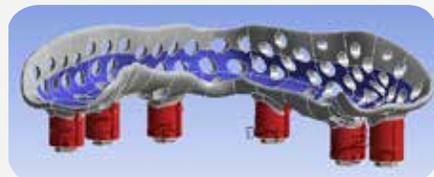


Personalized Implants Restore Smiles

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When people are missing multiple teeth and large sections of their oral bone structure, they are not good candidates for standard dental implants. The usual treatment for this condition is bone grafting, which requires multiple staged surgeries that usually take a year or more to complete. With the help of ANSYS Mechanical, OMX Solutions uses additive manufacturing to produce implants that fit the jaw and match facial contours and require only a single surgery. Those affected can have their appearance properly restored and can eat immediately after surgery.

Dental procedures can be trying for many people. A filling, an implant or even a root canal are minor compared to the replacement of multiple teeth and large sections of bone that is required when trauma, fractures, tumors, degenerative bone disease and other issues occur. Severe bone loss is usually treated by harvesting bone from the patient's rib or fibula (in the leg), which requires at least three traumatic surgeries over 12 to 18 months. These same problems, as well as osteoarthritis and other conditions, may necessitate the replacement of the temporomandibular joint (TMJ), commonly known as the jaw joint. The jaw joint may be replaced with off-the-shelf components that often leave patients with a poor fit and reduced functionality. OMX Solutions, a world leader in digital solutions for surgical challenges, has developed improved solutions by using digital design and additive manufacturing to produce custom implants that fit the



CAD model of Osseo-Frame



Before



After

“Simulation identifies potential *problems* with the *interactions between components* and gives an indication of potential points of *failure*.”

patient’s existing bone perfectly. OMX Solutions uses ANSYS Mechanical to simulate the bone and implant as a unit, which, when confirmed with physical testing, ensures that these implants can withstand forces associated with mastication. The result is made-to-order facial and jaw implants that improve surgical outcomes, enhance quality of life, significantly reduce the number of surgeries required and eliminate donor site pain and morbidity.

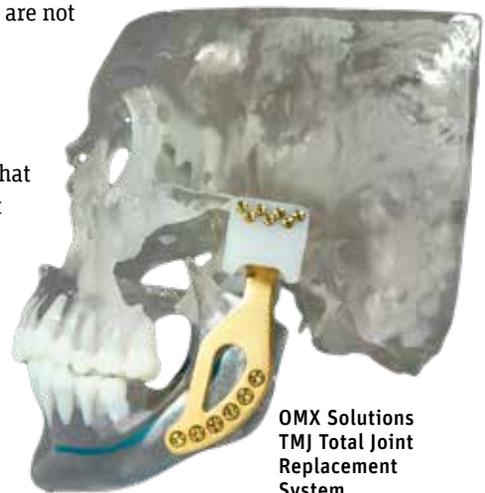
LIMITATIONS OF CONVENTIONAL IMPLANTS

When a large amount of bone and multiple teeth are missing, conventional dental implants do not provide enough stability to resist bite forces. Another option is a temporary removable denture, which can be uncomfortable and unstable. To remedy this, surgeons usually perform one procedure to remove a bone from the donor site and implant it into the jaw. Additional surgeries are required to implant teeth. The patient requires considerable time for recovery between surgeries, and the total time to complete the repair can be a year or more. Because the bone-grafting process is complex, it is difficult to match the patient’s facial contour, so patients are often left with an unbalanced look. Pain and donor site infection are also common.

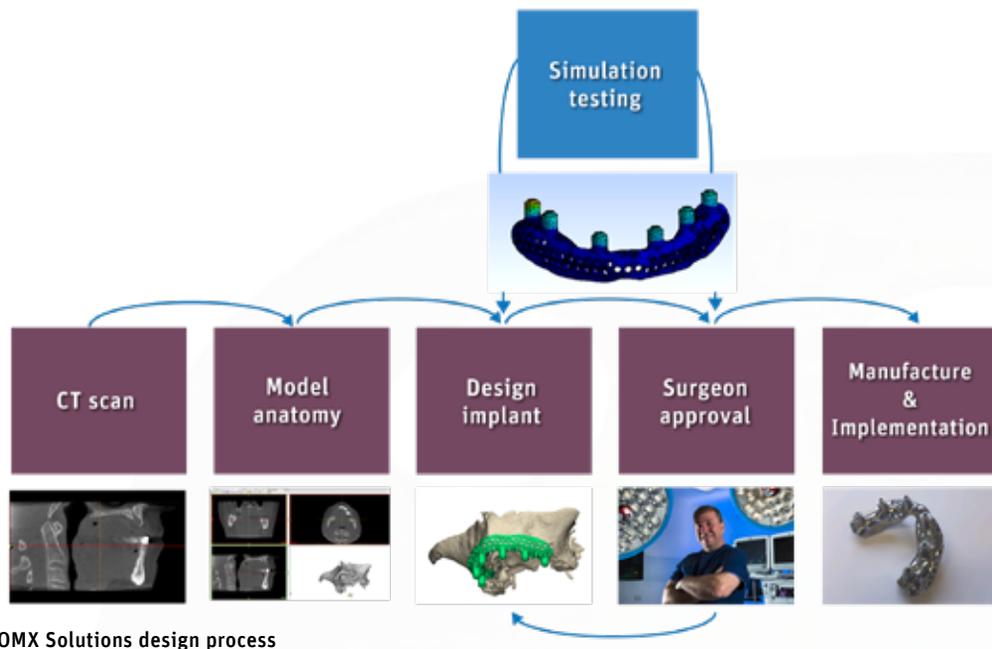
When TMJ replacement is required, the limited number of standard TMJ implant sizes available does not conform to the wide range of jaw and bone-loss configurations that are encountered in clinical practice. If there has been major bone loss, patients may be left with deformities and poor TMJ function because the stock implants are not fully compatible with the patient’s condition and morphology.

NEW APPROACH USES ADDITIVE MANUFACTURING

OMX Solutions has developed solutions to address these conditions. The OMX Solutions Osseo-Frame is a jaw implant that provides a secure, rigid bone replacement and mounting point for dental prostheses. It eliminates the need for bone grafts when the native bone site is not suitable for conventional dental implants. The implant is digitally designed and 3D printed to match the patient’s alveolar bone ridge, which ensures that the device perfectly fits to the natural bone without the need for bone modification. The microscrews and baseplate provide primary stability, so that the implant (and artificial teeth) can immediately be loaded without a protracted healing period.



**OMX Solutions
TMJ Total Joint
Replacement
System**



OMX Solutions design process

The OMX Solutions TMJ Total Joint Replacement completely replaces the patient’s temporomandibular joint. The 3D-printed titanium mandibular component is digitally sized and adjusted to fit each individual patient’s bone structure using the patient’s computed tomography (CT) data. The polyethylene fossa is also digitally sized and customized using computer numerical control (CNC) machining. The two then work together as a custom-fitted ball (condyle) and socket (fossa) joint.

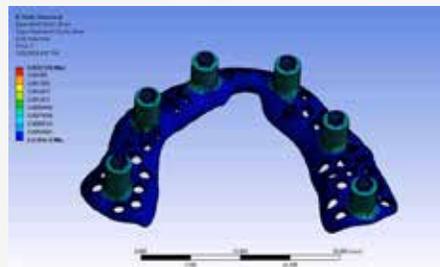
Both systems can be supplied with cutting, drilling and positioning guides to improve surgical precision.

DESIGN PROCESS FOR CUSTOM IMPLANTS

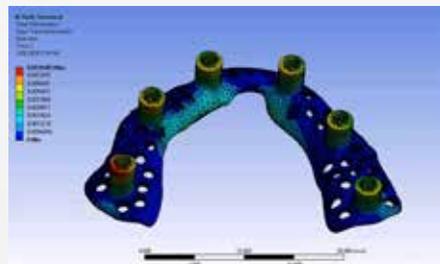
The first step in customizing these devices to the bone contours of the individual patient is to perform a CT scan that accurately shows the geometry of the patient’s existing bone structure. OMX Solutions production engineers then use Materialise Mimics® software to convert the CT scan output to a digital model of the patient’s bone and Materialise 3-matic® software to design the implant to closely match the patient’s 3D skeletal anatomy.

In designing custom implants, OMX Solutions production engineers must ensure that the entire assembly, including bone, attachments and implant components, will not fail. Without simulation, it would be necessary to print each implant and conduct physical tests on them. If it did not pass, it would be necessary to redesign, remanufacture and retest, which is expensive in both time and money. Moreover, conducting physical tests on the entire implant–bone assembly for every patient is not possible.

Patient-specific simulation is the only way for OMX Solutions to cost-effectively ensure the integrity of each implant.



Display of equivalent strain experienced in an Osseo-Frame



Display of total deformation occurring in an Osseo-Frame

ANSYS MECHANICAL SIMULATION

OMX Solutions selected ANSYS because of its intuitive user interface. The company's production engineers first simulate the device alone using the average bite force as found in the literature. This is typically the average bite force of a 25-year-old male, although the average patient for OMX products is older and has reduced muscle strength. As such, they have a less powerful bite, so this approach provides a comfortable margin of safety. Once they are confident with the device integrity, the engineers then simulate a full mock-up, including a multimaterial model of the bone derived from the CT scan and the screws attaching the implant to the bone. All materials are treated as nonlinear. This model includes frictional contacts between the bone, screws and the implant. Contact detection is used to register the contacts that occur between each face of each screw in the bone model and to identify any potential separation that may occur during use, such as the frame coming off the bone. The run time of this simulation is typically two to five hours on a 4-core personal computer.

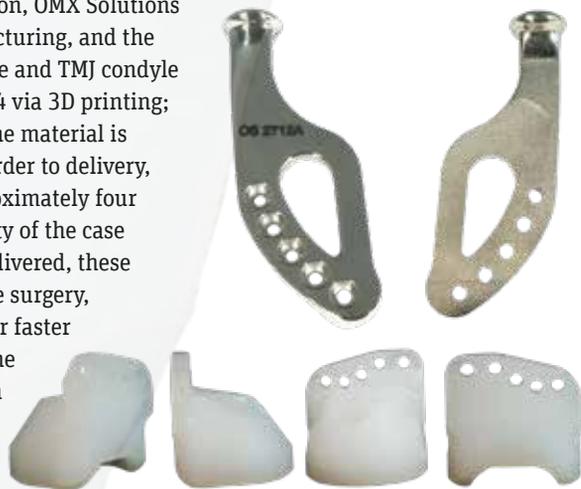
“OMX Solutions has developed improved implant solutions by using *digital design and additive manufacturing* to produce custom jaw implants that fit the patient’s existing bone perfectly.”

This simulation identifies potential problems with the interactions between components and gives an indication of potential points of failure. For example, it may show where the screw may cause bone fracture due to high levels of stress that are induced locally or where the screws are not capable of securely fastening the implant. When OMX Solutions production engineers are confident that the assembly is secure, they provide the design to the surgeon for review. The surgeon sometimes suggests changes based upon clinical feasibility and usability, in which case another round of simulation may be required.

Once they have approval from the surgeon, OMX Solutions transfers the digital design files to manufacturing, and the components are produced. The Osseo-Frame and TMJ condyle components are produced from titanium-64 via 3D printing; the fossa component is CNC machined as the material is currently not able to be 3D printed. From order to delivery, a custom implant can be produced in approximately four to eight weeks, depending on the complexity of the case and the experience of the surgeon. Once delivered, these devices are ready for installation in a single surgery, providing a permanent solution up to a year faster than traditional methods, at a fraction of the total surgical cost and significant reduction in pain and morbidity for the patient.

Those with bone loss and reduced jaw function can find it difficult to enjoy food and eat a healthy diet. They may also have reduced self-esteem because of their appearance. OMX Solutions implants

help these people rapidly recover their previous dental function and smile without undergoing a long series of operations. Patients who could not move their jaw in the past without pain can now eat and talk comfortably. People who had difficulty chewing and were not candidates for conventional implants can now eat normally. Patients whose faces had a sunken or lopsided look due to bone loss can be restored to their previous appearance. OMX Solutions custom implants restore a patient’s ability to eat, speak and smile with renewed self-confidence and peace of mind. 🇺🇸



TMJ Total Joint Replacement Systems components include mandibular (top) and fossa (bottom).