

IMAGE NAVIGATION LTD.

IGI System in Maxillofacial Surgery

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IGI IN MAXILLOFACIAL SURGERY:

Image guided navigation surgery is an established surgical modality that originated from neurosurgical procedures and has since been implemented in additional disciplines such as orthopedic and ENT surgery. This surgical modality allows the surgeon to navigate and target the advancement of the surgical instrument through live tissues based on the preacquired imaging scan of the patient. In neurosurgery, this enables the surgeon to target and eradicate an intracranial lesion through minimal opening of the skull and with minimal damage to unaffected tissues. In orthopedic surgery, surgeons are able to navigate the placement of long spinal screws (used to fixate spinal fractures) and avoid irreversible damage to the spinal cord.

The IGI implements these same principles of image guided surgery and was originally designed to guide the placement of dental implants. This demanded several important developments in the IGI technology that were required in order to adjust to the maxillofacial field: a) superior accuracy – paradoxically, the accuracy demand in dental implants is higher than in image guided neurosurgical procedures. Thus, the IGI was developed to offer 0.5mm accuracy while navigation systems in other surgical disciplines offer ~2mm accuracy. b) direct navigation of the jaw – the quality of navigation deteriorates as the distance between the operated site and the patient tracking appliance is increased. IGI was designed to offer direct tracking of operated jaw by a removable plastic appliance that fit directly onto the teeth. This close proximity ensures high navigation accuracy at the maxillofacial area. Other craniofacial navigation systems track the skull which i) results in a lower accuracy level at the upper jaw complex and ii) cannot compensate for the independent movement of the lower jaw. This means that the IGI in contrast with other craniofacial navigation systems allows efficient and accurate tracking of both the lower jaw and the upper jaw complex. c) solid attachment of the fiducial markers – the fiducial markers are used to synchronize the patient against the imaging scan and are the key for accurate navigation. The IGI use fiducial markers that are supported over the teeth (hard tissue solid attachment) while other craniofacial navigation systems use fiducial markers that are attached to the skin (soft tissue flexible attachment). This allows a more accurate and reliable synchronization of the patient for the IGI which translates into a more reliable and accurate navigation. d) removable attachment of the patient tracker – the IGI supports the tracking appliance of the patient over a tooth-supported appliance that can be mounted and dismounted without interfering with the navigation accuracy. Other craniofacial navigation systems support the patient tracking appliance using a dedicated head frame that cannot be dismount until the end of surgery and if dismounted require complete re-synchronization of the patient.

All these unique attributes position the IGI as a more generalized navigation platform that is superiorly adapted to offer surgical navigation in a wide range of maxillofacial surgical procedures. This concept has been well demonstrated in the case of resection of lower jaw tumors where the IGI was found to allow adequate and superior navigation in contrast to different well-established and considerably more expensive craniofacial navigation system. Thus, all the dedicated developments that were originally designed to support the use of the IGI in dental implants are found to have a much broader application in maxillofacial surgery. The basis of the navigation platform is already available but there are few software adaptations that are required to support the use of the IGI in other maxillofacial procedures.

IMAGE GUIDED NAVIGATION IN MAXILLOFACIAL SURGERY:

The maxillofacial region is a highly complex anatomical region with multiple vulnerable anatomical structures and nerve branches and with complex morphology. Thus, surgical interventions in this region require detailed orientation to allow accurate targeting of the operated structures and avoid inadvertent damage to unaffected tissues. In addition, any surgical interventions in this region can critically impact the facial appearance which further increases the demand to for highly accurate surgery.

In light of the above, a variety of maxillofacial surgical interventions can benefit from the real-time intraoperative orientation and navigation that is provided by image guided surgery.

RESECTION OF MAXILLOFACIAL TUMORS:

Currently, maxillofacial bony tumors are resected based on gross measurements that are made on the CT imaging of the affected site: the image of the tumor mass is identified on the CT and based on this image the surgeon freehandedly mark the tumor resection borders onto the patient. This approach in inherently inaccurate since it relies on the surgeon to transfer the imaginary resection border from the CT image to the patient. On the other hand, complete resection of the tumor is of critical importance to ensure complete removal of malignant cells and avoid future relapse. Due to this limitation, surgeons are inevitably required to extend the resection borders to compensate for the lack of accuracy in the surgical removal of the tumor mass. This leads to more aggressive resections which result in increased mutilation of unaffected tissues.

Image-guided surgery is reported as highly advantageous for removal of maxillofacial tumors. Image guided navigation allows to intraoperatively delineate the borders of maxillofacial tumors and allow both safer and more conservative resection. This reduces the risk of incomplete removal of the tumor cells while conserving unaffected structures. However, reports of resection of mandibular tumors are lacking due to the difficulty in mandibular synchronization during surgery. The IGI allows direct tracking of the operated jaw (through teeth supported template) which compensates for the mobile nature of the lower jaw. This was demonstrated in series of mandibular tumor cases where the IGI was shown to provide accuracy of less than 0.5mm. This accuracy level was found to be significantly superior to a different craniofacial navigation system (does not allow direct tracking of the lower jaw) for which the recorded navigation error was as high as 3,4mm.

DENTOALVEOLAR DISTRACTION OSTEOGENESIS:

Dentoalveolar distraction osteogenesis is used to augment the alveolar ridge to facilitate the placement of dental implants. In this procedure a segment of the alveolar bone is cut and is displaced gradually in order to allow apposition of bone in between the displaced segment and the base of the bone. This allows making the alveolar bone vertically longer to allow placement of dental implants.

The success of the procedure relies on the judicious cutting of the bone segment: a) bone segment of wider dimensions allows higher success rate but need to avoid damage to anatomical structures (mandibular nerve, adjacent roots), b) distracted bone segment must correspond in its distracted position to the future position of the implant. Thus, delineating the borders on the bone segment is important. However, currently the distracted bone segment is cut based on CT measurements without intraoperative navigation. IGI navigation platform can allow planning the borders of the bone segment while considering the adjacent

anatomical structures and the desired position of the implant. Then, during surgery the IGI can be used to transfer the planned borders of the bone segment to the patient. This allows maximizing the height of the distracted bone (improved success rate) and ensuring it corresponds to the future implant.

SINUS AUGMENTATION:

Sinus augmentation is a surgical procedures aimed to augment the bone at the posterior upper jaw for placement of dental implants. In the majority of cases this procedure is done in an open approach (open sinus lift) where a small window is cut into the wall of the maxillary sinus and bone is pushed inside to augment the height of the underlying dentoalveolar ridge. In these cases IGI can be used to enhance the orientation of the surgeon in localizing the optimal position for the sinus window.

In cases where minimal primary bone height is available, the augmentation of the sinus may be done in a closed approach (closed sinus lift). In this procedure the surgeon drill the osteotomy of the implant up to the floor of the sinus and then pushes bone replacement directly into the osteotomy without having cut a separate access window to the sinus. The risk in these cases is the potential perforation of the sinus floor which can lead to contamination of the augmented bone and to failure. In these cases the IGI can accurately guide the surgeon to stop drilling right at the floor of the sinus and minimize the risk of perforation. This simplifies the procedure for implant practitioners who are less experienced or wish to eliminate the uncertainty involved in this approach.

RECONSTRUCTION AND REDUCTION OF MAXILLOFACIAL FRACTURES:

In maxillofacial fractures segments of bone tend to move or collapse. Their correct repositioning is very important for future function and facial esthetics. Craniofacial navigation systems have been used to guide the repositioning of fractured facial bones by mirroring their position to the possibly non-injured opposing side of the facial skeleton. This allows to reconstruct the facial symmetry at greater accuracy which contributes to improved function and facial esthetics. IGI navigation platform can be developed to offer a similar feature while utilizing its high level of accuracy to allow the most accurate results.

ORTHOGNATHIC SURGERY:

This is a major surgery for orthopedic correction of the positions of the lower jaw and upper maxillofacial skeleton. The lower and upper jaws are separated from their bony base and are repositioned in a corrected position. This is an elective surgery aimed to enhance functional maxillofacial relations but mostly is motivated by patient's desire to improve facial cosmetic appearance. Accuracy is of major concern to minimize risk of surgical complications and to ensure accurate repositioning that supports improved function and facial profile.

Preparations for this procedure are comprehensive and include full presurgical setup using the casts of the patient. Yet, inaccuracies in the repositioning of the jaws do occur and may result in a substantial defect in function and in facial symmetry. In some cases this requires a subsequent corrective surgery. The IGI can be developed to guide the repositioning of the jaws at greater accuracy and save the time-consuming presurgical setup. The use of image guided navigation in this procedure ensures more reliable results and minimizes potential complications.