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Managing the variability of biomechanical characteristics before the preliminary design stage of a medical device

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ABSTRACT

The very high level of requirements for certification procedures often limit research and development departments to innovate using increments and iterations during the design process for medical devices (MD). Instead of this semi-empirical approach, a structured procedure, a breakthrough innovation should be used when designing an articular MD (prosthesis, implant). The search for concepts can be based on functional analysis and producing behavioural models of the joint in its natural state and/or equipped with the prosthesis. This paper shows how anatomical variables can be managed and integrated using a modular design approach.

1. Introduction

When developing medical devices, the clinical studies required and the very high level of specifications for certification procedures often restrict research and development departments to innovations involving alterations and iterations.

Instead of this quasi-empirical approach, a complete structured procedure should be used for a radical breakthrough innovation when designing an articular MD (prosthesis, implant). Functional analysis can then be applied to search for innovative concepts and produce behavioural models for the joint in its natural state and/or when equipped with a prosthesis. Moreau–Gaudry and Pazart proposed a framework for a technological innovation development for health application, based on: concept-research-tests-product-treatment, cycle [1].

We present studies carried out before the preliminary design stage of an innovative temporomandibular joint (TMJ) prosthesis. This paper describes the management and integration of anatomical and functional variabilities using a modular design approach.

To characterize a healthy TMJ and establish design criteria, joint displacements were defined and quantified experimentally; results produced some very wide intra- and inter-individual variations.

Our aim is not to control these variations but rather to design a prosthesis that could carry out its functions while incorporating natural or acquired articular fluctuations, displacements and geometry.

The example described here presents an experimental statistical analysis which records the distribution of the temporal slope angle. Using this distribution we were able to create a modular component, selecting three to five values for the angle being defined.

The difficulties involved in the production of a made-to-measure prosthesis and the limited distribution of the TMJ guide the designer towards a modular solution.

During the design phase of an innovative TMJ prosthesis, functional analysis techniques highlighted the need for a preliminary study to characterize the morphological and functional anatomy of the joint in order to define assessment criteria and quantify acceptance requirements [2]. This study focuses on the geometrical definition for the design of the TMJ key characteristics. There is little consideration to bio-material design and optimization (surface coating or textures) as refer by Ramsden et al. [3]. Moreover, the additive manufacturing opportunities on shape and material possibilities, as highlighted by Bartolo et al. [4] are today out of the scope, but may become solutions to face the problem of variability illustrated in this paper.

Different techniques exist to identify and re-create bones morphology and shapes based on X-rays or magnetic resonance imaging (MRI) [5].

In this study we developed a reverse identification based on the patient mandibular mobility measurements in order to calculate the TMJ geometrical parameters needed for the design. Specific metrology techniques were developed to quantify biomechanical characteristics experimentally such as displacements, actions, etc. TMJ displacements from the point of articular contact (Fig. 1) were quantified by stereophotogrammetry and muscle efforts were assessed by electromyography and MRI [6].

Results showed considerable intra- and inter-individual variations. This study describes how these variations were managed and integrated using a modular design approach.

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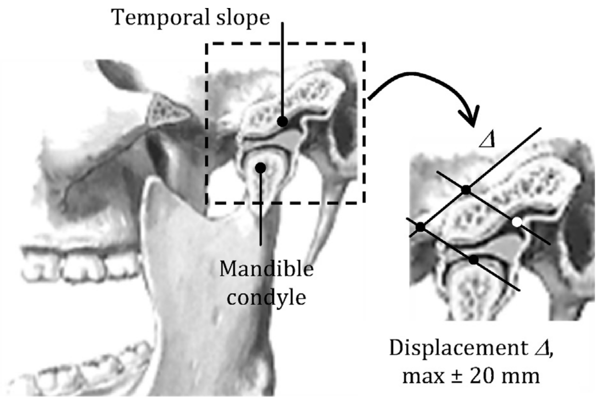

Fig. 1. TMJ and visualization of displacements.

2. TMJ prostheses

Within the world population as a whole, Wolford and Mehra point out that the implantation of a TMJ prosthesis concerns fewer than five thousand patients every year suffering from acute arthritis and fibrosis [7].

Occlusion corrections clearly give the patient both physical and psychological comfort and comparison of actual prostheses underlines that the inter-incisor opening can reach 20 ml. Speculand also points out different cases of failures that can require additional surgical procedures:

- Inflammation occurs with persistence of pain revealing an imperfect osseointegration of the screws accompanied by implant micro-displacements with respect to the bone,
- Prosthesis fracture (rare) happens near a screw or in a variation of the section where stresses tend to concentrate,
- Bone fracture seems to be the result of an insufficient number of screws or a too high intensity of loads on the condyle [8].

The two prosthetic models currently available (Fig. 2) require a very invasive approach, and major bone resection. They generate a risk of anterior or posterior dislocation of the joint and reduce the amplitude of articular displacement in translation Δ. Yet this displacement is necessary to establish mouth opening and give an inter-incisor distance which is comfortable for the patient.

Ramos et al. have measured the micro-mobility between the implant surface and bone and showed that it decreases when using an anatomical plate. Large micro-motions can induce the formation of fibrous tissue between bone and implant and produce instability. In the same time, the lower stiffness of the anatomical implant can reduce stress shielding effects and produce a favourable biomechanical environment for osseo-integration [9].

The dual goal of an innovation will now be to reduce the cumbersome nature of the temporal element and modify the

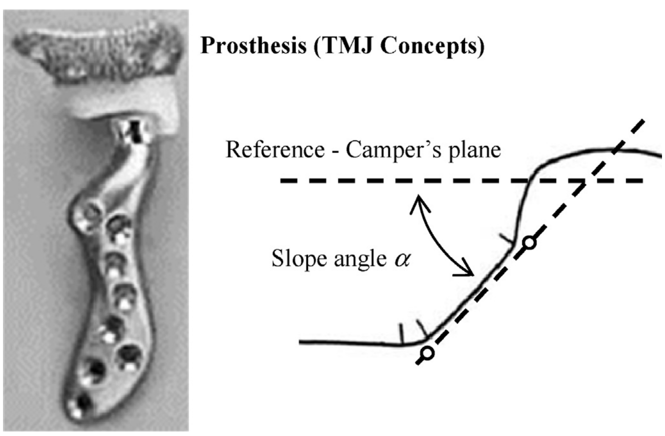

Fig. 2. Prosthesis and definition of slope angle.

mandibular element fixation so as to resemble natural opening and occlusion.

In order to carry out a concept search and then provide the element dimensions, the temporal geometry must be characterized to determine the value of the temporal slope angle α (Fig. 2) and provide information on individual variations.

3. Geometry of articular surfaces

A repeatability study was carried out on the experimental protocol to characterize TMJ articular displacements. This was then implemented and validated using two volunteers.

3.1. Protocol and stereophotogrammetry

To study the displacements of the mandible in relation to the skull in our volunteer, reference points were located on the lower jaw and on the maxilla. Because precision was essential, reference points were not located on the skin, as these can move over adjacent areas of bone [10].

Two gutters, interdependent of the two dental arches, were moulded from impressions taken from the volunteer using orthodontic materials. A rigid metal snap ring was inserted into each gutter and a plate was attached to the ring (Fig. 3). The cranial reference point on the upper plate was defined using three target points, with point H representing the barycentre, the lower reference point was associated to point B on the mandibular plate in the same way.

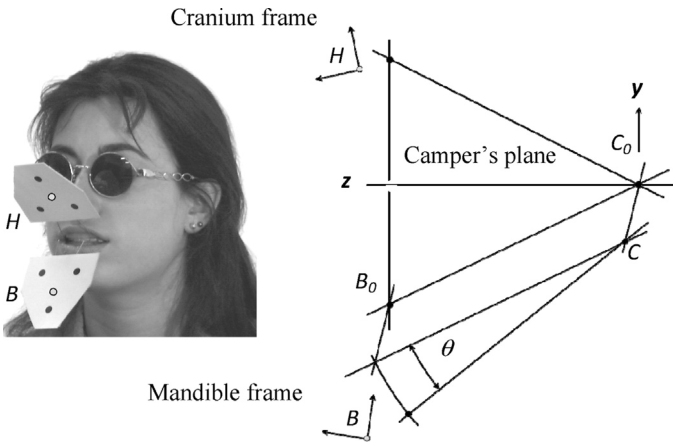

Fig. 3. Equipment and sagittal displacement C_0C.

In the sagittal symmetrical plane the projected centre of the condyles is in position C_0 initially and is written C during opening movement. Vectors C_0H and BC, which are known morphological characteristics, remain constant at the cranial and mandibular reference points respectively.

During the open–close movement and recording, vector C_0C which represents the displacement of the projected centre of the condyles can then be calculated by the vector sum C_0C,

$$C_0C = C_0H + HB + BC \text{ where,}$$

vector HB is obtained by stereophotogrammetry [11].

The open–close movement (Fig. 3), facilitated by the TMJ meniscus, is the result of sliding on contact and the simultaneous rotation of the angle θ of the mandible in relation to the skull.

3.2. Repeatability, uncertainty

To analyze the repeatability of the protocol, the upper and lower jaw plates were fixed to a base. The relative positions of the targets, and the dummy reference points C_0 and C (Fig. 3) were thus constant.