

MIA

Minimally Invasive Arthroplasty





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Hip and shoulder replacements are very aggressive surgeries which pose a high number of postoperative complications.

These complications increase the number of treatments patients receive and lengthen hospital stays.

It results in thousands of millions of dollars of extra cost for all the healthcare systems worldwide.

The **MIA project** was launched in 2005 with the aim to minimize the aggressiveness of such surgeries.

For this purpose, several minimally invasive joint replacement **MIA** systems have been designed (prosthesis and instrument set).

PARTIAL HIP MIA SYSTEM

Minimally invasive partial hip replacement **MIA** system

MIHA



TOTAL HIP MIA SYSTEM

Minimally invasive total hip replacement **MIA** system

T-MIHA



*Final Stage Pre-commercialization: Clinical Trial and CE Marking

*Concept Design

The first developed MIA system; **PARTIAL HIP MIA SYSTEM**, aims to minimize the aggressiveness of the treatment in displaced intracapsular hip fractures in patients over 80 years of age.

PARTIAL SHOULDER MIA SYSTEM

Minimally invasive partial shoulder replacement MIA system



MISA

*Concept Design

TOTAL SHOULDER MIA SYSTEM

Minimally invasive total shoulder replacement MIA system



T-MISA

*Concept Design

PROMOTER TEAM

In order to carry out the **MIA** project, a highly specialized team has been set up whose members have extensive experience in their own fields.

MEDICAL DEPARTMENT

It consists of 3 Trauma and Orthopaedic surgeons.

Their daily clinical practice takes place in a hospital environment.

Extensive surgical experience in the use of the different medical devices used in the treatment of hip fractures; both osteosynthesis methods (cannulated screws, DHS and intramedullary femoral nails) and hip arthroplasty (total hip replacement, bipolar partial hip replacement and unipolar partial hip replacement).

Dr. Javier Cortés Cubero

Principal promoter of the **MIA** Project.

Senior orthopaedic surgeon in the Trauma and Orthopaedic Surgery Department at the Hospital Clínico Universitario of Valencia.

Doctoral thesis at the Faculty of Medicine of the University of Valencia (www.uv.es). Research focused on the minimally invasive partial hip replacement **MIA** system (**PARTIAL HIP MIA SYSTEM**).

“Minimally invasive femoral head resection arthroplasty and placement of a hip arthroplasty device”



VNIVERSITAT DE VALÈNCIA

Dr. Francisco Baixauli García (PhD)

Head of the Trauma and Orthopaedic Surgery Department at the Hospital Universitario y Politécnico La Fe in Valencia.

Associate Professor of Trauma and Orthopaedic Surgery at the Faculty of Medicine of the University of Valencia.

Extensive clinical and research experience.

Thesis Director for Dr. Javier Cortés at the University of Valencia.

Dr. José Amaya Valero (PhD)

Clinical Head of the Musculoskeletal Tumors Unit in the Trauma and Orthopaedic Surgery Department at the Hospital Universitario y Politécnico La Fe de Valencia.

Programme Coordinator and Professor of Human Anatomy at the Faculty of Medicine of the CEU Cardenal Herrera University. www.uchceu.es

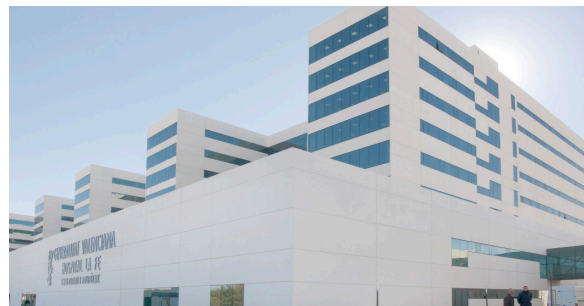
Extensive clinical and research experience.

Thesis Director for Dr. Javier Cortés at the University of Valencia.



Hospital Clínico Universitario de Valencia
clinicomalvarrosa.san.gva.es

Affiliated with the Faculty of Medicine at the University of Valencia. Serves a population of 320,000 people in Valencia and surrounding areas. It has 582 beds. The Trauma and Orthopaedic Surgery Department consists of 30 trauma and orthopaedic surgeons and 15 specialty registrars who deal with more than 300 hip fractures in the elderly per year.



Hospital Universitario y Politécnico La Fe de Valencia
www.hospital-lafe.com

Serves a population of 300,000 people in Valencia and surrounding areas. It has 1,000 beds. The Trauma and Orthopaedic Surgery Department consists of 41 trauma and orthopaedic surgeons and 20 specialty registrars who deal with more than 400 hip fractures in the elderly per year.

EQUIPO PROMOTOR

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TECHNICAL DEPARTMENT

Dr. Carlos Atienza Vicente (PhD)
Industrial Engineer.

Director of Innovation in Healthcare Technology at the Institute of Biomechanics of Valencia (**IBV**).
(www.ibv.org)

Associate Professor at the Universidad Politécnica de Valencia (Mechanical Engineering and Materials). (www.upv.es)

Thesis Director for Dr. Javier Cortés at the University of Valencia.

Mr. César Cloquell Ballester
Owner of Cloquell Consulting (Consulting services for national and international companies which manufacture trauma and orthopaedic products)
(www.cloquellconsulting.com)

Extensive experience in production and quality control in the manufacturing of products for Trauma and Orthopaedic Surgery (Surgical, 1991-2009).

LEGAL DEPARTMENT

Mr. Alberto García López
Intellectual property lawyer.

Founding partner of RMA law firm which specializes in Patents, trademarks and Copyright. (Barcelona-Valencia).
(www.rma.legal)

Mr. Jesús Ibáñez Benlloch
Commercial Law Lawyer.

Board member of the Commercial Law Department at Gómez Acebo & Pombo Law Firm in Valencia.
(www.gomezacebo-pombo.com)

COMMERCIAL DEPARTMENT

Mr. Alfredo Cortés Cubero

Holds a degree in Business Management by the London Open University. United Kingdom.

20 years experience in Marketing, Communication and Sales.

Mr. Ernesto Bacharach Martínez de Vallejo

Holds a degree in Business Management and Administration by the University of Valencia.

Extensive experience in consulting services regarding strategic planning and company formation.

PARTICIPATING COMPANIES

The Institute of Biomechanics of Valencia is considered a point of reference in Spain and in Europe for the biomechanical evaluation of products and services in the healthcare technology industry.

IBV - INSTITUTE OF BIOMECHANICS OF VALENCIA
www.ibv.org

The IBV is one of the most prestigious R&D technological centres in Spain where more than 150 people from different disciplines work (engineering, physics, medicine, physiotherapy, market research, industrial design, etc).

IBV's role during the development of the **PARTIAL HIP MIA SYSTEM** has been to collaborate in the development of:

Design of the instrument set for the femoral head removal in a minimally invasive way (**FHR Instrument set**).

Design of the **MIHA** prosthesis.

Design of the instrument set for the placement of the **MIHA** prosthesis (**MIHA Instrument set**).

Mechanic validation of the **MIHA** prosthesis according to the Standard **ISO 7206-4:2010**.



Institute of Biomechanics of Valencia (IBV)
www.ibv.org



INSTITUTO DE
 BIOMECÁNICA
 DE VALENCIA

The **IBV** is located within the **Universidad Politécnica de Valencia (UPV)** campus where more than 1600 scientists work on different projects.

The **Universidad Politécnica de Valencia (UPV)** is amongst the universities in Spain which earn more revenue regarding competitive research, R&D contracts, consulting services, service provision and technology licences.



UNIVERSITAT
POLITÈCNICA
DE VALÈNCIA

Universidad Politécnica de Valencia (UPV)
www.upv.es

EMPRESAS COLABORADORAS

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IVALMED

www.ivalmed.com

Manufacture in steel AISI 630 of part of the instrument set for the removal of the femoral head in a minimally invasive way (**FHR Instrumental**) and of the instrument set for the placement of the **MIHA** prosthesis (**MIHA Instrument set**).

IVALMED (Paterna, Valencia) is a company that specializes in the manufacture and repair of medico-surgical instruments. The Standard ISO 9001 and the CE marking have been followed for the manufacture of the medical CLASS I instrument set.



MIPESA

www.surgicalmachining.eu

Manufacture of the **MIHA** prosthesis components in titanium alloy Ti6Al4V.

MIPESA (La Alcuia, Valencia) holds the certification UNE EN ISO 13485 and it is audited by the Notified Body in the United Kingdom (SGS).

Extensive experience in the mechanical processing of trauma and orthopaedic surgery products for international companies: hip prosthesis, knee prosthesis, spine and osteosynthesis.



SCIENTIFIC ANATOMY

www.anatomycenter.com

Functional validation using anatomical pieces: femoral head removal instrument set (**FHR Instrument set**), **MIHA** prosthesis and instrument set for the placement of the **MIHA** prosthesis (**MIHA Instrument set**).

SCIENTIFIC ANATOMY (Paterna, Valencia) is a company that focuses in the training of specialised doctors and of healthcare companies specializing in the treatment, preparation and preservation of anatomical pieces for the development and study of the human anatomy, surgical techniques, etc.

**EXPERIOR**

www.experior.es

Design and monitoring of the clinical trial required for obtaining the CE marking.

EXPERIOR (La Pobla de Farnals, Valencia) is a **CRO** (Contract Research Organization) which offers a complete full service in all matters related to clinical trials following all current and existing national and international standards (ICH/GCP guidelines).

EXPERIOR's labour force exceeds 100 people from all different research related fields (pharmaceutical, medical, statistics, IT, etc).



ADVANTAGES OF THE MIA SYSTEMS

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The **PARTIAL HIP MIA SYSTEM** has achieved a **milestone** in the history of traumatology and orthopaedic surgery worldwide: **to replace the hip joint in a minimally invasive way, quickly, simply and performed by a single surgeon.**

BENEFITS FOR THE PATIENT

Reduction of surgery aggressiveness: **minimally invasive surgery.**

Reduction in approach and soft tissue dissection.

Reduction of bleeding and blood transfusions.

Simple and quick surgery performed by one single surgeon.

Reduction of post-operative medical complications.

Reduction of treatments to deal with complications.

Reduction of length of stay in hospital

Maintaining independence for basic activities of daily living.

Improvement in short-term and long-term prognosis.

The MIA systems optimize available resources by achieving extensive costs savings across all the healthcare systems in the world.

BENEFITS FOR THE HEALTHCARE SYSTEMS

Reduction of treatments to deal with complications.

Reduction of length of stay in hospital.

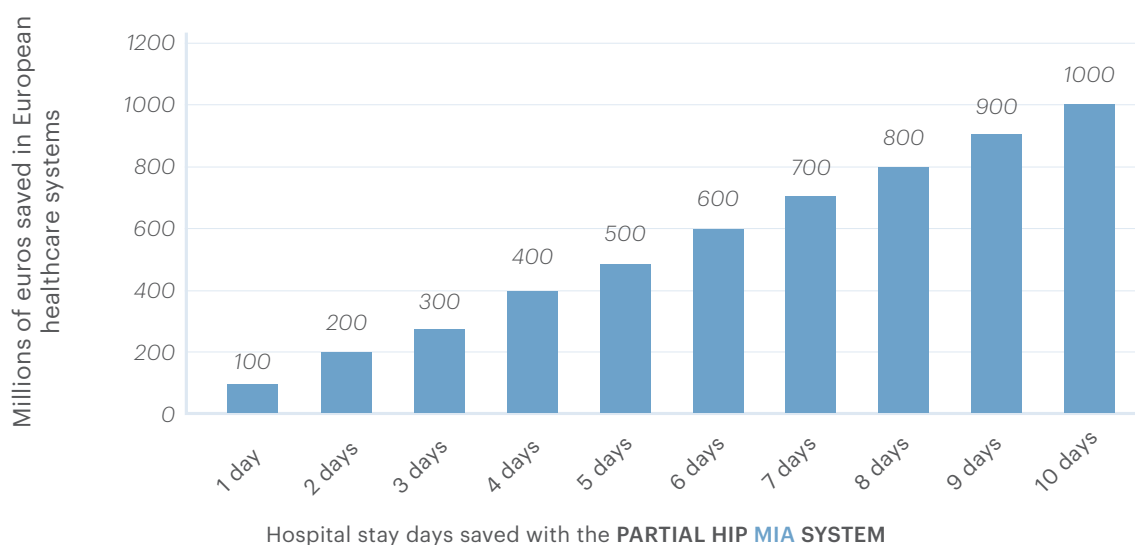
Reduction of rehabilitation and physiotherapy needs.

Reduction of hospital readmissions.

Increase in the availability of doctors since only one single surgeon is required to perform a hip or shoulder replacement with any of the MIA systems; as opposed to the current situation where 2-3 surgeons are required to perform a standard hip or shoulder replacement.

Increase in the number of hospital beds available.

Reduction of surgery waiting times for other pathologies.



Each day of hospital stay that is saved with the Partial Hip MIA System will mean a saving of 100 millions of euros for the European healthcare systems

PRESENT SITUATION OF THE MIA PROJECT

PARTIAL HIP MIA SYSTEM

Pre-commercialization Final Stage: Conduct the clinical trial and CE marking processing

TRL 8-9

2020-2022 CLINICAL TRIAL AND CE MARKING

Manufacture of the **MIHA** prosthesis, the FHR instrument set and the **MIHA** instrument set to carry out a clinical trial (**IVALMED, MIPESA**).

Clinical trial design (**CRO EXPERIOR**).

Conducting the clinical trial (**HOSPITAL UNIVERSITARIO Y POLITÉCNICO LA FE in Valencia**).

Processing and procurement the CE marking (**CLOQUELL CONSULTING**).

TOTAL HIP MIA SYSTEM

Concept Design Stage

TRL 1-2

2018 - 2020

Concept design of the instrument set for the removal of the femoral head in minimally invasive way using 3D design software.

Concept design of the acetabulum reaming instrument set in a minimally invasive way using 3D design software.

Concept design of the total hip prosthesis **T-MIHA** using 3D design software.

Concept design of the instrument set for the placement in a minimally invasive way of the **T-MIHA** prosthesis using 3D design software.

PARTIAL SHOULDER MIA SYSTEM

Concept design Stage

TRL 1-2

2018 - 2020

Concept design of the partial shoulder prosthesis **MISA** using 3D design software.

TOTAL SHOULDER MIA SYSTEM

Concept design Stage

TRL 1-2

2018 - 2020

Concept design of the total shoulder prosthesis **T-MISA** using 3D design software.

PATENTS

SPANISH PATENT (P20183056)

Filed in June 11, 2018.

PCT (ES2019/070399)

Filed in June 10, 2019. PCT (ES2019/070399)

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- RNFC-Registro Nacional de Fracturas de Cadera. España. Informe Anual 2018. <http://rnfc.es/>
- NHFD-National Hip Fracture Database. United Kingdom. Annual Report 2019. <https://www.nhfd.co.uk/>
- Australia and New Zealand Hip fracture Registry Annual Report 2019. <https://anzhfr.org/>
- Bohsali, K. I., Bois, A. J., & Wirth, M. A. (2017). Complications of Shoulder Arthroplasty. The Journal of Bone and Joint Surgery, 99(3), 256-269. doi:10.2106/jbjs.16.00935

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