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The modular endoprosthesis for mandibular body replacement – Part 1: Mechanical testing of the reconstruction

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ABSTRACT

Introduction: In this paper we present the results of the mechanical testing of a new generation modular endoprosthesis, which has been designed to improve the results of mandibular reconstruction.
Materials and methods: The new cementless endoprosthesis consists of a male part, a female part (both with screws on the stems), connected via a dove-tailed connection and secured with a coronal screw. The endoprosthesis was fitted into standardized blocks of synthetic bone (Synbone AG, Malans, Switzerland). The set-up was fixed to an ElectroPuls testing machine at one end and loaded at the other end 25 mm away. Three specimens were loaded continuously until failure to determine the average load to failure of the construct. Five specimens were then loaded cyclically between 10 and 150 N until either failure or 500,000 cycles. A finite element analysis was also performed on the set-up.
Results: Of the five specimens in the fatigue testing, only one survived while the other four either were bent or fractured at the stem of the clamped portion. The specimen that survived had very good bony contact with the prosthesis at the lower border. The connection of the modules via the dove-tailed design did not show any loosening. Finite element analysis showed areas of stress concentration at the superior surface of the stems to 188.8 MPa. This was well below the yield strength of titanium alloy of 897 MPa. Statistical analysis performed for specimens 1 to 4 to calculated lower tolerance bounds on cycles to failure, representing the estimated minimum achievable cycles to failure at 90, 95, and 99% of the population at 90 and 95% confidence levels, showed that the estimated mean cycles to failure was 10,132 cycles at the mean, minimum and maximum loads of 120 N and 18.4 N respectively.
Conclusion: Good bony contact seems to be essential at the lower border for long-term survival of the reconstruction. Small gaps increase the bending forces and thus shear stresses at the stem. The new design of the modular endoprosthesis is prone to stress concentrations at the superior surface of the stems. This is accentuated by the sharp screw threads of the stems. The loosening of the module connection seemed to have been stopped with the dove-tailed design.

1. Introduction

Reconstruction of continuity defects in the mandible after oncological resection or trauma are prone to problems such as fracture of the plates and screws used, dehiscence of the hardware, bone resorption and lack of adequate bone volume to enable placement of osseointegrated implants. Various methods have been advocated and tried with mixed results (Goh et al., 2008). The current gold standard is the microvascular free osteocutaneous flap, usually the fibula. This, however, necessitates a long complex operation which may not be suitable for every case. There is also surgical morbidity from another donor site, prolonged hospitalization time with increased cost and a long recovery process with delayed function. Many of these patients are elderly with multiple medical problems which make them unsuitable for a long reconstructive surgical procedure.

There has been a long history of success with the use of the endoprosthesis in orthopaedic surgery, mostly for hip replacement (Callaghan et al., 2000). Lately, in the field of musculoskeletal surgery, the use of modular endoprostheses has led to cost effective

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treatment of patients undergoing resection of part of the appendicular skeleton for oncological purposes with early function (Henshaw and Malawer, 2001). The endoprosthesis is cemented into the bony stump, acting as a grout to fix the stem in bone. There is still debate about the use of bone cement (polymethyl metacrylate) to cement the endoprosthesis stem to the bone stump. Direct bone contact at the bone cement interphase does not occur in most cases (Charnley, 1970). Aseptic loosening of the stem is the most common complication of using a cemented endoprosthesis. It is a gradual process whereby the mechanical integrity of the implant/bone interphase is lost and a fibrous tissue is formed. The precise mechanism is not known but the process is likely initiated by mechanical failure of the interface between bone and the cement. The use of non-cemented endoprosthesis has been advocated (press-fitted or screwed-in type) in an effort to prevent this (Huiskes, 1991).

Tideman and Lee (2006) proposed the use of the modular endoprosthesis, adapted to the mandibular region, as a potentially viable alternative to the microvascular free fibula flap. Studies have reported mixed success, using animal models, replacing defects of the mandibular body as well as the condyle/angle with a cemented modular endoprosthesis (Lee et al., 2008). A fibrous connective tissue capsule tended to form around the cemented stems. Animals with the mandibular body prosthesis had early function and showed bone growth at the lower border of the reconstruction (Lee et al., 2009). The peri-implant bone mineral density, however, decreased and the entire reconstruction tended to have problems with loosening of the connection screws which connected the modules (Wong et al., 2011a,b). This led to infection and dehiscence. On the other hand, the condyle prosthesis encountered little problems and withstood the forces of mastication well (Goh et al., 2009a,b).

The biomechanics of the mandible, however, is grossly different to that of the limb bones. In the mandible, the forces transmitted are mainly perpendicular to the long axis of the bone, the forces act mainly in a Class III lever system and there is a temperature variation from ingestion of food or liquids. The forces acting on the mandible are very complex and although there have been many studies utilizing a whole range of methods (or example strain gauges, finite element analysis) the forces acting on the reconstructed mandible are still not understood very well.

Many papers have been written about the biomechanics of the intact mandible (Vollmer et al., 2000; Van Eijden, 2000) as well as for different methods of internal fixation and reconstruction of defects for fractures, craniofacial deformities, rapid maxillary expansion, biodegradable plates/screws and orthognathic surgery (Meyer et al., 2002; Gallas Torreira and Fernandez, 2004; Chiodo et al., 2006; Meyer et al., 2006; Han et al., 2009; Parascandolo et al., 2010; Liu et al., 2011; Bockmann et al., 2011; Jank et al., 2010; Ramos et al., 2011). These authors have investigated, either via mechanical testing or finite element analysis, the stress/strain distribution after distraction, fracture fixation, splitting torque of different osteotomy designs and pull out strength of fixation materials. Ramos et al. (2011) investigated the effect of geometric variations of the condyle and fixation screws on temporomandibular joint implants, which has similarities to that of the modular endoprosthesis (condyle/ramus replacement). There have, however, been few studies done on the biomechanics of reconstructed mandibles as a whole (Tie et al., 2006; Kimura et al., 2006; Knoll et al., 2006).

The method of mechanical testing for any biological device depends on its ability to perform simple tests like a 3-point bending test and more complex constructs using masticatory robots to test load to failure (ultimate strength) or cyclic testing to failure. The objective of this paper is to describe the experimental evaluation of a new design of a third generation mandibular modular endoprosthesis, using standardized in vitro loading conditions on a reconstructed segment of a synthetic mandible, to look at fatigue performance and failure patterns. The hypothesis is that this new design will be able to withstand the simulated masticatory forces up to a defined end point.

2. Materials and methods

2.1. Design and fabrication of the modular endoprosthesis

The device, made of titanium alloy (Ti 6AL 4V), has two parts: (1) a male part with a self-tapping screw threads on the stem and a dove-tailed connection body and (2) a female part, again with self-tapping screw threads on the stem and a body with the corresponding dove-tailed outline (Fig. 1a). The contour of the buccal and lingual surfaces of the body of the module followed that of the mandible; the module body was to be placed along the lower border of the mandible. The two modules were connected by a connection screw inserted from the coronal part (Fig. 1b). A slight movement of 0.1 mm was designed as a stress breaker between the connection of the male and female part (dove-tailed connection). The stems were made to be screwed into the marrow space of the mandible. The dimensions of the assembled prosthesis were: (1) stem – 18 mm length and 4 mm diameter and (2) body – 15 mm in length, 16 mm high and 8.5 mm thick.

2.2. Synthetic mandible

We used synthetic mandibles, made of dense polyurethane and measuring 9 cm in length from gonial angle to symphysis, 7 cm in height from gonial angle to coronoid tip and 8 cm in width from angle to angle from Synbone (Synbone AG, Malans, Switzerland). There was a thick dense outer layer simulating the cortical layer and a much thinner porous inner layer simulating the cancellous layer of the mandible. The layers vary in thickness and do not replicate exactly the anatomical thickness of the cortical and cancellous portions. These synthetic mandibles have a well-established history of testing and the dense layer has similar material properties to mandibular cortical bone (Dichard and Klotch, 1994; Haug et al., 2001; Haug et al., 1996). Using Synbone, Bredbenner and Haug showed that the screw insertion torque and pull out strength for Synbone material is similar to cadaveric bone (Bredbenner and Haug, 2000). Two squares with dimensions of 2 cm × 2 cm were cut out from the right body of eight synthetic mandibles corresponding to the lower right first and second molar area; a standard plaster jig was used to ensure consistency in size and place. Pilot holes were drilled into the centre of the cancellous layer of the bone blocks to accommodate the stems of the endoprosthesis (Fig. 2) and the modules inserted by screwing in the stems. Contact was not observed between the dense layer and the stem. The endoprosthesis modules were then connected with the connection screw. A total of eight reconstructed test segments were made.

2.3. Test set-up

The test construct consisted of the reconstructed segments with the endoprosthesis inserted. One end (the male part) was fully clamped with a custom fixture, positioning the set-up horizontally, onto an electrical linear motor system (ElectroPuls E3000 Testing System, Instron Corp, Canton, Massachusetts, USA). The other end (the female part) was loaded vertically with a probe 10 mm away from the prosthesis body (Fig. 3).

Three specimens were subjected to a continuous single cycle load to failure (static testing) at a rate of 1 mm/min to a maximum of 500 N. Failure load, location and mode of failure were recorded.