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# Are postoperative intravenous antibiotics necessary after bimaxillary orthognathic surgery? A prospective, randomized, double-blind, placebo-controlled clinical trial

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*Abstract.* Postoperative antibiotic prophylaxis is often administered intravenously, despite an increased morbidity rate compared with oral application. This study investigates whether a postoperative oral antibiotic regimen is as effective as incorporation of intravenous antibiotics after bimaxillary orthognathic surgery. 42 patients who underwent bimaxillary orthognathic surgery between December 2008 and May 2010 were randomly allocated to 2 placebo-controlled postoperative antibiotic prophylaxis groups. Group 1 received oral amoxicillin 500 mg three times daily; group 2 received intravenous ampicillin 1 g four times daily, during the first two postoperative days. Both groups subsequently took oral amoxicillin for three more days. Clinically, the infection rate was assessed in both study groups for a period of 6 weeks after the surgery. 9 patients (21.4%) developed infection. No adverse drug event was detected. No significant difference ($p = 0.45$) was detected in the infection rate between group 1 (3/21) and group 2 (6/21). Age, type of surgical procedures, duration of the operative procedure, surgical procedure-related events, blood loss, and blood transfusion were all found not related to infection ($p > 0.05$). Administration of more cost-effective oral antibiotic prophylaxis, which causes less comorbidity, can be considered to be safe in bimaxillary orthognathic surgery with segmentalizations.

Key words: antibiotic; antimicrobial agents; bimaxillary osteotomies; infection; adverse drug event.

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Dentofacial deformities affect approximately 20% of the population. Such people may benefit from combined orthodontic treatment and orthognathic surgery[5]. Peterson estimated the infection rate for orthognathic surgery was 10–15%, which reduced to 1% with a perioperative antibiotic regimen[29]. Others record higher prevalences of infection after bimaxillary osteotomies, ranging from 1% to 33%[4,9,15].

Orthognathic surgery is considered to produce clean-contaminated wounds[2].

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Infecting microorganisms are part of the mixed endogenous flora of the oral cavity. Extraoral approaches, pose an additional risk of infection owing to skin microorganisms. Infections due to intraoral approaches, are caused mainly by streptococci, anaerobic Gram-positive cocci and anaerobic Gram-negative rods; staphylococci are the most important germs causing transcutaneous infection[34].

Perioperative antibiotic drugs have been used prophylactically worldwide to reduce postoperative infection rates without any consensus regarding the regimen. The rationale for such antibiotic prophylaxis in these procedures was the direct communication of surgically displaced osseous segments with the oral and nasal cavities, or the maxillary sinuses[32]. Controversies regarding the use of prophylactic antibiotics in orthognathic surgery result in a wide variation in the prophylactic antibiotic regimens in the literature[4,9,14,32,33]. Although some authors[28,35] doubt its role in intraoral orthognathic surgery, PETERSON[29] recommended a short-term perioperative antibiotic regimen, considering it to be effective in preventing postoperative wound infection. This recommendation corresponds to those of later studies[3,18,25,26]. YRASTORZA[35] suggested that routine prophylactic use of antibiotics in bimaxillary osteotomies should be reserved for specific cases, such as patients with decreased host defences and patients undergoing surgery with sizable bone grafts. To date there has been no clinical study comparing the efficacy of oral versus intravenous antibiotic regimens in bimaxillary orthognathic surgery reported in the English literature.

There are risks related to antibiotic usage. Immediate adverse effects such as anaphylactic shock, itching, urticaria, angioedema, rhinitis, bronchospasm, and laryngeal oedema are rare. Delayed adverse effects such as 'serum sickness' with urticaria, fever, polyarthralgia, lymphadenopathy and eosinophilia have been described[21,24]. Appropriate criteria to select the optimal antibiotic regimen for specific purposes include efficacy, risk of adverse advents, contraindications, treatment costs, and details about the clinical condition of the patient[26].

In most previous studies, the immediate postoperative antibiotic regimen was administered intravenously[4]. As the null hypothesis of this study was no significant difference in the prevalence of the infection rate with or without the postoperative intravenous antibiotic regimen, the aim of this study was to investigate if a postoperative oral antibiotic regimen was as effective as an intravenous antibiotic regimen in bimaxillary orthognathic surgery with segmentalization.

## Materials and methods

This prospective, single centre, randomized, double-blinded, placebo-controlled clinical trial was performed following the principles outlined in the Declaration of Helsinki and was approved by the local Human Ethics Committee.

All patients, male and female, aged 18–40 years, who underwent bimaxillary orthognathic surgery within the Discipline of Oral and Maxillofacial Surgery from December 2008 to May 2010, were enrolled in this study. Written informed consent was obtained from all participants.

Patients were excluded from the study when any of the following criteria were present: history of any type of previous surgery to the head and neck area, including previous orthognathic surgery; patients who were having distraction osteogenesis as part of the orthognathic surgery; history of malignancy of the head and neck region, and/or history of radiation to the head and neck region; known hypersensitivity to amoxicillin, ampicillin or other β-lactam antibiotics; known history of lactose intolerance; patients who had used any antibiotics in the 14 days prior to the surgery; patients with compromised host defences (e.g. diabetes mellitus, autoimmune disease, end-stage renal disease, severe alcoholic cirrhosis and neutropenia); and patients who were receiving immunosuppressive drugs that interfere with host defences (e.g. cyclosporine, steroids and cancer chemotherapeutic agents).

All participants were randomly assigned to two groups, corresponding to a list of computer-generated random numbers generated and kept by an independent pharmacist. Block randomization with a block size of four was used to ensure approximately equal numbers of subjects in each study group. They remained in the same allocation throughout the postoperative period. The details of the series were unknown to any of the surgeons. The pharmacist prepared the medications and placebo, which were identical in size, shape and colour; and dispensed them to the nurses in the ward in a sequentially numbered opaque sealed envelope. The code was revealed to the principal investigator at the end of the trial. The patients, surgeons and clinical assessors were blinded to the postoperative prophylactic antibiotic regimen.

### Antimicrobial prophylaxis

Postoperatively, participants in group 1 received oral amoxicillin (Bright Future Pharmaceutical Laboratories Ltd., Hong Kong SAR, PR China) 500 mg three times daily and intravenous placebo (normal saline) injection four times daily in the first 2 days after orthognathic surgery. Participants in group 2 were given intravenous ampicillin (Medochemie Ltd., Limassol, Cyprus) 1 g four times daily and oral lactose (placebo) three times daily for the first 2 days after the orthognathic surgery. All participants received oral amoxicillin 500 mg three times daily for another 3 days.

All participants received intravenous ampicillin 1 g during anaesthetic induction, and 500 mg every 6 h during the operation. In case an adverse reaction developed after the administration of amoxicillin, the antibiotic drug was changed to clindamycin (Pfizer PGM, Pocé Sur Cisse, France) and the case was withdrawn from the study.

### Surgical intervention

Orthognathic surgery was performed under induced hypotensive anaesthesia[8,12,22,37]. Intravenous tranexamic acid[7,37] (Daiichi Sankyo Co. Ltd., Tokyo, Japan) 20 mg/kg was administered to participants in both groups on induction of anaesthesia. Surgery was performed by senior staff and residents. The incision sites were infiltrated with lidocaine with 1:80,000 epinephrine (Lidocaton 2% 1:80,000, Weimer Pharma GmbH, Rastatt, Germany). All osteotomies were performed using burs and saws by Stryker® (Michigan, USA). The segments were internally fixed with titanium osteosynthesis plates and screws (Compact MF™ 2.0, Synthes-Stratec, Oberdorf, Switzerland). In cases with vertical subsigmoid osteotomy, mandibulomaxillary fixation was performed for 6 weeks. All surgical wounds were closed primarily with 4-0 and 3-0 Vicryl® sutures (Ethicon, Somerville, NJ, USA), without any drainage. Suture removal was performed 1 week after the operation. Compression chin dressing was applied after genioplasty for 2 days. Ice packs were applied for the first 2 days postoperatively.

Additionally, the patients were prescribed mefenamic acid (APT Pharma Ltd., Hong Kong SAR, PR China) 500 mg three times daily, intravenous