

A personalized 3D-printed prosthetic joint replacement for the human temporomandibular joint: From implant design to implantation



David C. Ackland^{a,*}, Dale Robinson^a, Michael Redhead^a, Peter Vee Sin Lee^a, Adrian Moskaljuk^a, George Dimitroulis^b

^a Department of Mechanical Engineering, University of Melbourne, Victoria, Australia

^b Department of Surgery, St Vincent's Hospital, Victoria, Australia

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ABSTRACT

Personalized prosthetic joint replacements have important applications in cases of complex bone and joint conditions where the shape and size of off-the-shelf components may not be adequate. The objective of this study was to design, test and fabricate a personalized 3D-printed prosthesis for a patient requiring total joint replacement surgery of the temporomandibular joint (TMJ). The new 'Melbourne' prosthetic TMJ design featured a condylar component sized specifically to the patient and fixation screw positions that avoid potential intra-operative damage to the mandibular nerve. The Melbourne prosthetic TMJ was developed for a 58-year-old female recipient with end-stage osteoarthritis of the TMJ. The load response of the prosthesis during chewing and a maximum-force bite was quantified using a personalized musculoskeletal model of the patient's masticatory system developed using medical images. The simulations were then repeated after implantation of the Biomet Microfixation prosthetic TMJ, an established stock device. The maximum condylar stresses, screw stress and mandibular stress at the screw-bone interface were lower in the Melbourne prosthetic TMJ (259.6 MPa, 312.9 MPa and 198.4 MPa, respectively) than those in the Biomet Microfixation device (284.0 MPa, 416.0 MPa and 262.2 MPa, respectively) during the maximum-force bite, with similar trends also observed during the chewing bite. After trialing surgical placement and evaluating prosthetic TMJ stability using cadaveric specimens, the prosthesis was fabricated using 3D printing, sterilized, and implanted into the female recipient. Six months post-operatively, the prosthesis recipient had a normal jaw opening distance (40.0 mm), with no complications identified. The new design features and immediate load response of the Melbourne prosthetic TMJ suggests that it may provide improved clinical and biomechanical joint function compared to a commonly used stock device, and reduce risk of intra-operative nerve damage during placement. The framework presented may be useful for designing and testing customized devices for the treatment of debilitating bone and joint conditions.

1. Introduction

The temporomandibular joint (TMJ) is a bi-lateral synovial articulation between the mandible and temporal bone, and is vital for speech, chewing, swallowing, and for expression of emotion. Pain and dysfunction of the jaw is common and ranges in prevalence from 33% to 86% (Carlsson, 1999). Prosthetic total joint replacement surgery is the established treatment for severe degenerative joint conditions of the TMJ when conservative treatment is not effective. It has been shown to reduce pain and restore jaw function in cases of developmental abnormalities, advanced degenerative joint disease such as osteoarthritis, tumors, as well as trauma (Giannakopoulos et al., 2012; Sidebottom and Gruber, 2013; van Loon et al., 1995); however, poor

functional outcome, pain, infection and nerve damage have attributed to complication rates of up to 14.0% (Kanatas et al., 2012; Leandro et al., 2013). A shortcoming of current commercially available off-the-shelf prosthetic TMJ components is the limited capacity of a small number of standard implant sizes to conform to the wide range of jaw morphologies and bone pathologies that present clinically, while maintaining adequate fixation under physiological loading. In cases of large tumor resection resulting in bone loss, patients may be left with gross deformities and poor mandibular function when stock prosthetic components cannot be effectively employed.

Three-dimensional (3D) printing, also known as rapid prototyping or additive manufacturing, is a manufacturing process in which objects are made by melting, fusing or depositing materials in layers to

* Corresponding author.

E-mail address: dackland@unimelb.edu.au (D.C. Ackland).

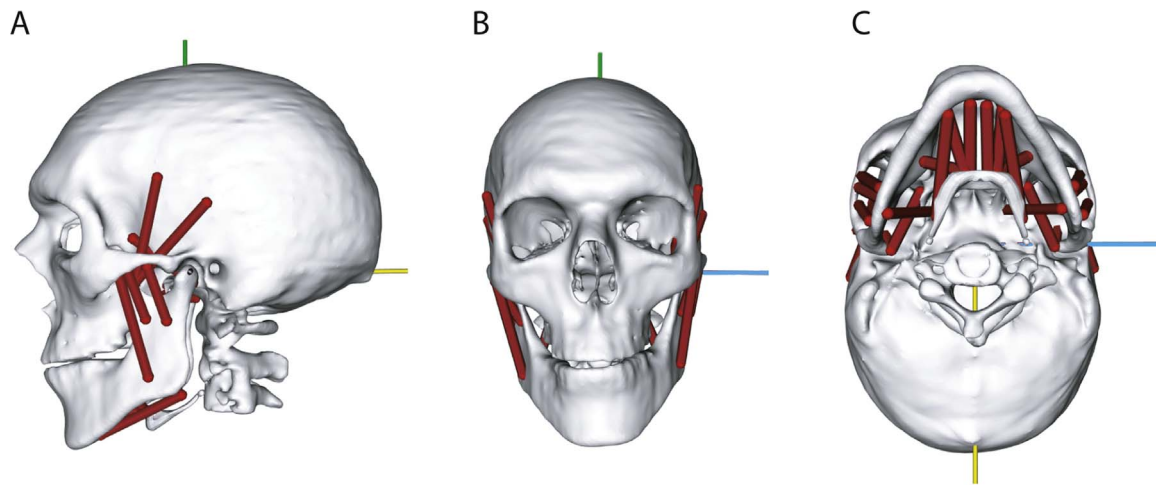


Fig. 1. The scaled-generic rigid-body musculoskeletal model used to evaluate muscle and joint loading including lateral view (A), anterior view (B) and inferior view (C). Green, blue and yellow lines indicate superior, lateral and posterior directions, respectively. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

produce a 3D object. Implantable devices such as prostheses may be fabricated into nearly any imaginable geometry, but critically, they can be ‘personalized’ by using x-ray, MRI or CT scans to inform the implant design and creation of a patient-specific digital 3D print file. With the recent advent of metal laser sintering and melting technology, 3D printing has been used to fabricate low-cost dental, skull and jaw bone implants, with a number of companies adopting the technology for commercial application (Banks, 2013; Ventola, 2014). The ability to quickly produce personalized components solves a critical problem in orthopaedics and maxillofacial surgery where standard implants are anatomically inadequate; however, despite the recent advances in 3D printing, transformative medical applications for this technology are at their infancy. Medical implants most often require biomechanical evaluation and standardized testing for scientific and regulatory requirements prior to commercialization and industry manufacture.

The resultant force incurred at each TMJ is predominantly a function of the combined activation of the muscles that attach to the mandible. Net joint moments at the TMJ may be calculated from measurements of joint kinematics and bite force (Ackland et al., 2015; Banks, 2013); however, the TMJ is a mechanically redundant musculoskeletal system – many muscles span each joint, and a net joint torque can be produced by an infinite combination of muscle forces. Thus, it is impossible to determine the forces in individual muscles from calculations of net joint torques alone. Computational modelling is the only means available to quantify muscle, joint and implant loading non-invasively during human movement. A number of studies have applied modelling and simulation techniques to evaluate TMJ loading during biting and chewing (Ackland et al., 2015; Koolstra and van Eijden, 2006); however, almost all previously developed musculoskeletal models of the jaw have been generic in anatomy. Since skull and jaw anthropometry, muscle-tendon paths, and muscle strength can vary significantly among individuals, calculations of muscle and joint loading ought to reflect these anatomical differences, as they have been shown to have a large influence on resultant joint loading (Ackland et al., 2012).

The objective of this study was to present a framework for developing, testing and fabricating a novel ‘Melbourne’ patient-specific 3D-printed prosthesis for the treatment of end-stage osteoarthritis of the TMJ in a 58-year-old female patient. Specific aims were to use patient-specific musculoskeletal modeling to design the prosthetic TMJ and then evaluate its response to physiological loading prior to fabrication, compare the load response to that of a commercially available prosthetic device, and trial the joint replacement procedure on cadaveric specimens prior to implantation of the prosthesis in the

recipient. The framework, which represents immediate translation of medical imaging, computer modelling and 3D printing technology to clinical practice, may be used for development and testing of other implantable components in maxillofacial and orthopaedic surgery.

2. Methods

2.1. Subject recruitment

One female subject (age: 58 yrs, weight: 69 kg) with symptomatic and radiographically confirmed diagnosis of osteoarthritis of the left TMJ was recruited. The subject, who experienced chronic jaw pain and poor range of jaw-joint motion, fulfilled the National Institute of Health and Clinical Excellence (NICE) guidelines for TMJ replacement and had no previous history of jaw surgery or neurological conditions.

2.2. Implant development

Computed Tomography (CT) images of the subject's entire head were acquired using a SIEMENS® scanner with a slice thickness of 0.75 mm and an image resolution of 620×620 pixels. Three-dimensional geometries of the subject's skull, mandible, glenoid fossa and articular disks were segmented and reconstructed from the image dataset using commercially available software (Amira, FEI, France). Using a computer aided design package (SolidWorks, Dassault Systems, Paris, France), a novel ‘Melbourne’ prosthetic joint replacement design for the TMJ was developed for the subject to match closely the three-dimensional anatomy derived from the musculoskeletal model (Fig. 1). The condylar component was designed to follow the ascending contour of the mandibular ramus and attach to the ramus with six bi-cortical screws. The screws followed closely the posterior and inferior border of the mandible, and in this way, avoided possible damage to the mandibular nerve and inferior dental canal that runs deep in the bone and supplies feeling (sensation) to the lower teeth, gums and chin. A pear-shaped window in the condylar component facilitated reattachment of the masseter, which must be partially removed during surgical placement of the condylar component. The articular head of the condylar component was designed circular and slightly flattened to facilitate greater translation of the prosthetic TMJ during mastication. The fossa component was designed to sit on the articular eminence slightly anterior to the glenoid fossa of the temporal bone when the mandible is at rest, and was fixed with six screws. The concavity of the fossa was hemispherical in geometry, designed to match the condylar head anatomy, and allow translation of the condyle.

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