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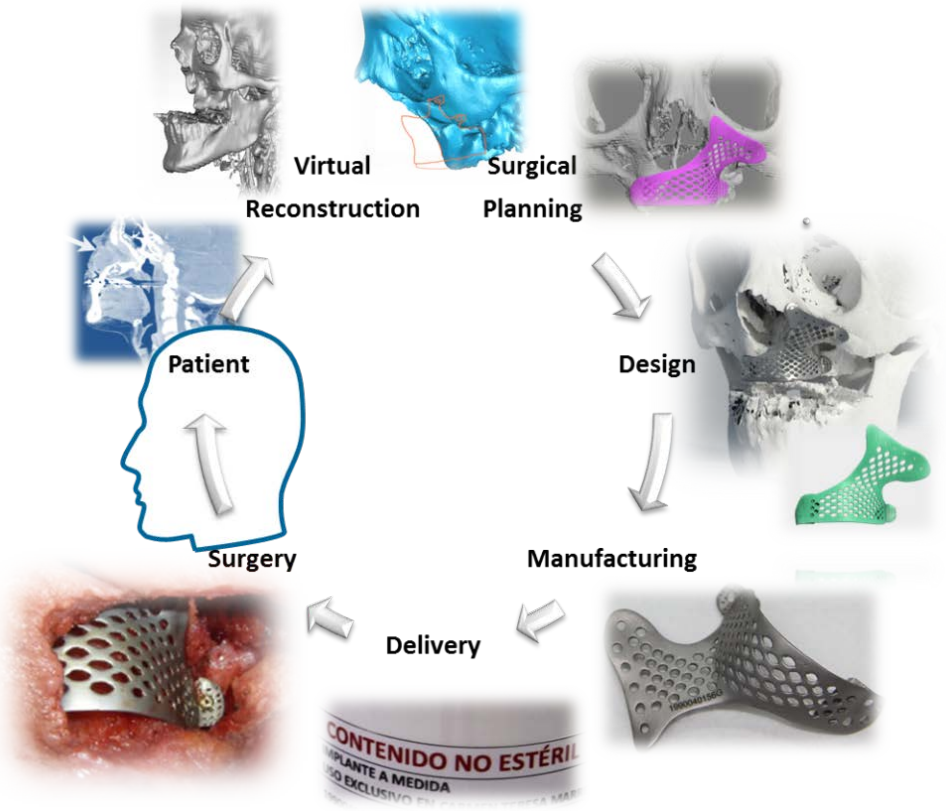
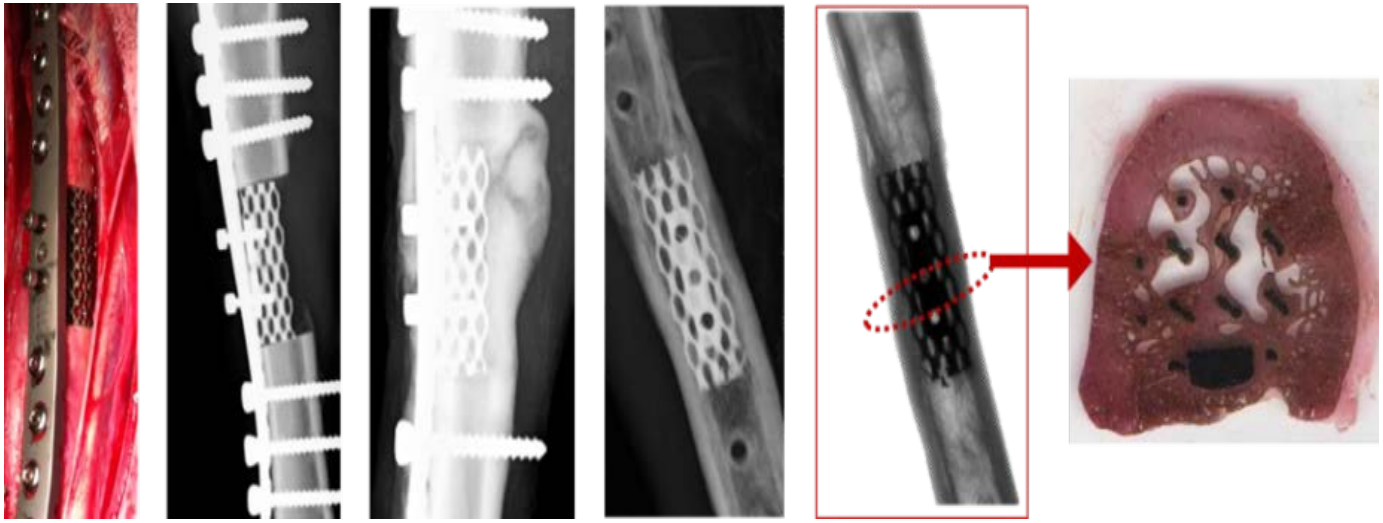
Gobierno de Canarias

The Canary Islands Institute of Technology (ITC) is an applied research Institute belonging to the Regional Government of Canary Islands (Spain). ITC is active in different research fields. The Biomedical Engineering Department (BED) represents a spike of excellence in bone loss reconstruction and regeneration. Since 2011, we develop custom made implants for singular bone surgeries, In the following images we present our work flow:



Surgeon´s phone number is required for fast **WHATSAPP** communications and feedback during the development time. **Patient CT images study with slice spacing of max 1 mm** is also required to carry out a **virtual 3D reconstruction of the patient anatomy** fitting well with the real bone, it is a requisite for the next steps. A **Plastic anatomical model** is manufactured starting from 3D reconstruction and is used for surgical planning and for validation of implants and instruments. **Surgeon inputs on surgical planning** are required to set up **design of implant and specific instruments** for space orientation and guided cuts. During this phase engineers will be in strict cooperation with the surgeon to rapidly convert basic ideas into optimal solutions. **A link to a 3D model of bone and implants is sent to the Surgeon** for **final approval**. **The implant and the instruments are then manufactured and shipped in not sterilized conditions** to the Hospital. The **surgeon will evaluate the devices simulating the surgical procedure** on the plastic model. The surgical devices will be then sterilized and packaged in the hospital before the surgery.

The BED skills and equipment include all Computer Assisted design and manufacturing process of direct and inverse engineering, including additive and substractive numeric control manufacturing in metal and polymeric implantable materials. We are active in bone reconstruction and regeneration and can design and produce load bearing implants and also scaffolds for tissue regeneration. Our main field of translational result is focused on the use of biomimetic full porous Titanium scaffold for regeneration of critical bone defects



ITC is at the moment working with Orthopedic, Crane-Maxilo-Facial (CMF), Spine and thoracic surgical Department of different hospitals in Spain, Italy, Argentina, Colombia. A new spin-off company of ITC, OSTEOBIONIX, has been founded and it is already active in introducing patient´s specific implants service in other European and foreigner countries. In the following images we present some of our more relevant clinical cases.

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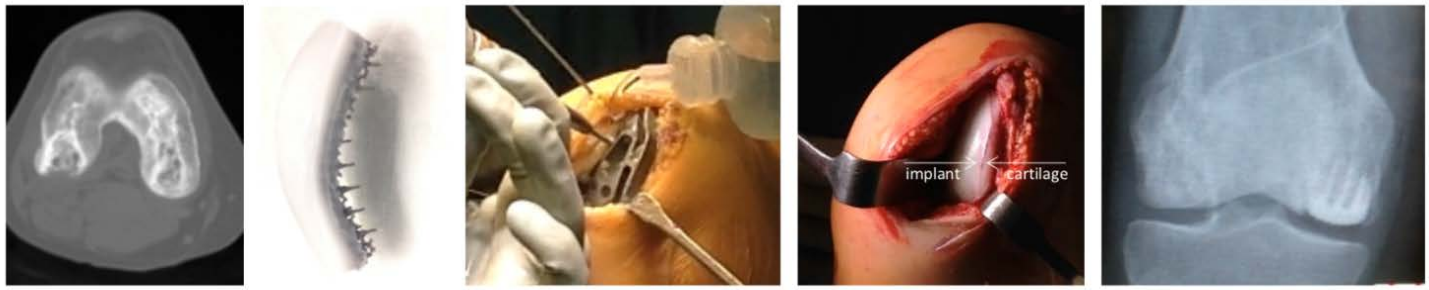
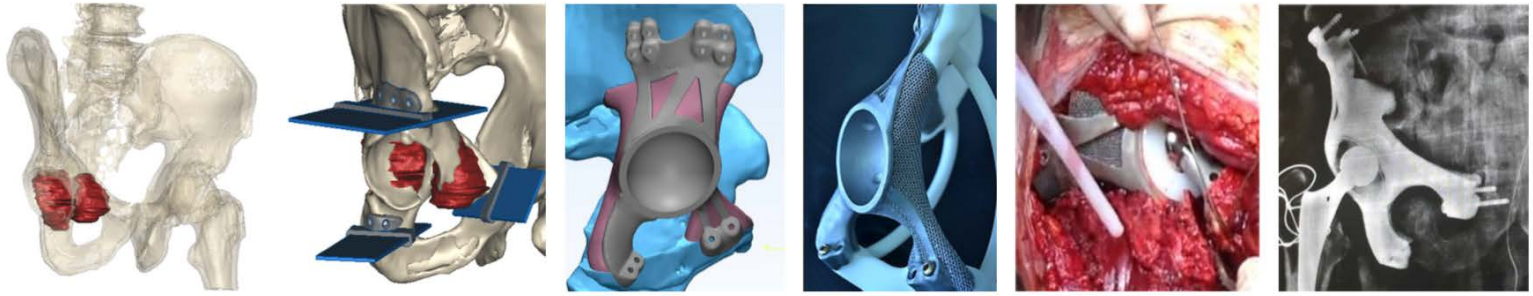
Orthopaedic – Knee



focal defect repair (milling guide + porous titanium & polycaprolactone
5 cases (Italy)

Orthopaedic – Hip



large hip reconstruction
20 cases (mostly in Argentina with Raomed)

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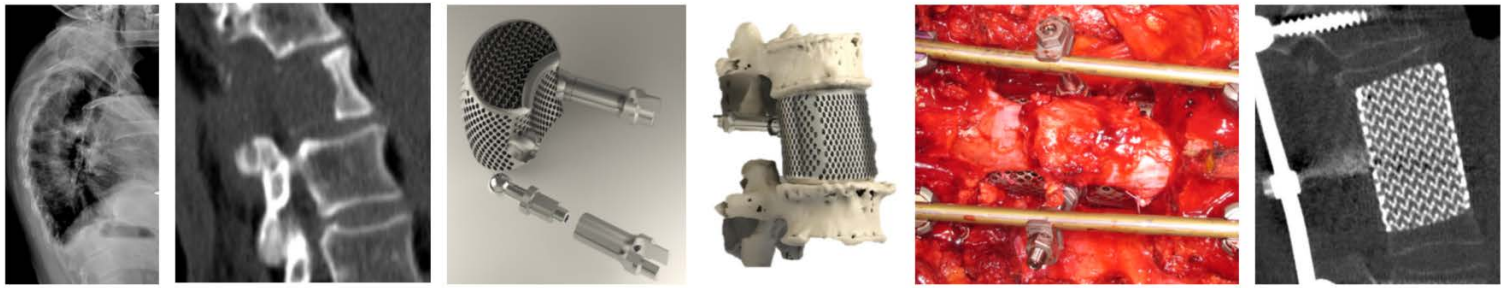
Thoracic

large rib cage reconstruction (ribs and part of the sternum)
12 cases (6 larger and 6 smaller implants)

Maxillofacial - TMJ

TMJ and mandible reconstruction
30 simpler TMJ and more complex cases (Spain) + 10 cases (Argentina with Raomed)

Spine



T12 reconstruction case (porous titanium implant – 90% air)

20 vertebral reconstruction cases (Italy)

UNSATISFIED NEEDS AND TOPICS FOR NEXT DEVELOPMENT IN COLLABORATION WITH NA-MIC

There are some surgical needs, still not satisfied but in our opinion relatively easy to be solved, if developed in the right technological environment that can introduce some big advantages in the surgery of many of clinical cases we are used to treat:

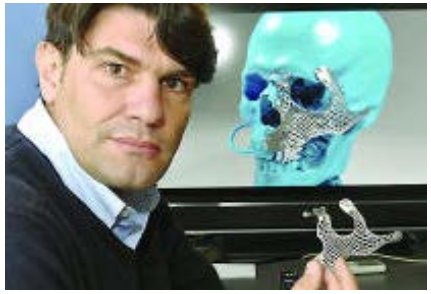
1. A software simulator of bone sliding on their articular surfaces with registration of bone volumes that produce impingement and reduce range of movement. We are always involved in difficult reconstruction of not yet functional elbows in response to bad consolidation of previous fractures and anatomical loosening of congruence in joint movement. It should be very useful to have a software that starting by a CT of the patient could simulate bone sliding of humerous and ulna while monitoring the range of articular movement and the volumes of relative bone impingment. The final results should be a color map of bone regions were at different colors are associated volumes of bone impingement at defined range of movement. In such a case surgeons and design engineers could be able to easily define which part of bone have to be removed to restore a selected functional range of movement. We actually do it with a lot of work moving manually both bones in different positions finding out an estimation of bone volume be removed. This method is time consuming, not precise and only possible in an advanced mechanical engineering environment. No one of the cad software we know is able to record a volume map of conflict of two solids sliding in contact with them. The solution of this problem could also help in the design of rasps for hip prosthesis.

2. An augmented reality system to be used in some very difficult custom made surgeries like vertebral body en-block resection with emphasis in sacrum replacement, acetabular reconstruction or some maxillofacial difficult surgeries, were noble soft tissues (vessels and nerves) are in the surrounding area that has to be cutted and there is a big risk to damage them. Traditional navigation procedure are not suitable for already long surgeries because they needs long time for set-up. A combination of custom made small guides fixed on easy achievable and geometrically significant anatomical regions, could reduce the time for pattern recognition procedure for maching pre-operatory and intra-operatory reference systems, even assuming a bigger error always in an acceptable range. During the surgery, one or two millimeters of error is very common even using custom made patients specific implants and in any case this error is always more reasonable that to lose 30/40 minutes to setup a navigation system. The engineering required work for

planning a custom made implant assisted by navigation system is quite huge and this is another barrier to the regular use of navigation in difficult surgeries already assisted by custom made implants and instruments.

3. A software for orthognatic planning that can be friendly used by a maxillofacial surgeons and that can habilitate him to manage also TMJ centers of rotation during anatomical displacement after simulation of osteotomies. In Europe the more diffused software is Dolphin, it is very expensive, hard to manage and with big functional limitations. It should be interesting to develop an easy intuitive open source software that can be at the same time suitable for bone cutting planning and implant design.

KIND REGARDS



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