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Contribution of Orthopilot® navigation system to orthognathic surgery

Rodolphe Lartizien

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Année : 2019

CONTRIBUTION OF ORTHOPILOT™ NAVIGATION SYSTEM
TO ORTHOGNATHIC SURGERY

*APPORT DU SYSTEME DE NAVIGATION ORTHOPILOT™
EN CHIRURGIE ORTHOGNATIQUE*

THÈSE
PRÉSENTÉE POUR L'OBTENTION DU TITRE DE DOCTEUR EN MÉDECINE
DIPLOME D'ÉTAT

Rodolphe LARTIZIEN

[Données à caractère personnel]

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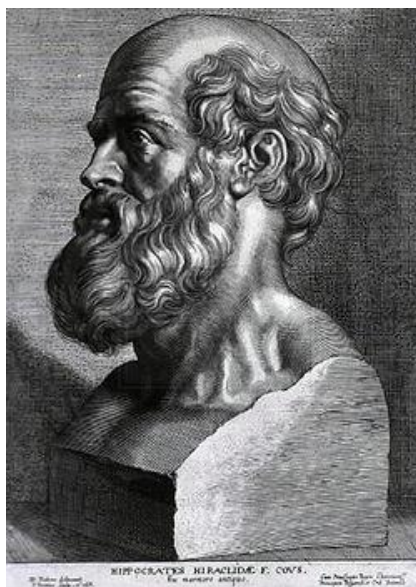
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En présence des Maîtres de cette Faculté, de mes chers condisciples et devant l'effigie d'HIPPOCRATE,

Je promets et je jure d'être fidèle aux lois de l'honneur et de la probité dans l'exercice de la Médecine.

Je donnerai mes soins gratuitement à l'indigent et n'exigerai jamais un salaire au dessus de mon travail. Je ne participerai à aucun partage clandestin d'honoraires.

Admis dans l'intimité des maisons, mes yeux n'y verront pas ce qui s'y passe ; ma langue taira les secrets qui me seront confiés et mon état ne servira pas à corrompre les mœurs, ni à favoriser le crime.

Je ne permettrai pas que des considérations de religion, de nation, de race, de parti ou de classe sociale viennent s'interposer entre mon devoir et mon patient.

Je garderai le respect absolu de la vie humaine.

Même sous la menace, je n'admettrai pas de faire usage de mes connaissances médicales contre les lois de l'humanité.

Respectueux et reconnaissant envers mes Maîtres, je rendrai à leurs enfants l'instruction que j'ai reçue de leurs pères.

Que les hommes m'accordent leur estime si je suis fidèle à mes promesses.

Que je sois couvert d'opprobre et méprisé de mes confrères si j'y manque.

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ABBREVIATIONS AND ACRONYMS

AR : Augmented-Reality

AVE : Anterior Vertical Excess

BSSO : Bilateral Sagittal Split Osteotomy

CAD/CAM : Computer-Aided Design / Computer-Aided Manufacturing

CAS : Computer-Assisted Surgery

ONS : Orthopilot™ Navigation System

PSI : Patient-Specific Implants

PVE : Posterior Vertical Excess

Ra : axial Rotation

Rf : frontal Rotation

Rs : sagittal Rotation

Tbf : back / front Translation

Trl : right / left Translation

Ttb : top / bottom Translation

RESUME

La chirurgie assistée par ordinateur a une place toujours plus importante dans notre pratique quotidienne. Nous utilisons en routine le système de navigation Orthopilot™ (ONS) au cours de nos chirurgies orthognatiques. Le but de notre travail, au travers de trois publications internationales, était d'explorer les différents intérêts de cet outil. Dans une première partie, nous avons démontré l'intérêt pédagogique de l'ONS dans l'apprentissage du repositionnement condylien au cours des ostéotomies mandibulaires. L'utilisation de l'ONS permet aux jeunes chirurgiens d'améliorer leur précision et leur gestuelle chirurgicale. Nous avons ensuite mesuré, grâce à la navigation, le degré d'imprécision du transfert de planification des ostéotomies de Le Fort I via les gouttières occlusales traditionnelles. Nous avons montré que le transfert était plus imprécis dans le plan sagittal. Cette imprécision était également corrélée à l'importance du déplacement du maxillaire. Enfin, lors de la dernière partie de ce travail, nous avons démontré que l'ONS, utilisé de manière semi-active, permettait d'améliorer la précision du repositionnement du maxillaire lors de ces mêmes ostéotomies. Ce travail a donc permis de démontrer différentes formes de l'apport de l'ONS en chirurgie orthognatique mais aussi certaines de ces limites actuelles. Avec les évolutions technologiques, il est tout à fait envisageable de l'améliorer en y intégrant des données de planification 3D et en optimisant l'ergonomie, notamment par le biais de la réalité virtuelle.

Mots-clés : Chirurgie orthognatique; chirurgie assistée par ordinateur; navigation chirurgicale; planification chirurgicale; formation chirurgicale; ostéotomies de Le Fort I; repositionnement condylien

ABSTRACT

Computer-assisted surgery is increasingly widespread in our everyday practice. We routinely use the Orthopilot™ Navigation System (ONS) during our orthognathic surgeries. The aim of our work, through three international publications, was to explore the different interests of this tool. In a first part, we demonstrated the pedagogical interest of the ONS to learn condylar repositioning during mandibular osteotomies. The use of ONS allowed trainees to improve their accuracy and surgical skills. In a second part, we measured, thanks to the navigation, the inaccuracy of planning transfer of Le Fort I osteotomies with traditional occlusal splints. We showed that the transfer was more inaccurate in the sagittal plane. This inaccuracy was also more important in case of larger maxillary movements. Finally, during the last part of this work, we demonstrated that the ONS, used semi-actively, could improve the accuracy of the maxilla repositioning during these same osteotomies. This work demonstrated many benefits of the ONS but also some of its current limitations. With the technological evolutions, it is quite possible to improve it by integrating 3D planning data and by optimizing the ergonomics, notably through the augmented-reality.

Key-words : orthognathic surgery ; computer-assisted surgery, surgical navigation ; surgical planning ; surgical education ; Le Fort I osteotomy ; condyle repositioning

GENERAL INTRODUCTION

The early 90s witnessed the development of Computer-Assisted Surgery (CAS) in a wide range of specialties including maxillofacial surgery (1). CAS could be defined by the integration of computer technologies within the patient surgical management in order to improve its planning, achievement and assessment accuracies. CAS is particularly useful for orthognathic surgery because the local anatomy is complex, complicating the planning treatment. Computer technologies are involved in several or in all of the stages of the patient management (2-4). The figure 1 shows this sequence.

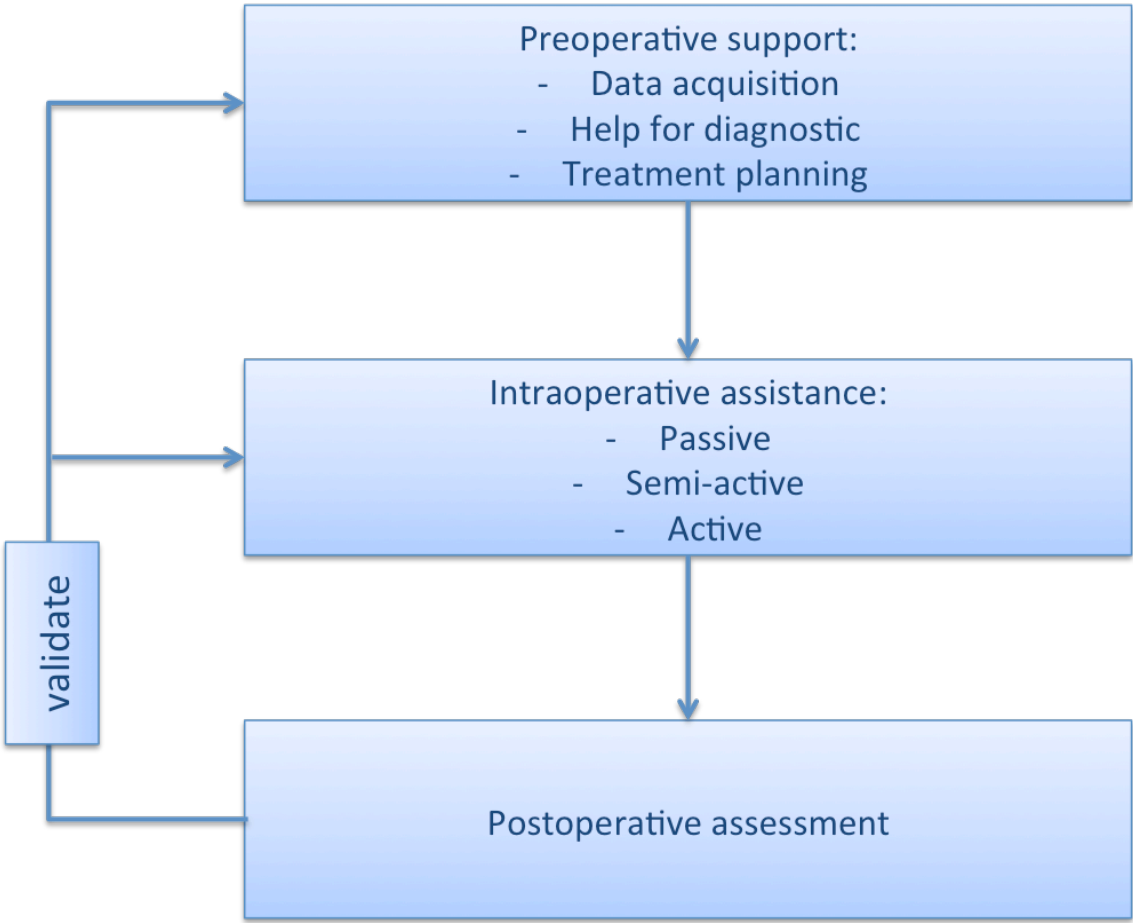


Figure 1 Computer-Assisted Surgery sequence

Initially, digital technologies and computer software were used to make a diagnosis and to establish a treatment plan, integrating various imaging data, e.g. 3D CT-scan, laser scan or Cone-Beam.

The second step was to improve the accuracy of the transfer of surgical planning to the operating room with an intra-operative assistance. This interactive assistance took different forms:

- A *passive assistance* to control the surgical gesture or its outcome with the use of Computer-Aided Designed/Computer-Aided Manufacturing (CAD/CAM) surgical guides or splints, patient-specific implants and navigation.
- A *semi-active assistance* to guide the surgical gesture to achieve the planned outcome as done by a navigation system used as a positioning tool.
- An *active assistance* with surgical robots which could autonomously perform operative steps.

The final step is the post-operative assessment comparing the final surgical outcome to the planning and permitting the validation of the previous steps.

Computer-Assisted Navigation system has been gradually recognized in oral and maxillo-facial surgery (5-7). Indeed, it was reported that navigation could improve surgical reliability and patient safety (8).

The principle of Navigation is comparable to global positioning systems commonly used in automobiles and is composed of 3 primary components: a localizer, analogous to a satellite in space; an instrument or a surgical probe, representing

track waves emitted by global positioning system unit in vehicle; and an imaging data set or a reference position, analogous to a road map.

The Navigation system allows real-time localizing of a surgical instrument in the operating field as well as representing its position in a virtual model. This model is created using the imaging data of the patient (image-based navigation) or a reference position of a structure previously recorded (imageless navigation).

There are different types of navigation systems according to the technology involved:

- A mechanical navigation
- An electromagnetic navigation
- A video-optical navigation

Video-optical systems are the most popular.

The intra-operative assistance, as seen above, could be either passive or semi-active. Passive systems are now frequently used in particular for trauma or cancer and reconstructive surgery. Semi-active systems are more rare and there are only a few studies about them.

Our work was focused on the utilization and the benefits of navigation during orthognathic surgery.

We routinely use in our unit the OrthopilotTM Navigation System (ONS) for condyle repositioning during bilateral sagittal split osteotomy. Its accuracy and its benefit for anatomical and functional outcomes have been previously demonstrated by Bettega et al. (9-11). This system has also been used to control the position of the maxilla during Le Fort I osteotomies.

Our present work is divided in three sections corresponding to three international publications. The first one dealt with the educational interest of the navigation system to learn condyle repositioning after mandibular sagittal split osteotomies.

This article was published in the *International Journal of Oral and Maxillofacial Surgery* (12). The second section evaluated the accuracy of traditional occlusal splints for maxillary repositioning in Le Fort 1 osteotomy. This article was published in the *British Journal of Oral and Maxillofacial Surgery* (13). The last one concerned the improvement of this positioning thanks to the navigation system. The manuscript was submitted in the *International Journal of Oral and Maxillofacial Surgery* and currently under review. We concluded with a discussion comparing navigation and patient-specific implants for orthognathic surgery and by the possible evolution expected with the new technologies currently available.

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PART I

Learning condyle repositioning during orthognathic surgery
with a surgical navigation system

ABSTRACT

Condyle repositioning during bilateral sagittal splint osteotomy (BSSO) is a challenging step for the inexperienced surgeon. We aimed at demonstrating the benefit of navigation for learning the condyle repositioning. We treated 100 patients who underwent a BSSO. A trainee performed the condyle repositioning of one side in two phases. In the first one the trainee positioned without watching the screen of the Orthopilot Navigation system (ONS). In the second one, the trainee could use the ONS to replace the condyle. Heuristic, anatomical and functional scores of each phase were recorded. Heuristic (17% vs 75%; $p < 0.0001$), anatomical (35% vs 86%; $p < 0.0001$) and functional (14% vs 56%; $p < 0.0001$) scores were significantly greater with the ONS. The ONS is a promising and original intra-operative learning tool for the repositioning of the condyle during BSSO.

Keywords: orthognathic, surgery; computer-assisted, surgery; condyle repositioning; surgical education; medical education

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PART II

Quantification of the inaccuracy of conventional model surgery in Le Fort I osteotomy : evaluation of 30 patients controlled by the Orthopilot navigation system

ABSTRACT

Occlusal splints are commonly used during traditional orthognathic surgery to position the maxilla. We had for aim to quantify with the Orthopilot™ navigation system the inaccuracy of the maxillary positioning (in 3 dimensions) in traditional model surgery. 30 Le Fort I osteotomies were performed with a standard technique. The position of the maxilla was recorded by the navigation system and defined by 3 values of translation and 3 values of rotation. The recorded data was compared to the planned data. The accuracy of positioning was classified in distinct classes with three major criteria (conformity, non-conformity, failure) according to the discrepancy. The positioning of the maxilla was in conformity with operative planning in 10% CI95 [2%-27%] of our Le Fort I osteotomies and in failure in 73% CI95 [54%-88%]. The dispersion of the discrepancy was more important in the sagittal plane especially for the sagittal rotation and for the back front translation, reflecting a greater inaccuracy in this plan. The frontal orientation of the maxilla was better controlled. The risk of maxillary malposition was proportional to the planned maxillary advancement.

Keywords: orthognathic, surgery; maxillary repositioning; 3D analysis; Le Fort I osteotomy; computer-assisted, surgery; occlusal splints; conventional articulator model surgery

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PART III

Accuracy improvement of maxillary repositioning in Le Fort I osteotomy
with Orthopilot™ Navigation System : evaluation of 30 patients

ABSTRACT

Traditional model surgery with facebow transfer is not very accurate. We aimed to demonstrate that the Orthopilot™ Navigation System (ONS) improves the accuracy of maxillary repositioning during Le Fort I osteotomy. 30 patients underwent Le Fort I osteotomy alone or associated to sagittal split osteotomy. The maxilla positioning was performed in two phases. First, the maxilla was positioned with the traditional occlusal splint and the position (“without ONS”) was recorded by the ONS. In the second phase, ONS was used to improve positioning; and the final position (“with ONS”) was recorded, after osteosynthesis. Positioning data were compared to planning data. Positioning data with and without ONS were also compared. Accuracy was classified in distinct classes with three major criteria (conformity, non-conformity, failure) according to the discrepancies. Conformity rate was significantly greater with ONS (7% without ONS vs 27% with ONS; $p=0.01$). Failure rate was significantly lower with ONS (60% without ONS vs 23% with ONS; $p=0.002$). Dispersions of discrepancies were usually lower in all direction with ONS. Navigation reduced the risk of discrepancy without cancelling it, especially when large movements are planned. The ONS improved the accuracy of traditional occlusal splint during Le Fort I osteotomy.

Keywords: orthognathic surgery; computer assisted surgery ; Le Fort I osteotomy ; maxillary repositioning ; accuracy ; 3D analysis

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GENERAL DISCUSSION

We had explored different contribution of Orthopilot™ navigation system to orthognathic surgery. We will discuss the place of navigation in current clinical practice taking into account the new technologies currently available.

Navigation and Patient-specific implants

The development of computer-assisted surgery in orthognathic surgery was made possible by the lack of accuracy and reliability of traditional model surgery (1, 2) and by the emergence of new technologies. There are three main approaches: 1) 3D virtual planning and CAD/CAM occlusal splint; 2) 3D virtual planning, surgical guides and patient-specific implants (PSI); 3) 3D intraoperative navigation. The use of CAD/CAM occlusal splint avoid inaccuracies inherent to model surgery but there are still issues due to the occlusal splints (3, 4). PSI and navigation could overcome this problem. One may wonder what the best method is.

It is difficult to compare precisely the two methods. The first difficulty is the multiplicity of the available systems. There is also a lack of consensus for accuracy assessment and the level of evidence of the current literature is very low. Several papers had reported that PSI could accurately transfer the surgical plan for maxillary repositioning (5-7) better than traditional (8) and CAD/CAM (9) occlusal splints. However, we noticed that, as traditional model surgery, PSI are less accurate in the sagittal plan (5, 9). We must keep in mind that, despite the statistical significance, the clinical benefits seemed less important (8). However, in most of these papers, the validity of the statistical analysis is questionable; especially when accuracy is evaluate by mean values comparison. The reduction of operative time is another advantage of PSI. In their systematic

review, Van den Bempt et al. (10) concluded: « the reduction in operating time gives this technique the potential to replace interocclusal splints as the standard of care ». Ergonomics of current PSI are also notable. Concerning condyle repositioning during BSSO with PSI, there are only few studies assessing their accuracy (6) and no one evaluated the surgical outcomes. Moreover, Suojanen et al. (11) did not recommend the use of PSI for BSSO without splint due to poor fitting. PSI seemed to be more suitable in case of high oblique sagittal split osteotomy. New types of PSI for mandible are promising and need to be evaluated (12). It is also interesting to note that splint-less surgery with PSI do not take the occlusion as an intra-operative reference. Thus, performing maxillomandibular or mandibular procedure with PSI can lead to unacceptable final occlusion. That is why several authors (5, 8) did not use PSI for BSSO. Another drawback of PSI is its lack of intraoperative flexibility. Indeed, unexpected events, such as bad-split for example, could make their use impossible. This is particularly critical because PSI allow inexperienced surgeon to perform orthognathic surgery alone. Moreover, their pedagogical interest was not demonstrated and there is a risk of loosing preoperative thinking. PSI are also costly but this issue can be tempered by the reduction of operative room occupation, nevertheless for the moment, the gain of time does not compensate the extra cost.

The use of navigation during Le Fort I osteotomies was assessed in several studies. The accuracy for planning transfer with passive (13, 14) or semi-active (15) systems was emphasized. Furthermore, Zinser et al. had shown that their system of semi-active navigation was more accurate than occlusal splints from traditional model surgery (16). The outcomes achieved with ONS were also promising. However, there is still some difficulty to stabilize manually the maxilla during the

osteosynthesis. The other drawback we have discussed previously is that 2D planning could lead to inaccuracy, but this is now solved by the generalization of CT-scan 3D planning. Concerning the condyle repositioning, the improvement of anatomical and functional outcomes with ONS was demonstrated previously (17, 18). We also highlighted its pedagogical potential. The major drawback of navigation is the increase of surgical time. It needs only 5 to 10 minutes to install the navigation tools. However, the most time consuming is the time necessary to position accurately the bone fragment (maxillary or condyle); in some condition (mostly in asymmetric dysmorphism), it is necessary to remodel bone pieces in order to optimize the positioning. The cost of the system is not a challenge; the hardware is now very common and not expensive and the cost of the consumable is very low (few euros per surgery). The problem is the availability of the system; this market is not yet considered by the industrial. The OrthopilotTM system is based on infrared technology; other systems are in study. In particular, electromagnetically systems were evaluated in several pilot-studies (19, 20). Their benefit are not well established, they had, as the first infrared system, the major inconvenient to need a cable connection to the monitor. Their accuracy is impaired by the proximity of metallic tools, which is problematic in our surgery, and the field generator needs to be closed to the head, which is quite cumbersome.

However, there is a lack of study comparing navigation to PSI. During this work, we have also noticed that the primary outcome used in the major part of previous studies did not seem suitable for assessing accuracy. Indeed, as seen above, analysis based on mean or absolute mean of the discrepancy from the planned position could be confusing. Analysis of the distribution of discrepancies in each dimension given in those studies is more relevant. It would be interesting to evaluate

the accuracy of PSI with the nine classes we used, and compare it to accuracy of ONS. Thus, we planned a prospective study on this subject. But, interestingly, while PSI are routinely used in orthognathic and reconstructive surgery, the ANSM did not give us the authorization to perform this study because the industrial could not prove the safety of PSI; especially concerning titanium degradation products after additive manufacturing process! One may lead to question about the difference between research and clinical practice.

Finally, the two approaches could be complementary. We can imagine a maxilla-first procedure with PSI for the maxilla and navigation for the condyle repositioning in order to add up the advantages of each method in terms of accuracy and clinical outcomes. However, the current high cost of such an approach may be an obstacle and could be reserved to difficult cases.

Perspectives for Orthopilot™ Navigation System

The most popular form of computer-assisted orthognathic surgery is the combination of virtual planning, surgical guide and PSI. Semi-active navigation systems dedicated to orthognathic surgery are still very uncommon. Our work highlighted different benefits of ONS in orthognathic surgery, as well as some limitations of its current configuration. New technologies will allow improving this device. The integration of 3D planning would enhance the accuracy of planning transfer, especially in case of Le Fort I osteotomy. By adapting the ancillary, it would also permit to expand the ONS applications such as to traumatology surgery for example. The recent years witnessed the emergence of augmented-reality (AR)

(21). Although this technology needs some improvement, the first results are promising. It is quite possible to imagine an association of AR and navigation, enhancing the ergonomics of the system and the intraoperative perception of the surgeon. Overlay of planned position in the surgeon's visual field or discrepancies scores, via AR glasses, are some example of future possible evolutions. Technologies miniaturization could even allow to place the optical localizer on the AR glass in order to reduce the issue of visual contact between those localizer and the reflective markers.

Conclusion

Through three international publications, we explored different benefits of the Orthopilot™ navigation system in orthognathic surgery. In a first work we evaluated the pedagogical interest of this navigation system in the learning of condylar repositioning during mandibular osteotomies. In a second work we measured, with this tool, the inaccuracy of planning transfer of Le Fort I osteotomies via traditional occlusal splints, in order to evaluate our clinical practice. The last part of our work consisted in demonstrating that the navigation, used in a semi-active way, could improve the accuracy of maxilla repositioning during these same osteotomies. In view of current technological developments, it is quite possible to improve this navigation system by incorporating 3D planning data become current and optimizing ergonomics, including through augmented-reality.

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THÈSE SOUTENUE PAR : Rodolphe LARTIZIEN

TITRE :

APPORT DU SYSTEME DE NAVIGATION ORTHOPILOT™ EN CHIRURGIE ORTHOGNATHIQUE

CONTRIBUTION OF ORTHOPILOT™ NAVIGATION SYSTEM TO ORTHOGNATHIC SURGERY

CONCLUSION :

Au travers de trois publications internationales, nous avons exploré différents intérêts du système de navigation Orthopilot™ en chirurgie orthognathique.

Dans un premier travail nous avons exploré l'intérêt pédagogique de ce système de navigation dans l'apprentissage du repositionnement condylien au cours des ostéotomies mandibulaires.

Nous avons ensuite mesuré, avec cet outil, le degré d'imprécision du transfert de planification des ostéotomies de Le Fort I via les gouttières occlusales traditionnelles, de façon à évaluer notre pratique clinique. La dernière partie de notre travail a consisté à montrer que la navigation, utilisée de manière semi-active, pouvait améliorer la précision du repositionnement du maxillaire lors de ces mêmes ostéotomies.

Au vu des évolutions technologiques actuelles, il est tout à fait envisageable d'améliorer ce système de navigation en y intégrant des données de planification 3D devenues courantes et en optimisant l'ergonomie, notamment par le biais de la réalité virtuelle.

VU ET PERMIS D'IMPRIMER

Grenoble, le : 21/08/19

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et par délégation

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