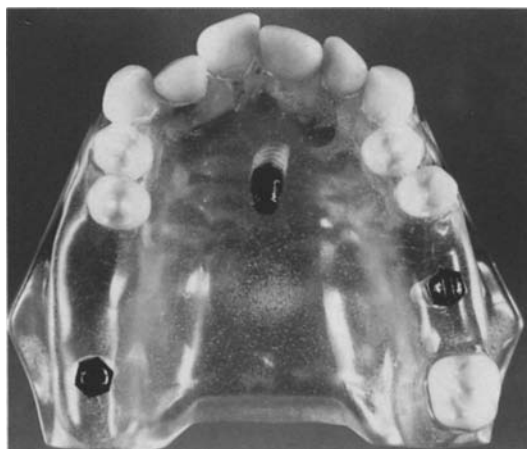


Figure 4 Model to demonstrate various implantation areas for orthodontic anchorage.



Figure 5 BIOS implant *in situ* integrated into the orthodontic segmented-arch appliance (>stainless steel TPA 0.32 × 0.32) during distalization of the maxillary molar in an adult patient.

orthodontic treatment to avoid extra-oral appliances. However, the fixtures have to remain stable long enough for complex orthodontic treatment.

One of the most important questions, which has to be answered in the clinical studies (Fig. 5) is regarding the degradation properties and kinetics under a constant load over a few months *in vivo*, even if the forces used in tooth movement are not very high.

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