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Biomaterials 26 (2005) 1389–1396
Biomaterials
www.elsevier.com/locate/biomaterials

The tissue response to an alkylene bis(dilactoyl)-methacrylate bone adhesive

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Received 23 December 2003; accepted 30 April 2004

Available online 3 July 2004

Abstract

Gluing is an attractive technique to fix small bone fragments. However, to date no bone adhesive could be established successfully for all day clinical use.

The purpose of this experimental study was to investigate the biocompatibility of a new bone glue based on alkylene bis(dilactoyl)-methacrylate in 36 rabbits. Monocondylar osteotomy of the distal femur was performed and bone glue was applied into the osteotomy gap in 24 rabbits. The remaining 12 animals served as controls. In all rabbits the osteotomy was subsequently stabilized by K-wire osteosynthesis. Six animals of the glue group and 3 controls were euthanized after 7, 21, 42, and 84 days, respectively. Fracture healing and degradation pattern of the glue was studied using histological, histomorphometrical, scanning electron microscopical, and radiological methods.

Good resorption of the glue by mononuclear and multinucleated giant cells without prolonged inflammatory processes was observed in the glue group. Histomorphometrical analysis did not reveal any significant differences in fracture healing between the glue and control group at any time. Complete remodelling of the former osteotomy gap was found in all rabbits after 84 days.

This bioresorbable bone adhesive exhibited good biocompatibility and its degradation did not interfere with physiological fracture healing.
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Keywords: Bone adhesive; Polymethylmethacrylate; Biocompatibility; Degradation; Bone remodelling; Histomorphometry

1. Introduction

Gluing is an attractive alternative technique to fix bone fragments in orthopaedic and trauma surgery. There are several advantages of this technique compared to nailing or plating.

Firstly, gluing enables good fixation of small fragments, e.g. in comminuted fracture sites. Secondly, fixation of fragments by gluing is leading to more homogenous weight bearing distribution within the fracture site compared to pinning where load is mainly punctually transferred on the pins [1–3]. In consequence, the risk of implant failure by punctual stress-overload, like often seen in plating, due to high rigidity and stiffness of metallic implants can be reduced by gluing [4,5]. Moreover, in articular fractures glue seam can act as ''subchondral spacer'' to compensate joint surface displacement.

Several preconditions have to be met by a bone adhesive for its all day clinical use. It must have sufficient adhesive properties, good short- and long-term biocompatibility without interference with physiological fracture healing processes including fast biodegradability [3,6]. Furthermore, the criteria of a strong and flexible bond, adequate time of action, and possibility of sterilization should be fulfilled [7,8].

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0142-9612/$ - see front matter © 2004 Elsevier Ltd. All rights reserved.
doi:10.1016/j.biomaterials.2004.04.048

Many efforts have been undertaken in the past to generate substances with adhesive properties for bone gluing purposes. Cyanoacrylates exhibited bad biocompatibility and high infection rates [4,9], whereas methacrylates [4,10] and fibrin systems [6] lacked sufficient adhesive stability. Therefore, all these substances could not be established for all day clinical use [4–6]. Established adhesives, e.g. fibrin and protein–aldehyde systems, are not indicated for bone but for soft tissue gluing.

An alkylene bis(dilactoyl)-methacrylate bone adhesive has been developed, which is not comparable to other current adhesives regarding chemical properties, biocompatibility and degradation [11,12]. This glue has some relationship to polymethylmethacrylate (PMMA) which has been used extensively in dentistry [6], and in orthopaedic surgery for anchoring of prostheses [13]. Preliminary in vitro data showed good biocompatibility and biodegradability characteristics of this new class of polymers [12].

The purpose of the present study was to investigate the biocompatibility of alkylene bis(dilactoyl)-methacrylate in a rabbit model. Fracture healing and degradation pattern of the adhesive, especially oseointegration due to the cellular migration of osteoblasts, as well as inflammatory tissue reactions were studied using histological, histomorphometrical, and radiological methods.

2. Materials and methods

2.1. Material: bone adhesive

The bone adhesive used in the current study is based on alkylene bis(dilactoyl)-methacrylate—a new class of low molecular weight polymers—combined with a comonomer and acts as a two-component system [4,12]. The first one is an unpolymerized highly viscous component. The second component contains a nonreactive oligomer without reactive end groups and solubilized alkyl boron as radical donator initiating polymerization process into highly branched, hydrolyzable networks [12].

Starting components are ethylene glycol and lactide leading to condensation reaction of a multifunctional alcohol and dimers of lactic acid generated by an acidic ring opening reaction of lactide (Fig. 1). This nonreactive condensation product—1,2-ethylene glycol-oligo lactic acid—is esterified by methacrylic acid producing a highly reactive end-product. The highly viscous macromolecule—1,2-ethylene glycol-oligo lactic acid-dimethacrylate (ELAMA)—can easily be polymerized through irradiation either by photoinitiation combined with irradiation or by high energy light.

In situ application is done using a two-chamber cartridge containing the monomer in the first and the initiator of the polymerization with the polymer itself in the second cartridge [12]. The adhesive exhibits doughy consistency after mixing of the components and starts hardening after about 1 min. Final stable state of the glue is reached after 24 h.

2.2. Study design

Thirty-six healthy 2-year-old female ZiKa rabbits with mature skeleton and an average body weight of 3.200 ± 200 g were used for the current study. Approval by an institutional review board was obtained prior to surgery. The operations were performed in an operating room under aseptic conditions. After randomization of the animals a monocondylar osteotomy of the distal femur was performed and subsequently stabilized either by glue application plus K-wire osteosynthesis or by K-wire osteosynthesis alone. The adhesive was applied into the osteotomy in 24 rabbits before osteosynthesis; the remaining 12 animals served as controls. Six animals from the glue group and 3 controls were euthanized after 7, 21, 42, and 84 days, respectively. Fracture healing and degradation pattern of the adhesive was studied using histological, histomorphometrical, scanning electron microscopical, and radiological methods.

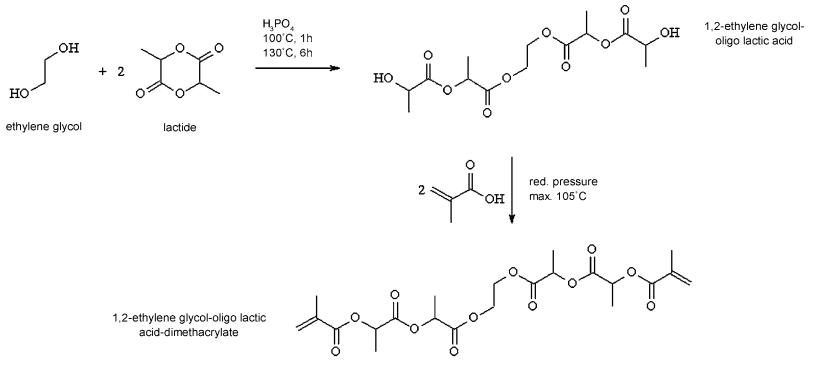

Fig. 1. Synthesis of the new polymer 1,2-ethylene glycol-oligo lactic acid-dimethacrylate (ELAMA). Educts for synthesis: (1) ethylene glycol, (2) lactide and (3) methacrylic acid.

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