ALMA MATER STUDIORUM
UNIVERSITÀ DI BOLOGNA

SERVIZIO SANITARIO REGIONALE
EMILIA-ROMAGNA
Istituti Ortopedici Rizzoli di Bologna
Istituto di ricovero e cura a carattere scientifico

San Michele in Bosco
Area Monumentale I.R.C.C.S.

MIMAS Implant Safety Workshop 15th - 16th September 2021

Epidemiological data of patients with hip, knee and shoulder implants submitted to MRI

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LTM
Laboratorio di Tecnologia Medica

Introducing IOR

Istituto Ortopedico Rizzoli, Bologna, Italy (IOR)

A public hospital dedicated to orthopaedics (1896) and a research centre (1989), integrated in to the national/regional health service

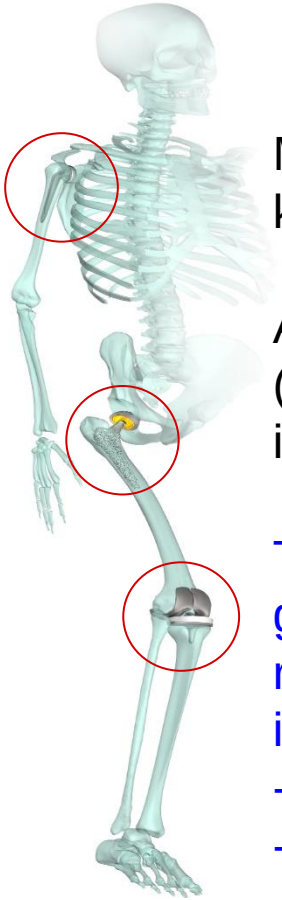
Laboratorio di Tecnologia Medica - activities on:

Biomechanics of the musculoskeletal system

Industrial research for the validation of new prosthetic devices and biomaterials

Post-marketing surveillance of prosthetic devices (Implants registry)

ISTITUTO ORTOPEDICO RIZZOLI 1896-2021 40 ANNI DI IRCCS



Orthopaedic implants vs. MRI

More than 200,000 new arthroplasties (hip, knee, shoulder) in Italy per year

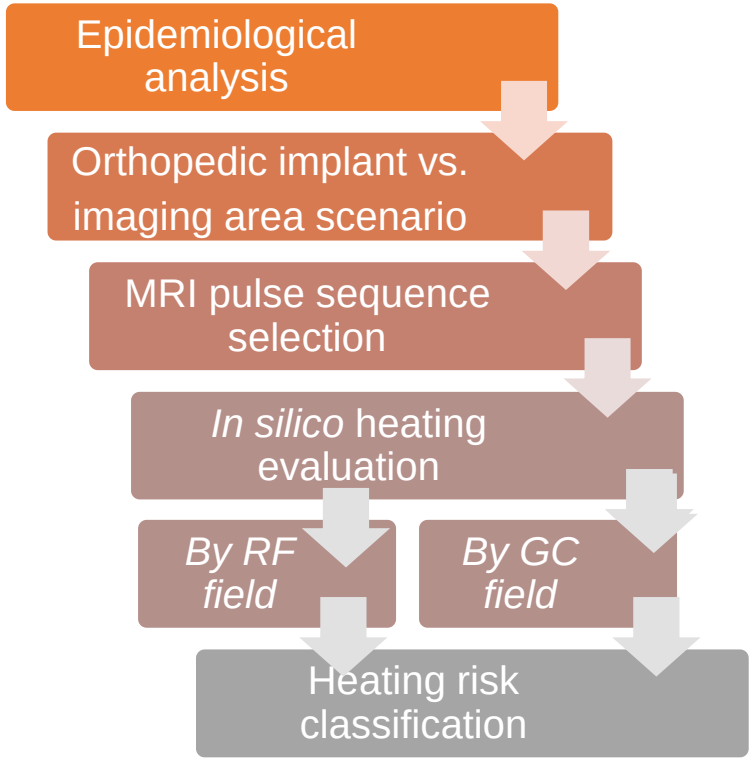
An even larger number of fixation devices (surgical staples, screws, plates, etc) implanted

The adoption of MRI in orthopaedics is growing. It is therefore more frequently required a risk assessment for heating effects in presence of metallic implants, due to:

- radiofrequency (RF) – (ASTM F2182)
- switching gradient coil (GC) (not considered in ASTM F2182)

Overview of the heating risk definition process for hip, knee, shoulder implants

MIMAS project (2018-2021): Procedures allowing medical implants manufacturers to demonstrate compliance with MRI

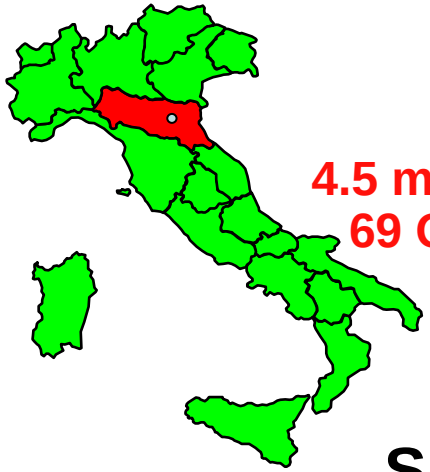


Epidemiological analysis - Aims

- how often a prosthetic patient requires an MRI scan?
- what are the most frequent body regions imaged by MRI in prosthetic patients?
- what are the most frequent MRI exams for prosthetic patients?

Registry of the Orthopaedic Prosthetic Implantology Regione Emilia-Romagna

(RIPO, https://ripo.cineca.it/authzssl/index.htm)



4.5 millions inhabitants
69 Orthopedic Units

Growth rate >10,000 new implants/year

Covering 98% of implanted devices

Since 2000

HIP > 187,000 implants

KNEE > 114,000 implants

Since 2008

SHOULDER > 8,000 implants

Epidemiological analysis - Methods

- **PATIENT GROUP SELECTION**

➔ Only one/two hip, knee or shoulder prostheses and no other implant

➔ Implanted in 2013

➔ With at least one MRI scan in the 3 years after surgery

Epidemiological analysis - Methods

Cross-comparison and extraction from Clinical Services Databases provided in the Emilia-Romagna region

ASA

Assistenza Specialistica Ambulatoriale, collects **specialist outpatient** assistance provided to individual patients by public and private providers of the region integrated in to the NHS

RIPO

Registry of the **Orthopaedic Prosthetic Implantology**, collects data from 69 Orthopaedic Units in public or private Hospitals, integrated in to the NHS

SDO

Scheda di Dimissione Ospedaliera, includes all the clinical services provided to individual patients during **hospital staying** by public and private hospitals of the region integrated in to the NHS

Epidemiological analysis - Results

total number of **patients** implanted in 2013 is **11658**

34.3 % males (average age: 69.9 years)

65.7 % females (average age: 73.6 years).

16.8 % with hip surgery (1155/6875 patients)

26.9 % with knee surgery (1032/3838 patients)

27.6 % with shoulder surgery (81/294 patients)

~~19.4 % with additional prosthesis surgery (126/651)~~

20.5 % has got at least one MRI scan in the three years after surgery

34.0 % males
66.0% females

first year (8.2 %)

second year (7.1 %)

third year (5.1 %)

Epidemiological analysis - Results

	Prosthesis							
	hip		knee		shoulder		all three prosthesis	
MRI exam	number of exams	% of MRI exams	number of exams	% of MRI exams	number of exams	% of MRI exams	number of exams	% of MRI exams
head	390	19.8%	361	19.4%	26	16.5%	777	19.5%
chest	34	1.7%	25	1.3%	3	1.9%	62	1.6%
spine	749	38.0%	716	38.5%	51	32.3%	1516	38.0%
musculoskeletal	641	32.6%	607	32.7%	68	43.0%	1316	33.0%
abdomen/pelvis	125	6.3%	119	6.4%	9	5.7%	253	6.3%
other	30	1.5%	31	1.7%	1	0.6%	62	1.6%
total	1969	100.0%	1859	100.0%	158	100.0%	3986	100.0%

MRI **exams** done within the next 3 years from the surgery to the patients implanted in 2013

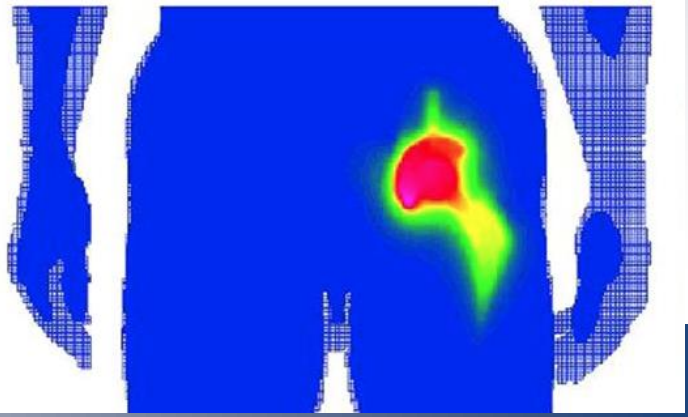
Epidemiological analysis - Discussion

A significant percentage of patients with hip, knee or shoulder implants are regularly submitted to MRI scan (up to 8.2% in the first year after surgery)

Most of the MR exams on prosthetic patients are not applied near the prosthesis, and for clinical investigations not related to the prosthesis itself

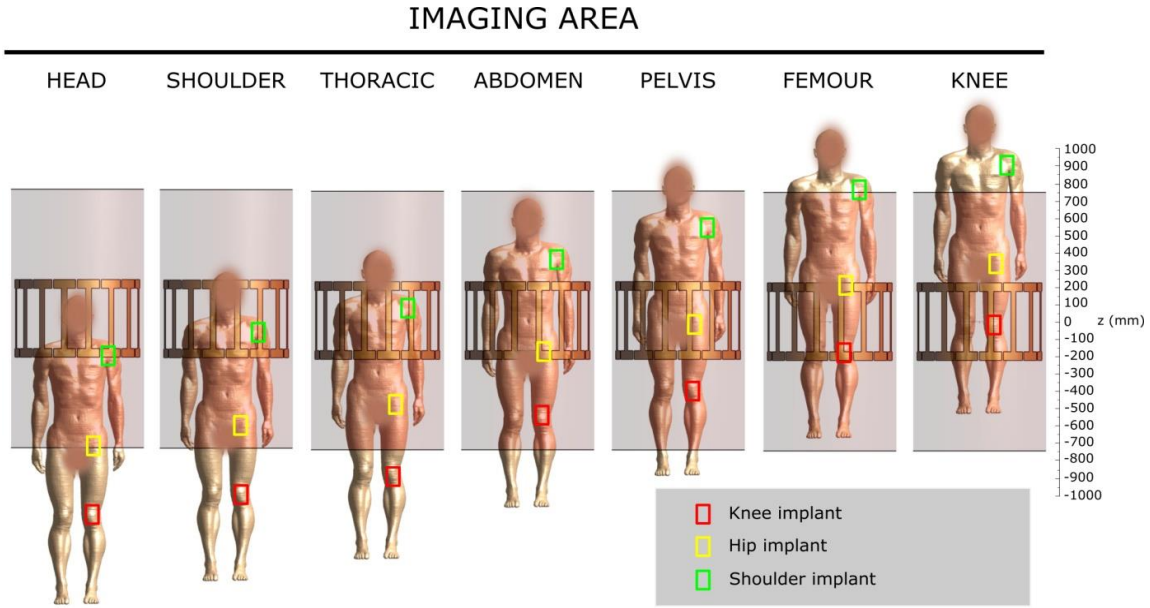
There is a great variability of implant type, imaging area, MRI sequences, giving hundreds of different scenarios for heating risk analysis in daily clinical practice

HOW TO GET A FLEXIBLE METHOD FOR HEATING RISK ASSESSMENT IN CLINICAL PRACTICE?



In-silico heating risk evaluation

In-silico heating risk evaluation for hip, knee and shoulder implants simulated in the realistic locations inside a human body, performing MRI exams in different imaging areas, and for different MRI sequences to define the most hazardous scenarios (ref. 1)



1) Heating risk evaluation for MRI on patients with hip, knee and shoulder arthroplasty, V. Clementi, U. Zanovello, A. Arduino, C. Ancarani, F. Baruffaldi, B. Bordini, M. Chiampi, L. Zilberti, and O. Bottauscio, submitted to Scientific Reports

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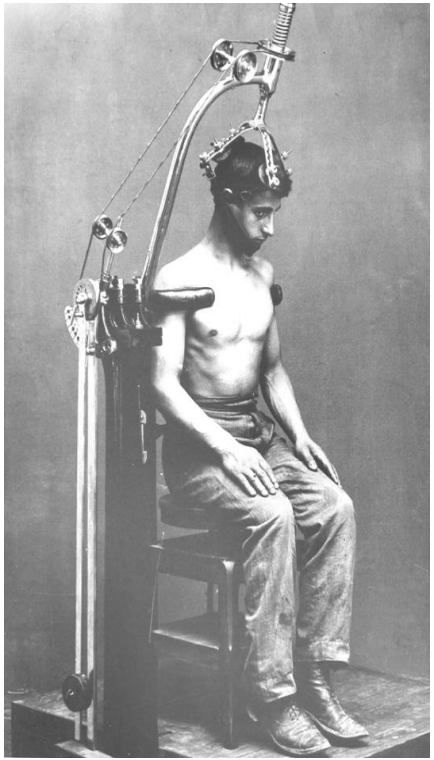
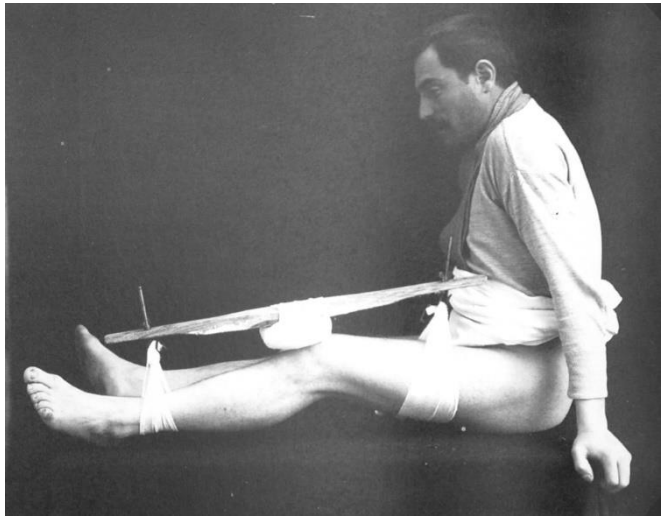
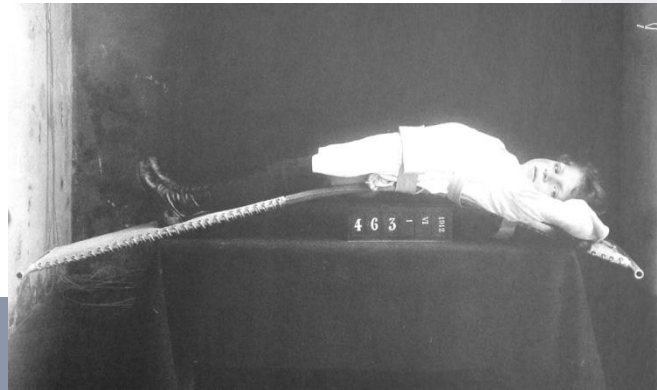




Thank you



Pictures from the historical archive of the Istituto Ortopedico Rizzoli (1900-1910 c.a)