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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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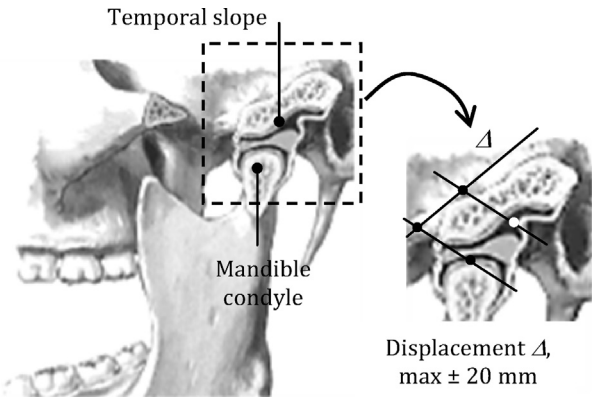

Fig. 1. TMJ and visualization of displacements.

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 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.

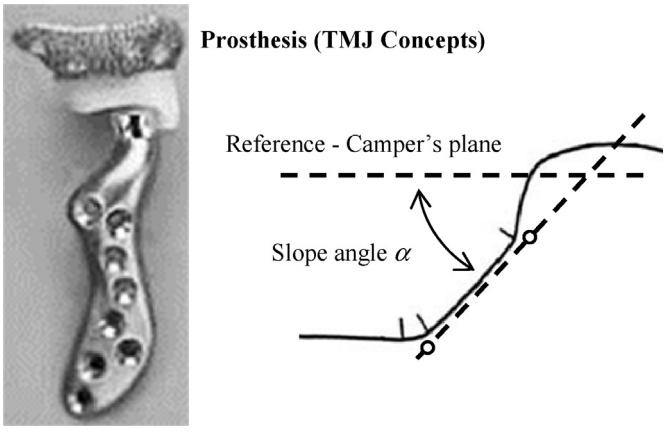

Fig. 2. Prosthesis and definition of slope angle.

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.

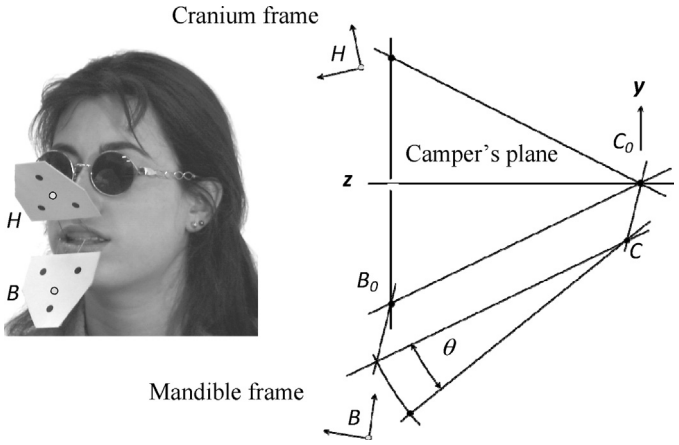

Fig. 3. Equipment and sagittal displacement C_0C.

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.

The equipment was displaced manually within the field of the cameras; the amplitude of the imposed displacements was very much greater than the amplitude of the head movements overall. Data were recorded and processed as described above.

Thus displacements calculated from point *C*, the imagined centre of the TMJ, in relation to point C_0, quantified the uncertainty of the measurement associated with the overall displacement of the plates in the filmed area.

The absolute value of error remained less than 0.7 mm while displacement from point *C* could reach 20 mm at maximal opening. The value of the ratio $2 \times 0.7/20$ (7%) confirmed that the method was valid.

3.3. Characterization and design variables

Major objectives in alloplastic TMJ reconstruction for improvement of life quality are pain relief and a better control of the mandibular kinematics [12]. This control of mandibular kinematics can be gauged in particular by a significant increase in inter-incisive distance during maximum opening.

Design variables inherent in the geometric characteristics of the TMJ determine maximum inter-incisive distance. This distance is influenced simultaneously by length of the slope Δ, angle of inclination α and amplitude of rotation θ.

As the rotation θ and the *z*-translation of point *C* represent the two main displacements during an open–close movement, the relation between rotatory displacement and translatory displacement was defined by a coefficient named the "preponderance coefficient" as follows:

$$Cp = \frac{\text{Rotation } \theta}{z\text{-translation } Tz} \quad \text{where,}$$

θ was expressed in (°) and *Tz* in (mm). Then, this coefficient *Cp* quantifies a ratio which is characteristic of the subject studied [13,14].

4. Variations in characteristics

During the concept search, the aim is not to control individual variations in biomechanical characteristics, but rather, based on quantification, to design and optimize a prosthesis that can carry out its functions while at the same time incorporating intra- and inter-individual fluctuations.

4.1. Intra-individual variations

Intra-individual variability may result from a range of causes: temporal (structural modification of tissue due to ageing), pathological, behavioural (environment, fitness, experimental conditions, etc.).

In a healthy volunteer, repeated recordings (three to five) enable us to assess the influence of changes in behaviour, to establish a significant value for the inter-incisive maximum opening distance, displacements of point *C* in the sagittal plane and hence the natural temporal slope angle α (Fig. 4).

4.2. Inter-individual variations

Inter-individual variability, on the other hand, is linked only to anatomical-physiological factors specific to the individual volunteers (overall geometry and local distribution of biological tissue...).

A representative sample of thirty-two subjects was studied who could potentially be concerned later by a TMJ prosthesis implant. Pathological cases were excluded from this study; four subjects with major asymmetries or pathologies were not selected.

The *Cp* coefficient was determined for each standard volunteer. It was a continuous random variable whose mean value (2.07) and square deviation (0.77) were determined in the sample [13,14].

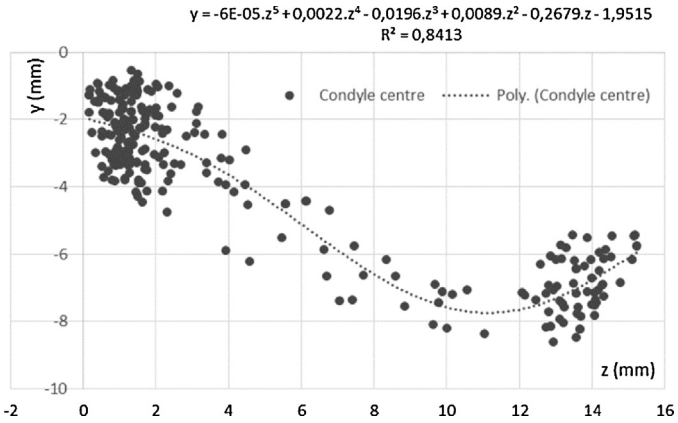

Fig. 4. Point *C* displacements in the sagittal plane for one volunteer.

This coefficient distribution could be studied by applying a Laplace–Gauss function for each *xi* subject value, by the relation:

$$f(xi) = \frac{1}{\sigma\sqrt{\pi}} e^{1/2(xi-\mu/\sigma)^2}$$

The variable was determined relative to the maximal open jaw amplitude and followed a normal distribution (Fig. 5). The results discriminate groups presenting weak inter-individual variations in relation to the collective values [13].

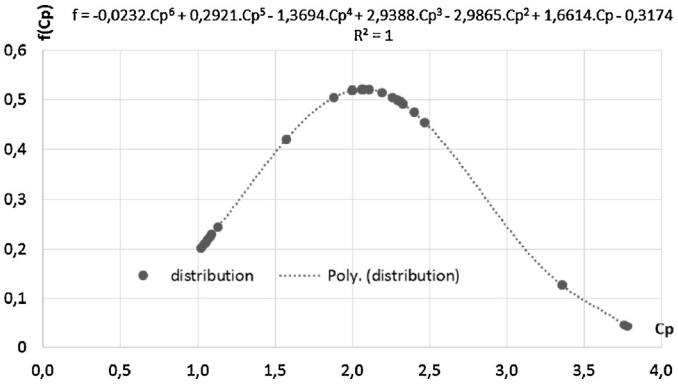

Fig. 5. Distribution of *Cp* coefficient among 32 volunteers.

5. Design criteria

Table 1 shows the values calculated for the *Cp* coefficient and dimensions of temporal slope, length Δ, slope angle α and their square deviations. These two characteristic slope elements determine the choice of prosthesis or modules during surgery.

Table 1
Displacement and slope angle α versus coefficient *Cp*.

Group	1-Tr.	2-Mix.	3-Rot.
Cp	[1.02, $\mu - \sigma$]	[$\mu - \sigma$, $\mu + \sigma$]	[$\mu + \sigma$, 3.76]
Cp mean	1.0	2.1	3.6
nb. subjects	7	17	4
Δ (mm)	$11.4_{(1.2)}$	$10.5_{(1.0)}$	$6.1_{(1.1)}$
α (°)	$18.2_{(1.4)}$	$30.5_{(7.4)}$	$47.2_{(1.5)}$

5.1. Temporal slope

Three groups were formed from the mean value of *Cp* by standard deviation. Three well-individualized values of the temporal slope angle can then be distinguished, corresponding to each of the three groups as well as weak inter-individual variations.

Thus a temporal slope can be correlated with a kinematic characteristic.

For group 3 (4 volunteers), mouth opening is obtained by a quasi-pure rotation around the condylar axis and a short *z*-translation. For groups 1 (7 volunteers) and 2 (17 volunteers), the opening movement is in two phases: first, concomitant rotation and translation of point *C* on the temporal slope and then quasi-pure rotation. During this second phase, major demands are made on the disc-condyle system, which is virtually stationary and short for group 1.

5.2. Partial definition of the implant

In order to get close to the patient's specific geometric and kinematic characteristics, five models of the temporal part of the prosthesis are defined. Three correspond to the groups formed previously; two complementary models correspond to cases located at the interval boundaries (see Fig. 6).

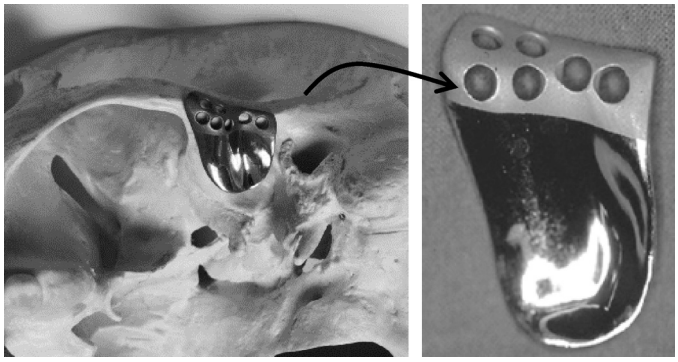

Fig. 6. Temporal plate (TMJ Medical).

6. Conclusions

There is never translatory displacement which is not combined with rotatory displacement. This finding makes it possible to define a characterization coefficient, to analyze inter-individual variations and thus to discriminate between individuals in order to determine groups presenting common kinematical and geometrical characteristics.

The disc-condyle displacements associated with open jaw amplitude can be analyzed in each anatomical zone and for each group. Thus, the correlation between the kinematic character defined by *Cp* and the trajectory related to the geometries of the temporal-bone facets can be assessed. Each group is correlated to a geometrical model that generates a specific trajectory. The results of the experimental study determine the angle α defining the trajectory of the condyle centre along the temporal slope with respect to the Camper's plane.

The limited use of TMJ prostheses combined with difficulties in producing a made-to-measure component tend to guide the designer towards a modular solution. For an operation, an initial selection can be made by preoperative scan which is then confirmed when the operation is in progress. By providing the surgeon with a range of five temporal modules, the slope angle that is most similar to that of the patient being treated can then be selected.

The additive manufacturing and 3D printing technique developed for rapid prototyping has already been used successfully to produce finished parts in industries such as aerospace, dentistry, etc. It will eventually be possible to produce a prosthesis component that is implantable, biocompatible and tailor-made.

Acknowledgments

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