

REPORT

R.I.P.O.

(Register of Orthopedic Prosthetic Implantology)

Overall data Emilia-Romagna Region Hip and knee prostheses

1st January 2000 – 30th September 2002

Data elaborated by Register of Orthopedic Prosthetic Implantology
(RIPO)

Medical Technology Laboratory – I.O.R.



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Foreword

This report, elaborated by the Register of Orthopedic Prosthetic Implantology (RIPO), presents the most significant results of the descriptive statistical analyses performed on operations of hip arthroplasty carried out in Emilia-Romagna, between 1st January 2000 and 30th September 2002.

The data include, besides primary arthroplasty, revision surgery, prosthesis removal and hemiarthroplasty.

A section is dedicated also to knee arthroplasty.

The Emilia-Romagna Regional Authority has ordered that, from 1st January 2000, all hip arthroplasty operations carried out in public hospitals, or private hospitals with Regional Authority endorsement, be communicated, by means of an appropriate data form, to RIPO. These forms are then inserted into a databank. If any essential information is missing (identification of the patient, type of prosthesis, etc.), the person responsible in the unit for providing such information is asked to supply it.

The experience gained since a pilot project started inside Rizzoli Orthopaedic Institute at the beginning of the 1990's enables us to state that RIPO's work carried out so far represents an essential document of *Evidence-Based Medicine* in the field of arthroplasty, which will help us to make an objective assessment of the efficacy of prosthetic surgery.

Note on methodology

Elaboration includes data concerning the period 1st January 2000 to 30th September 2002, which arrived before 30th March 2003. The collection of data about the knee started in July 2000.

To provide more useful information in some graphs, at the top of the columns, percentages are indicated, in relation to the overall total of each subsample analyzed.

For all units a report about their own data, which can be easily compared to the regional averages, is attached to this report.

The data collected so far present a maximum follow-up of about three years; therefore preliminary assessments on the survival of prostheses can be made, although they are, of course, limited. Over the years to come more efficacious evaluations will be possible, including the survival curves of various types of prostheses, also in relation to the patients' characteristics (sex, age, disease). The data will be useful for carrying out surgery; there will be more reassurance from the objective results in the indication for surgery choice of prosthesis. The patients will also be able to receive more precise information on the risk of failure of this type of surgery.

This report also includes a section about the situation in the region of prostheses that are recalled by the Health Ministry.

RIPO is helped by CINECA (Consorzio Interuniversitario di Calcolo) for technical support.

Bologna, 15 April 2003

PART ONE: HIP PROSTHESES

1. RIPO support

The following table shows the average support for RIPO per hospital.

BOLOGNA PROVINCE	January – September 2002		
	N° operations communicated to RIPO	N° operations communicated by S.D.O.	% support RIPO.
AZIENDA BOLOGNA CITY			96.9%
Hospital Maggiore	113	111	
Hospital Bellaria	0	1	
Private hospital "Villa Erbosa"	56	61	
Private hospital "Villa Nigrisoli"	84	88	
Private hospital "Villa Torri"	100	103	
Private hospital "Villa Laura"	89	88	
Private hospital "Villa Regina" (not credited)	10	14	
Total	452	466	
Azienda Ospedaliera S. Orsola-Malpighi	176	224	78.6%
Orthopaedic Institutes Rizzoli	933	933	100.0%
AZIENDA BOLOGNA NORTH			102.0%
Hospital Bentivoglio	52	44	
Hospital Budrio	-	7	
Total	52	51	
AZIENDA BOLOGNA SOUTH			77.5%
Civil hospital Vergato	27	31	
Private hospital "Prof. Nobili"	2	7	
Private hospital "Villa Chiara"	2	2	
Total	31	40	
AZIENDA IMOLA			83.6%
Civil hospital Imola	178	190	
Castel San Pietro Terme	-	23	
Total	178	213	
FERRARA PROVINCE			84.8%
Stabilimento Ospedaliero di Cento	164	111	
Civil hospital Argenta	113	123	
Civil hospital Comacchio/ Delta	30	74	
Hospital Bondeno	-	54	
Total	307	362	
Azienda Ospedaliera di Ferrara	162	180	90.0%

FORLÌ-CESENA PROVINCE	January – September 2002		
	N° operations communicated to RIPO	N° operations communicated for S.D.O.	% support RIPO.
AZIENDA FORLÌ			74.2%
Hospital "Morgagni - Pierantoni" Forlì	120	165	
Private hospital "Villa Serena" Forlì	10	10	
Total	130	175	
AZIENDA CESENA			90.7%
Hospital "M. Bufalini" Cesena	152	168	
Hospital Bagno di Romagna	-	4	
Hospital Cesenatico	-	2	
Private hospital "Malatesta Novello" Cesena	122	125	
Private hospital "S. Lorenzino" Cesena	-	3	
Total	274	302	
MODENA PROVINCE			
AZIENDA MODENA			99.1%
Hospital S. Agostino - Estense	249	238	
Civil hospital Infermi, Carpi	125	127	
Hospital Finale Emilia	-	2	
Hospital S. Maria Bianca, Mirandola	61	49	
Civil hospital Castelfranco Emilia	-	38	
Civil hospital, Sassuolo	58	62	
Civil hospital, Vignola	115	166	
Hospital, Pavullo	43	46	
Hesperia Hospital	25	24	
Private hospital Prof. Fogliani	25	25	
Total	701	777	
Azienda Ospedaliera Policlinico di Modena	14	95	14.7%
PARMA PROVINCE			
AZIENDA PARMA			106.9%
Civil hospital, Fidenza	57	34	
Hospital Santa Maria, Borgo Val di Taro	38	40	
Hospital San Secondo Parmense	-	13	
Private hospital "Città di Parma"	29	29	
Total	124	116	
Azienda Ospedaliera di Parma	237	304	77.9%
PIACENZA PROVINCE			
AZIENDA PIACENZA			101.5%
Civil hospital, Piacenza	210	212	
Presidio Val Tidone, Castel San Giovanni	40	37	
Presidio Val D'Arda, Fiorenzuola D'Arda	95	89	
Presidio Cortemaggiore	-	2	
Total	345	340	

RAVENNA PROVINCE	January – September 2002		
	N° operations communicated to RIPO	N° operations communicated by S.D.O.	% support RIPO.
AZIENDA RAVENNA			94.5%
Hospital S. Maria delle Croci, Ravenna	81	90	
Presidio Ospedaliero, Lugo	171	175	
Hospital Infermi, Faenza	65	68	
Private hospital "Domus Nova"	4	4	
Private hospital "S. Francesco"	84	91	
Private hospital "Villa Maria Cecilia"	31	32	
Private hospital "S. Pier Damiano"	95	102	
Total	531	562	
REGGIO EMILIA PROVINCE			
AZIENDA REGGIO EMILIA			79.0%
Hospital, Guastalla	59	52	
Hospital S. Sebastiano, Correggio	-	6	
Hospital Montecchio Emilia	40	41	
Hospital Scandiano	43	42	
Hospital S. Anna, Castelnovo Monti	46	46	
Private hospital "Villa Salus"	19	19	
Private hospital "Villa Verde"(not credited)	-	56	
Total	207	262	
Arcispedale Santa Maria Nuova, Reggio Emilia	178	178	100.0%
RIMINI PROVINCE			
AZIENDA RIMINI			95.3%
Hospital Infermi, Rimini	73	76	
Hospital G. Ceccarini, Riccione	129	131	
Hospital, Cesenatico	-	2	
Hospital, Sant'Arcangelo	-	3	
Private hospital "Villa Maria"	1	1	
Total	203	213	
TOTAL	5235	5793	90.4%

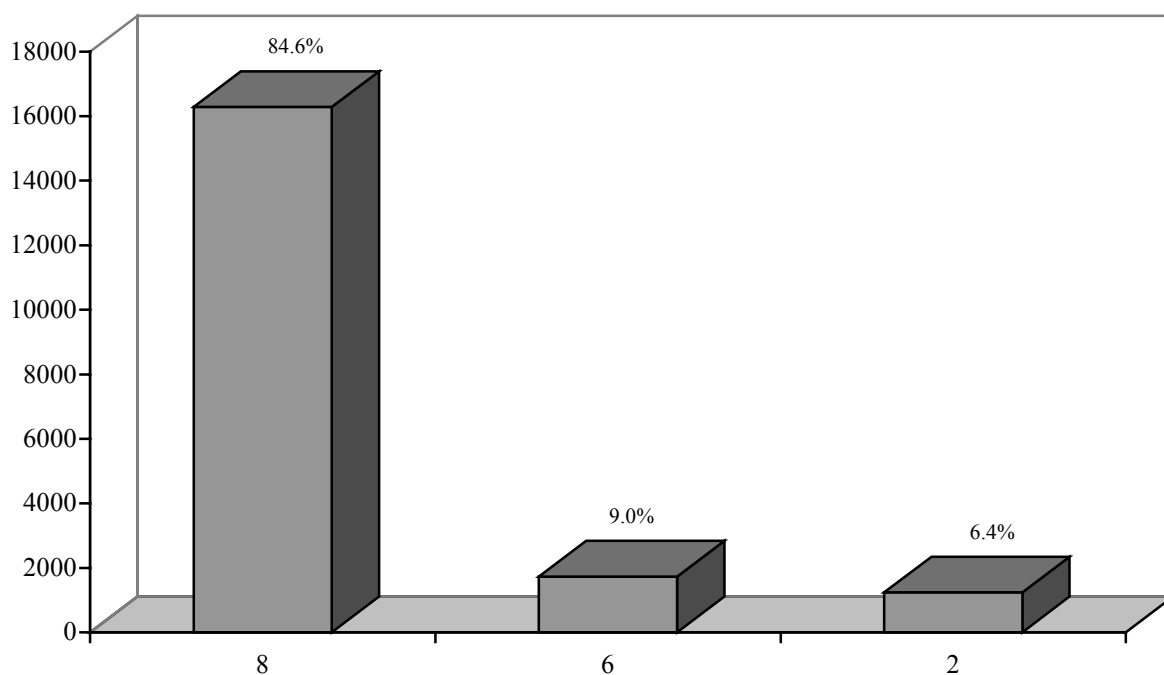
A data check is in progress for support above 100.0%.

2. Quality of data

The reliability of data provided by the units is assessed at the time they are inserted into the databank. An index number between 2 (data missing or incongruent) and 8 (data complete and probable) is assigned to each admission form.

Number of arthroplasty operations carried out on patients with admission date between 1st January 2000 and 30th September 2002.

Quality	Number operations	Percentage
8	16.286	84.6%
6	1.729	9.0%
2	1.239	6.4%
Total	19.254	100.0%



The quality of the data supplied to RIPO is much better than that of past years, although it would be desirable that all the units fill in the form as clearly and fully as possible. The use of self-adhesive labels describing the prostheses enables unequivocal identification of the implant and the registration of the production batch. In 2000 only 70% of the data supplied to RIPO was of satisfactory quality, in 2002 this percentage was much higher, 93%.

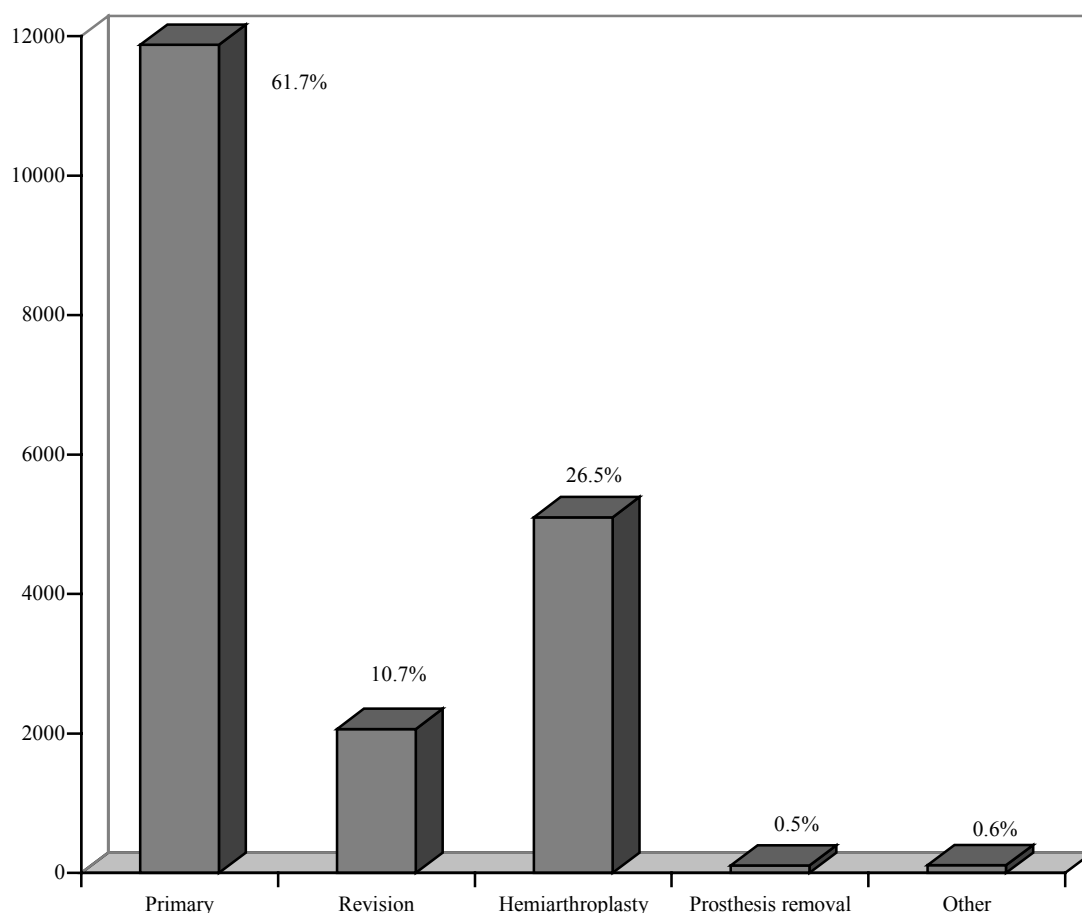
3. Type of operation

Number of arthroplasty operations carried out on patients with admission date between 1st January 2000 and 30th September 2002, according to *type*.

Type of operation	Number of operations	Percentage
Primary	11.876	61.7%
Revision*	2.063	10.7%
Hemiarthroplasty	5.101	26.5%
Prosthesis removal	105	0.5%
Other**	109	0.6%
Total	19.254	100.0%

* 835 total revisions, 840 cup revisions, 275 stem revisions, 108 head revisions 5 hemiarthroplasty.

** Including 61 luxation reductions, 20 debridements, 2 hematoma drains, 3 ossification removals, 5 fixation device removals, and 4 partial prosthesis removals.



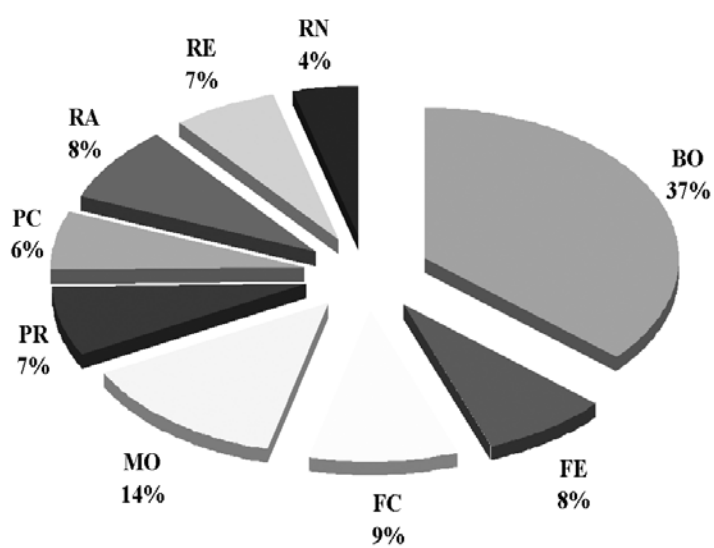
Reimplantation includes both revision operations of both components and partial revisions.

The percentage distribution of primary total arthroplasties remained constant throughout the three years.

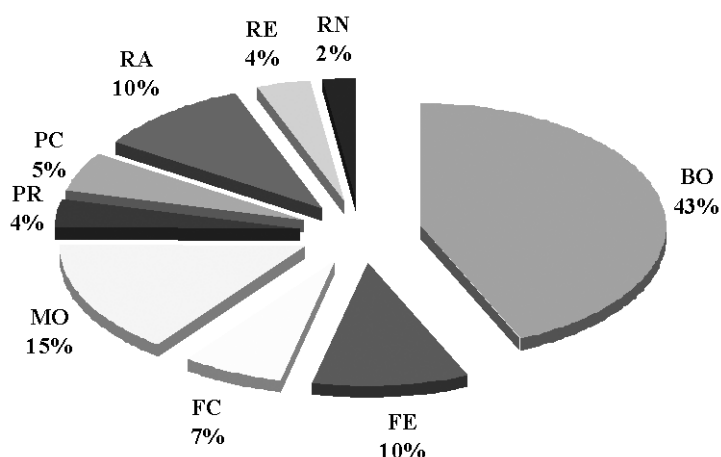
Number of arthroplasty operations carried out on patients with admission date between 1st January 2000 and 30th September 2002, according to *type* and *province*.

Province	Primary	Revision	Hemiartroplasty	Prosthesis removal	Other	Total
Bologna	4.319	895	1.295	85	80	6.674
Ferrara	971	211	505	3	2	1.692
Forlì-Cesena	1.122	140	348	2	2	1.614
Modena	1.587	306	753	5	7	2.658
Parma	890	74	384	1	3	1.352
Piacenza	742	109	302	4	9	1.166
Ravenna	958	206	609	1	4	1.778
Reggio Emilia	800	79	595	3	2	1.479
Rimini	487	43	310	1	-	841
Total	11.876	2.063	5.101	105	109	19.254

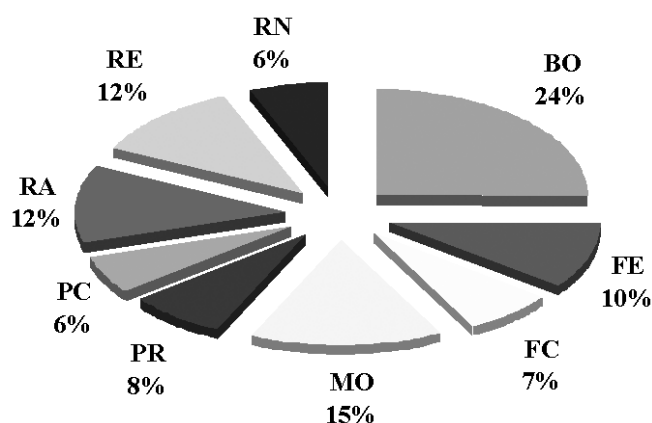
Percentage distribution of **primary arthroplasty operations** in the provinces of Emilia Romagna:



Percentage distribution of **revision operations** in the provinces of Emilia Romagna:



Percentage distribution of **hemiarthroplasty** in the provinces of Emilia Romagna:



The percentages indicated at the side of each “slice” are calculated in relation to the total number of operations of that type carried out in the region.

Is evident that about 43.0% of revisions are carried out in the province of Bologna.

In the provinces of Piacenza and Ravenna the lowest number of hemiarthroplasty operations is carried out.

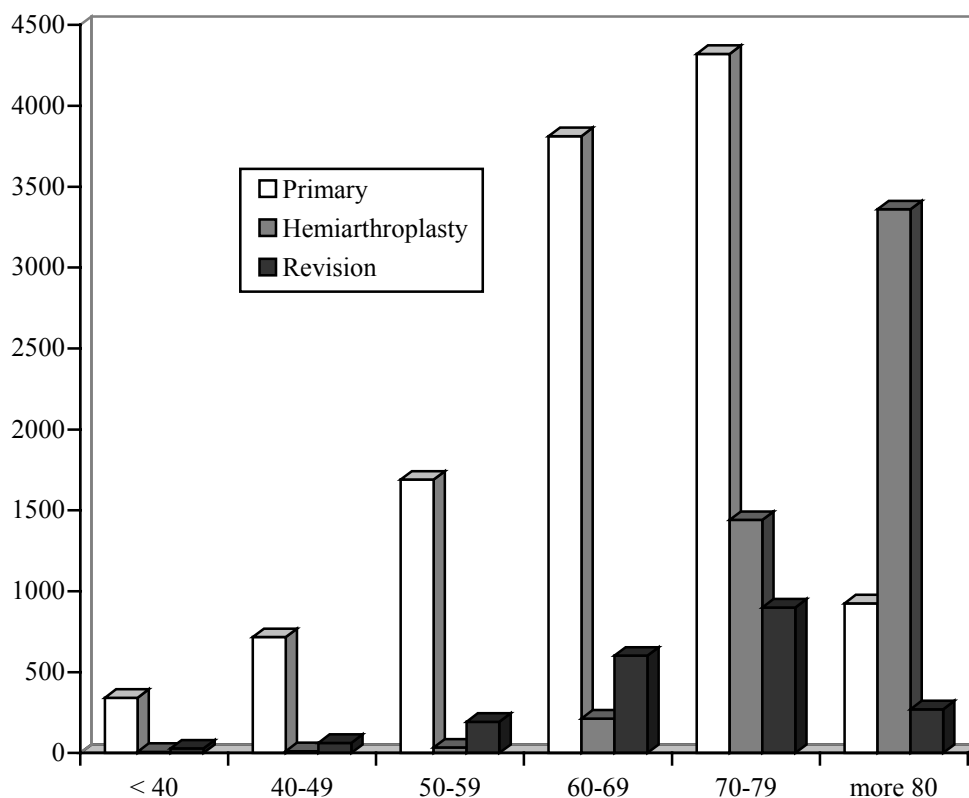
The data are absolute and not normalized by number of residents.

4. Descriptive statistics of patients

4.1. Age

Number of arthroplasty operations carried out on patients with admission date between 1st January 2000 and 30th September 2002, according to *type of operation* and *age group* of patients at the time of surgery.

Type of operation	<40		40-49		50-59		60-69		70-79		≥ 80		Total
	N.	%	N.	%	N.	%	N.	%	N.	%	N.	%	
Primary	342	2.9	717	6.1	1690	14.3	3812	32.4	4320	36.5	925	7.8	11.806
Revision	7	0.2	11	0.2	34	0.7	213	4.2	1441	28.4	3360	66.3	5.066
Hemiartroplasty	28	1.4	63	3.1	193	9.4	602	29.2	900	43.7	271	13.2	2.057
Prosthesis removal	-	-	8	7.6	9	8.6	31	29.5	42	40.0	15	14.3	105
Other	4	3.6	3	2.7	19	17.5	30	27.5	32	29.4	21	19.3	109
Total*	381		802		1945		4.688		2.735		4.592		19.143



* In 111 cases (0.6%) the data were not supplied to RIPO

The **hemiarthroplasty** were mostly, but not exclusively, implanted in persons over the age of eighty. The percentage of patients over 80 treated by hemiarthroplasty was stable throughout the three-year analysis of the register (22.7% in 2000, 24.6% in 2001 and 24.3% in 2002).

The percentage of patients under 50 treated by arthroplasty was also stable (6.2%).

Type of operation	Mean age	Range
Primary	66.2	14-100 years
Revision	69.5	22-100 years
Hemiarthroplasty	82.3	23-104 years
Prosthesis removal	69.3	43-96 years
Other	68.9	20-96 years
General	70.8	14-104 years

The mean age of patients undergoing hemiarthroplasty is much higher than those undergoing arthroplasty, although the range is similar.

The following tables show the mean age divided according to the year of surgery. The data appear stable.

Primary arthroplasty for arthritis		
	Mean age	Range
Year 2000	68.3	31-100 years
Year 2001	68.8	16-99 years
Year 2002	68.8	32-100 years

Hemiarthroplasty due to fracture		
	Mean age	Range
Year 2000	82.4	32-104 years
Year 2001	82.4	39-101 years
Year 2002	82.5	27-102 years

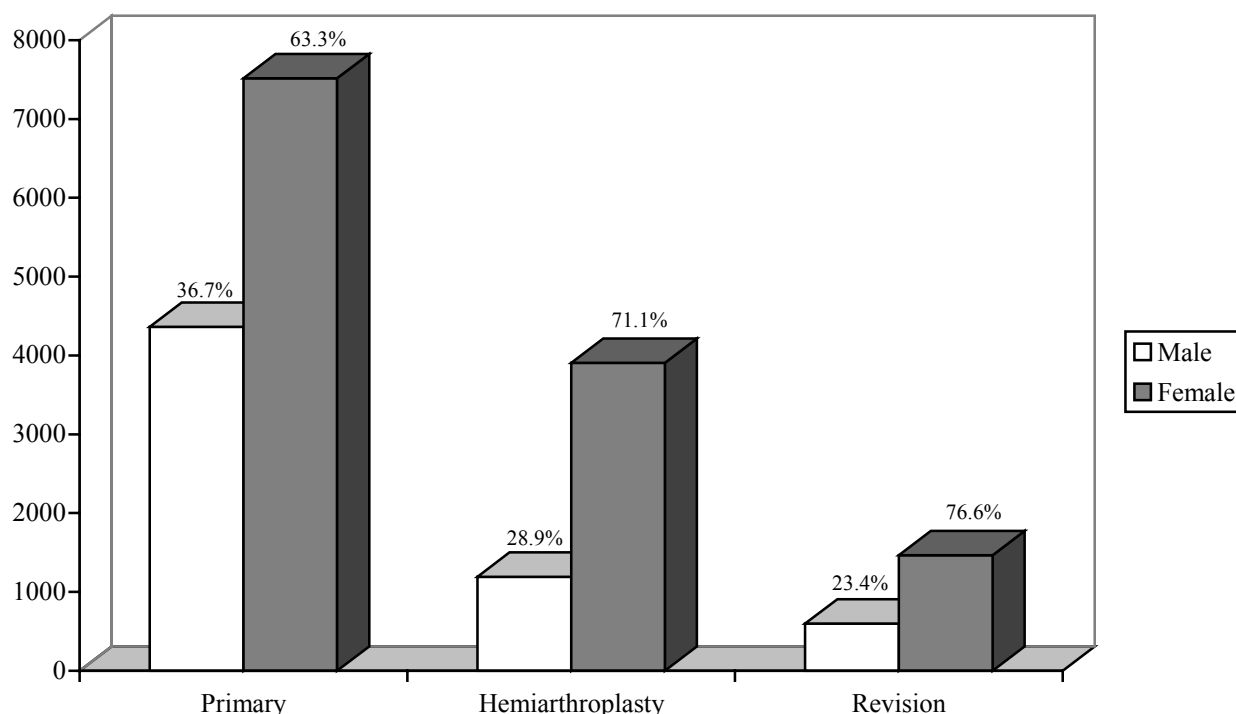
With similar diseases, the choice of treatment is different according to the patient's age.

Prosthesis due to femoral neck fracture		
	Mean age	Range
Arthroprosthesis	70.2	19-98 years
Hemiarthroplasty	82.4	27-104 years

4.2. Sex

Number of arthroplasty operations carried out on patients with admission date between 1st January 2000 and 30th September 2002, according to *type of operation* and *sex* of patient.

Type of operation	Male	Female	Total
Primary	4.361	7.515	11.876
Revision	1.194	3.907	5.101
Hemiartroplasty	598	1.465	2.063
Prosthesis removal	38	67	105
Other	69	40	109
Total	6.260	12.994	19.254



The female sex is more affected by diseases that require operations of arthroplasty and hemiartroplasty, due to their predisposition to coxarthrosis and osteoporosis, and longer life expectancy.

This datum also appears to be stable: in the three years of the register, women have accounted for 68.1%, 67.3% and 67.5% of all patients undergoing hip arthroplasty.

Regarding only *hemiartroplasty*, the percentage of women was 77.9% in 2000, 76.2% in 2001 and 75.5% in 2002, with a slightly negative trend.

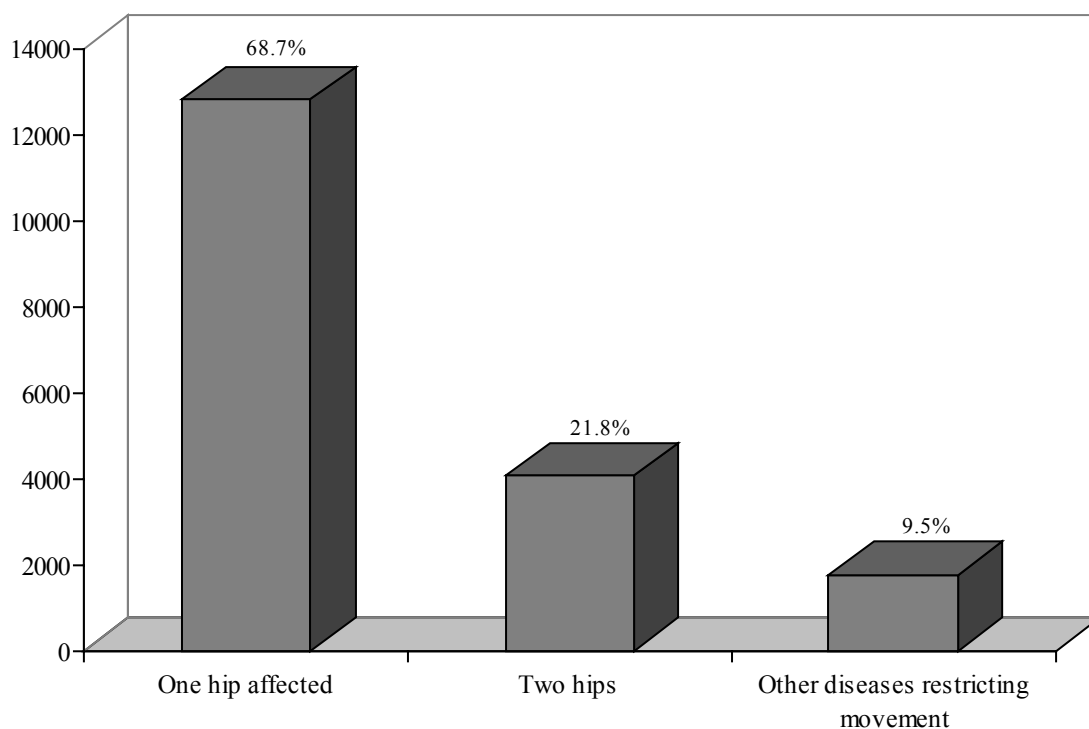
Concerning *primary arthroplasty* the female sex accounted for 64.0% of cases in 2000, 62.4% in 2001 and 63.7% in 2002.

4.3. Clinical condition

Number of arthroplasty operations carried out on patients with admission date between 1st January 2000 and 30th September 2002, according to *clinical condition* of patients at the time of surgery

Clinical condition	Number	Percentage
One hip affected	12.814	68.7%
Two hips affected	4.070	21.8%
Other diseases restricting movement	1.775	9.5%
Total*	18.659	100.0%

* 595 cases (3.1%) were not reported to RIPO.



Percentages have not changed compared to last year.

The following table indicates the clinical condition of patients admitted to public and private hospitals, and scientific institutions for primary arthroplasty or revision surgery.

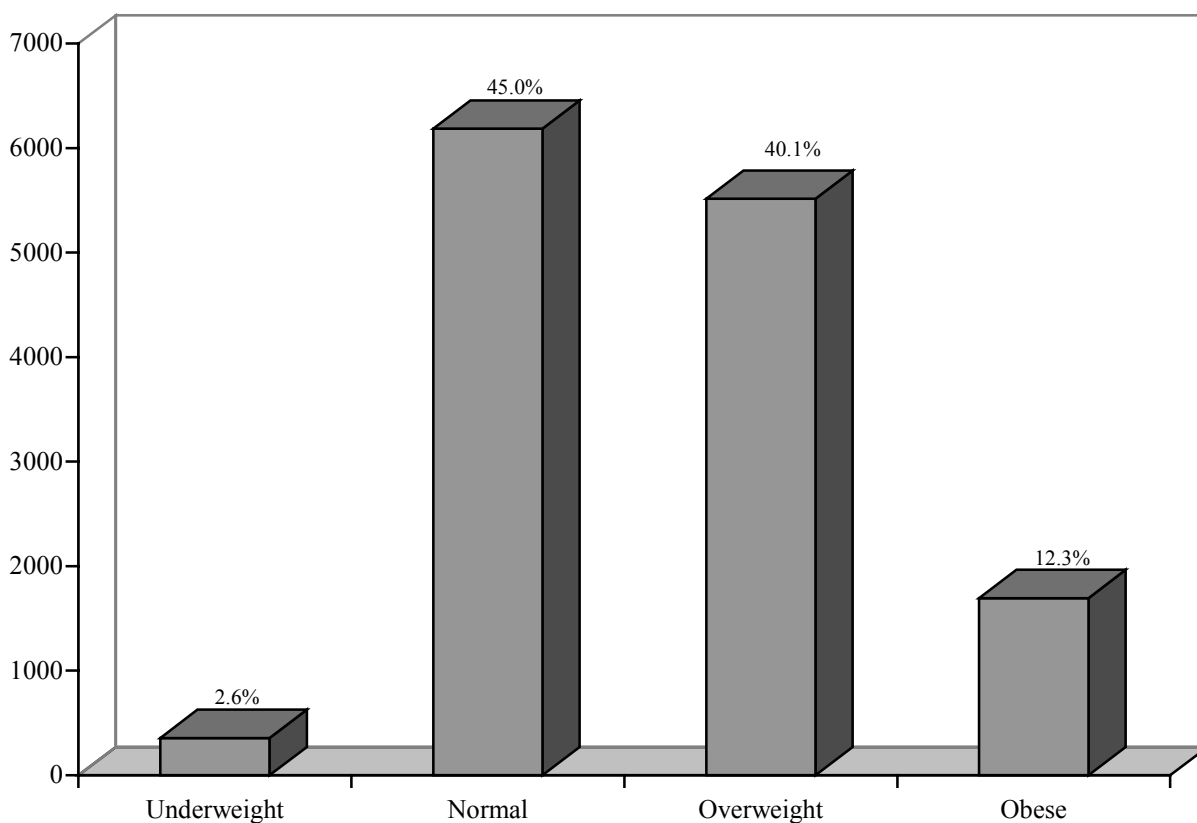
Clinical condition	Public	Private	I.O.R
One hip affected	73.9%	63.8%	63.9%
Two hips affected	16.9%	30.5%	28.1%
Other diseases restricting movement	9.2%	5.7%	8.0%
Total	100.0%	100.0%	100.0%

4.4. Body mass index

Number of arthroplasty operations carried out on patients with admission date between 1st January 2000 and 30th September 2002, according to *body mass index* of patients at the time of surgery.

Body Mass Index	Number	Percentage
Underweight (≤ 19)	356	2.6%
Normal (20-25)	6.186	45.0%
Overweight (26-29)	5.515	40.1%
Obese (≥ 30)	1.695	12.3%
Total*	13.752	100.0%

* 5,502 cases (28.6%) were not reported to RIPO



Underweight and obesity, calculated according to BMI [weight in kg/(height in meters)²], are characteristics found in more than 50% of patients undergoing hip arthroplasty.

This information, however, is not completely reliable due to the high percentage of values not supplied to RIPO (more than a quarter of the total).

With regards to this, it should be noticed how absolutely objective data, and not subject to intraregional variability, is widely missing. For example, obese people account for only 4% of patients undergoing hip arthroplasty in the public hospital of one province, and as much as 20% in the public hospital of a neighboring one.

4.5. *Diagnosis according to operation*

Number of primary arthroplasty operations carried out on patients with admission date between 1st January 2000 and 30th September 2002, according to *diagnosis*.

Diagnosis in primary arthroplasty	Number	Percentage
Primary arthritis	7.756	65.3%
Sequelae of LCA and DCA	1.586	13.4%
Femoral neck fracture	1.116	9.4%
Femoral head necrosis (idiopathic, due to dialysis, due to steroids)	621	5.2%
Post traumatic arthritis	273	2.3%
Rheumatic arthritis	190	1.6%
Post traumatic necrosis	186	1.6%
Epiphysiolysis sequelae	27	0.2%
Perthes disease sequelae	21	0.2%
Tumor	20	0.2%
Septic coxitis sequelae	14	0.1%
TBC coxitis sequelae	10	0.1%
Paget's disease sequelae	7	0.1%
Other	41	0.4%
Total*	11.868	100.0%

* 8 data missing, equal to 0.004% of the series

Diagnosis in primary arthroplasty	Percentage		
	Year 2000	Year 2001	Year 2002
Primary arthritis	66.8%	65.1%	63.6%
Sequelae of LCA and DCA	13.5%	13.3%	13.1%
Femoral neck fracture	9.0%	9.1%	9.3%
Femoral head necrosis idiopathic	4.8%	5.3%	5.0%
Post traumatic arthritis	2.1%	2.1%	2.7%
Post traumatic necrosis	1.3%	1.5%	2.0%
Rheumatic arthritis	1.4%	1.6%	1.4%
Other	1.1%	2.0%	2.9%

Percentage distribution is similar over the three years

Notice a slight increase in arthroplasties performed for post-traumatic diseases from 3.4% to 4.7%.

With regards to distribution of diseases according to type of healthcare center, Hospital Agencies and Local Health Agencies have similar percentages, and they treat a high number of femur fractures, unlike the private centers. Rizzoli has a high percentage of treatment for sequelae of congenital and infant diseases and for traumas.

Diagnosis in primary arthroplasty	Percentage			
	AOSP	Private	AUSL	I.O.R
Primary arthritis	65.8%	75.5%	65.2%	54.7%
Sequelae of LCA and DCA	12.9%	11.1%	11.3%	21.4%
Femoral neck fracture	11.6%	1.3%	12.6%	6.4%
Femoral head necrosis idiopathic	4.2%	5.4%	5.4%	4.2%
Post traumatic arthritis	1.5%	2.3%	1.3%	5.4%
Post traumatic necrosis	0.9%	1.2%	1.6%	2.3%
Rheumatic arthritis	1.4%	1.6%	1.0%	2.7%
Other	1.7%	1.6%	1.6%	2.9%

Number of hemiarthroplasty carried out on patients admitted to hospital between 1st January 2000 and 30th September 2002, according to *diagnosis*.

Diagnosis in hemiarthroplasty	Number	Percentage
Femoral neck fracture	4.995	98.1%
Tumor, pathological fracture	41	0.8%
Primary arthritis*	21	0.4%
Post traumatic arthritis*	9	0.2%
Sequelae femoral neck fracture	7	0.1%
Other	18	0.4%
Total**	5.091	100.0%

* data not fully reliable

** 10 data missing, equal to 0.2% of the series.

Almost all hemiarthroplasty were implanted in the treatment of femoral neck fractures or their sequelae. The treatment of primitive or secondary coxarthrosis seems unlikely.

The treatment of femoral neck fracture, in patients matched for age, differs between public centers (AOSP and AUSL) and IOR (Istituto Ortopedico Rizzoli). In the former hemiarthroplasty is preferred, while in the latter about a third is treated by total joint arthroplasty. Relatively few fractures are treated in private centers, therefore, comparison cannot be performed.

Distribution of percentage of patients affected by femoral neck fracture, according to *type of operation* and *healthcare center*.

Type of operation	Percentage			
	AOSP	Private	AUSL	I.O.R
Primary	13.5%	51.7%	17.6%	27.9%
Hemiarthroplasty	86.5%	48.3%	82.4%	72.1%
Patients mean age	80.0 years	75.7 years	80.4 years	80.4 years

Number of revision operations carried out on patients admitted between 1st January 2000 and 30th September 2002, according to *diagnosis*.

Diagnosis in revision surgery	Number	Percentage
Total aseptic loosening	708	34.5%
Cup aseptic loosening	657	32.0%
Stem aseptic loosening	233	11.3%
Prosthesis luxation	119	5.8%
Prosthesis removal	53	2.6%
Septic loosening	38	1.8%
Bone fracture	33	1.6%
<i>Hemiartroplasty stem loosening</i>	54	2.7%
Pain without loosening	27	1.3%
Prosthesis breakage	26	1.3%
<i>Acetabular osteitis</i>	20	1.0%
<i>Hemiartroplasty luxation</i>	19	0.9%
Polyethylene wear	14	0.7%
<i>Pain without hemiarthroplasty loosening</i>	6	0.3%
Insert breakage	4	0.2%
Other (ossifications, trauma, fracture...)	42	2.0%
Total*	2.053	100.0%

* 10 data missing, equal to 0.5% of the series of revision operations

In italics the cause of hemiarthroplasty revision

On the whole, aseptic loosening is the cause of more than 77% of revisions carried out in the region.

Septic loosening, although limited to 1.8%, represents a worrying figure, especially considering that even revisions performed for “prosthesis removal” may be due to infection.

However, it should be highlighted that many revisions are performed on patients who undergo primary arthroplasty in other regions.

5. Types of prostheses

The following tables show the types of prostheses (cups, stems and hemiarthroplasty) commonly used in Emilia-Romagna, according to primary and revision surgery.

Cups used in *primary surgery*

TYPE OF CUP	NUMBER	%
ANCA FIT – Cremascoli	2.858	24.1%
CLS – Sulzer	1.193	10.0%
FITMORE – Sulzer	736	6.2%
ABG II – Howmedica	628	5.3%
STANDARD CUP – Sulzer	604	5.1%
DUOFIT PSF – Samo	596	5.0%
MULLER – Cremascoli	498	4.2%
TRILOGY – Zimmer	444	3.7%
REFLECTION – Smith & Nephew	362	3.0%
ABG – Howmedica	326	2.7%
ELLIPTICAL CUP – Stratec	257	2.2%
CONTEMPORARY – Howmedica	243	2.0%
MULLER – Samo	233	2.0%
MULLER – Sulzer	231	1.9%
ZCA – Zimmer	207	1.7%
SECUR-FIT – Osteonic	162	1.4%
OSTEOLOCK – Howmedica	157	1.3%
METASUL STAR CUP – Sulzer	144	1.2%
BICON-PLUS – Endoplus	125	1.1%
DURALOC – DePuy	122	1.0%
ALBI – Cremascoli	112	0.9%
SPH CONTACT – Lima	110	0.9%
MULLER – Smith & Nephew	104	0.9%
EASY – Hit Medica	94	0.8%
MARBURG – Allopro Sulzer	84	0.7%
MULLER – Lima	75	0.6%
SPH PEG – Lima	71	0.6%
CFP – Link	62	0.5%
HILOCK LINE – Symbios	47	0.4%
RAC CEDIOR – Sulzer	45	0.4%
INTERSEAL – Wright	41	0.3%
S II – Link	38	0.3%
VITALOCK CLUSTER – Howmedica	34	0.3%
CBF – Mathys	33	0.3%
MC MINN – Link	33	0.3%
MULLER – Hit Medica	33	0.3%
VITALOCK TALON – Howmedica	30	0.3%
UNKNOWN	35	0.3%
TOTAL	11.207	94.4%

The remaining 669 cups (5.6%) were of 45 different types, with less than 30 per type. This number also includes 21 **surface coatings**.

On the whole, 83 different types of cups were used in primary operations.

Cups used in *total revision surgery*

<i>TYPE OF CUP</i>	<i>NUMBER</i>	<i>%</i>
ANCA FIT – Cremascoli	160	19.2%
STANDARD CUP – Sulzer	87	10.4%
MULLER – Sulzer	57	6.8%
CONTEMPORARY – Howmedica	56	6.7%
TRILOGY – Zimmer	46	5.5%
LOR – Allopro Sulzer	33	4.0%
MULLER – Cremascoli	30	3.6%
OSTEOLOCK – Howmedica	29	3.5%
FITMORE – Sulzer	25	3.0%
SECUR–FIT – Osteonic	25	3.0%
MULLER – Samo	24	2.9%
CLS – Sulzer	21	2.5%
PROCOTYL–E – Cremascoli	21	2.5%
HAC CERAFIT CUP – Ceraver Osteal	20	2.4%
MC MINN – Link	18	2.2%
CONICAL SCREW CUP – Protek	15	1.8%
TOTAL	667	79.9%

The remaining 168 cups (20.1%) were of 40 different types, with less than 15 per type.

On the whole, 57 different types of cups were used in revision surgery.

Stems used in *primary surgery*

<i>TYPE OF STEM</i>	<i>NUMBER</i>	<i>%</i>
AnCA FIT – Cremascoli	1.902	16.0
CLS – Sulzer	1.325	11.2
CONUS – Sulzer	1.069	9.0
ABG – Howmedica	592	5.0
MERIDIAN – Howmedica	501	4.2
ABG II – Howmedica	432	3.6
SPECTRON – Smith & Nephew	350	2.9
MRL – Cremascoli	339	2.9
EXETER – Howmedica	318	2.7
VERSYS CEMENTED LD – Zimmer	265	2.2
P507 – Samo	254	2.1
JVC – Cremascoli	241	2.0
VERSYS FIBER METAL TAPER – Zimmer	237	2.0
AD – Samo	215	1.8
AnCA–FIT CLU – Cremascoli	202	1.7
ULTIMA – DePuy	197	1.7
LC – Samo	197	1.7
DEFINITION – Howmedica	188	1.6
PROXILOCK FT – Stratec	187	1.6
AHS – Cremascoli	187	1.6
SL PLUS – Endoplas	179	1.5
SYNERGY – Smith and Nephew	164	1.4
EURO HIP SYSTEM – Cremascoli	155	1.3
STEM – Cremascoli	150	1.3
DUOFIT RKT – Samo	143	1.2
LUBINUS SP2 – Link	128	1.1
MS 30 – Sulzer Protek	122	1.0
C 2 – Lima	112	0.9
BASIS – Smith & Nephew	100	0.8
PROFEMUR – Cremascoli	90	0.8
CORAIL – DePuy	89	0.7
EASY – Hit Medica	85	0.7
AnCA – Cremascoli	84	0.7
CITATION – Howmedica	77	0.6
PERFECTA – Wright	66	0.6
CFP – Link	58	0.5
VERSYS CEMENTED – Zimmer	54	0.5
C STEM – Depuy	54	0.5
SL – Lima	54	0.5
G3 – Citieffe	51	0.4
OMNIFLEX – Osteonics	48	0.4
BHS – Smith & Nephew	47	0.4
PPF – Stratec	44	0.4
FULLFIX – Mathys	40	0.3

(continues)

<i>TYPE OF STEM</i>	<i>NUMBER</i>	<i>%</i>
MULLER AUTOBLOCCANTE – Sulzer	38	0.3
CBC – Mathys	37	0.3
AC – Howmedica	35	0.3
SL REVISION – Sulzer	33	0.3
ALLOCLASSIC SL – Allopro Sulzer	30	0.3
S.ROM – Johnson & Johnson	30	0.3
SL – Hit Medica	30	0.3
VERSYS HERITAGE – Zimmer	30	0.3
TOTAL	11.655	98.1%

The remaining 221 stems (1.9%) were of 55 different types, with less than 30 per type. On the whole 110 different types of stem were used in primary surgery.

Stems used in total revision surgery

<i>TYPE OF STEM</i>	<i>NUMBER</i>	<i>%</i>
PROFEMUR – Cremascoli	219	26.2%
SL REVISION – Sulzer	178	21.3%
RESTORATION T3 – Howmedica	38	4.6%
AnCA FIT – Cremascoli	35	4.2%
S.ROM – Johnson and Johnson	34	4.1%
CONUS – Sulzer	30	3.6%
MP RECONSTRUCTION – Link	26	3.1%
ZMR – Zimmer	23	2.8%
AnCA – Cremascoli	22	2.6%
AD – Samo	17	2.0%
EXETER – Howmedica	16	1.9%
CLS – Sulzer	15	1.8%
JVC – Cremascoli	13	1.6%
CBK – Mathys	13	1.6%
C2 – Lima	11	1.3%
CONELock REVISION – Stratec	10	1.2%
AnCA-FIT CLU – Cremascoli	10	1.2%
TOTAL	710	85.0%

The remaining 125 stems (15.0%) were of 50 different types, with less than 10 per type.

On the whole 71 different types of stems were used in primary surgery.

It should be pointed out that in 20% of primary operations **heads and stems manufactured by different companies** were implanted in the same operations.

HEMIARTROPLASTY

TYPE OF HEMIARTROPLASTY (cup + stem)	N.	%
SPERI-LOCK + SL –Hit Medica	572	11.2%
SPERI-LOCK + SPERI-SYSTEM II – Hit Medica	427	8.4%
HEAD BIARTICULAR + SL –Lima	419	8.2%
ULTIMA + ULTIMA LX – Johnson & Johnson	288	5.6%
CENTRAX + HIP FRACTURE – Howmedica	263	5.2%
CUP SEM + STEM SEM – D.M.O.	231	4.5%
CUP BIPOLAR + CCA Mathys	206	4.0%
RETENTIVE MOBILE CUP – Cedior + ORTHO-FIT – Allopro	194	3.8%
MODULAR BIPOLAR + STANDARD STRAIGHT – Protek	181	3.5%
C1 + AB – Citieffe	158	3.1%
BICENTRIC + RELIANCE Howmedica	150	2.9%
CUP MOBILE BIARTICULAR + SL – Permedica	148	2.9%
CUP MOBILE + AHS – Cremascoli	146	2.9%
HEAD ELLIPTIC + LC –Samo	125	2.5%
HEAD BIPOLAR + SL – Amplimedical	123	2.4%
SPERI-LOCK – Hit Medica + MRL – Cremascoli	107	2.1%
CUP MOBILE + MRL – Cremascoli	103	2.0%
CENTRAX + EXETER – Howmedica	75	1.5%
CUP MOBILE – Cremascoli + VERSYS – Zimmer	74	1.5%
CUP MOBILE TEKNO-FIN +STANDARD STRAIGHT – Protek	74	1.5%
C1 – Citieffe + DEON – Bioimpianti	59	1.2%
HEAD BIARTICULAR – Lima + SL –Hit Medica	58	1.1%
C1 – Citieffe + VERSYS – Zimmer	55	1.1%
RETENTIVE MOBILE CUP – Cedior + METABLOC – Protek	55	1.1%
JANUS + FIN – Bioimpianti	52	1.0%
JANUS Bioimpianti + SPERI-SYSTEM II – Hit Medica	43	0.8%
HEAD BIARTICULAR – Lima + ALBI PTC – Cremascoli	38	0.7%
BICONTACT AESCULAP + BICONTACT AESCULAP	35	0.7%
HEAD BIARTICULAR + DUOFIT CKA Samo	33	0.6%
HEAD BIARTICULAR – Lima + LOGICA LIMA	33	0.6%
CENTRAX + DEFINITION – Howmedica	30	0.6%
TOTAL	4.555	89.3%

The remaining 546 hemiarthroplasty (10.7%) were of 30 different types, with less than 30 for type.

In 8.5% of hemiarthroplasty operations the head and stem were from different manufacturers. In 2001 this percentage was 7.2%, in 2002 it increased to 9.1%.

In 26.4% of cases the hemiarthroplasty were composed of a stem and cup from different manufacturers.

The absolute number of *different models* of cups and stems used in **primary surgery** according to year. :

Year operations	Primary surgery	
	Stems	Cups
2000	93	87
2001	98	92
2002	94	90

Absolute number of different models of cups and stems used in **total revision surgery** according to year:

Year operations	Total revision surgery	
	Stems	Cups
2000	48	58
2001	55	64
2002	48	59

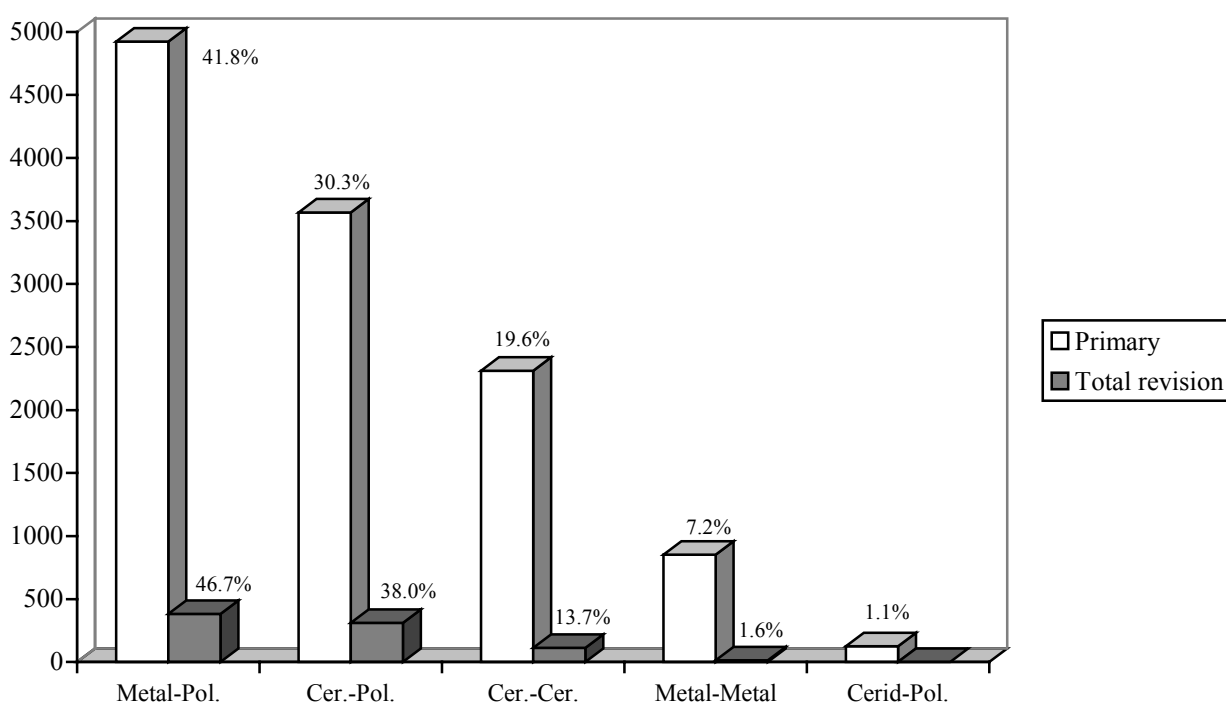
A marked dispersion of data is evident. The low number of the population homogeneous for the type of component implanted will make the statistical analysis of the efficacy of the device difficult.

In 12.7% of revision operations a *reinforcement ring* was used. The most commonly used reinforcement ring was the MULLER – Sulzer (38.9% of cases) followed by the Burch-Schneider – Sulzer (17.9%), and in the remaining 43.2% another type of ring was used.

Number of arthroplasty operations performed on patients admitted between 1st January 2000 and 30th September 2002, according *to type of operation* and *articular coupling*.

Coupling	Primary	Total revision
Metal-polyethylene	4.923	382
Ceramic-polyethylene	3.568	311
Ceramic-ceramic	2.312	112
Metal-metal	852	13
Cerid-polyethylene	125	-
Total*	11.780	818

* 96 missing data in the primary and 17 in the revision operations



Year operations	Primary surgery			
	met-pol	cer-pol	cer-cer	met-met
2000	45.2%		18.5%	7.1%
2001		31.6%		7.6%
2002	40.9%		21.0%	7.2%

During the three years there was a decrease in the number of metal-polyethylene couplings, and a slight increase in the number of ceramic-polyethylene and ceramic-ceramic couplings. The Cerid-polyethylene coupling does not appear in the table (55 cases in 2000, 50 in 2001, and 20 in 2002).

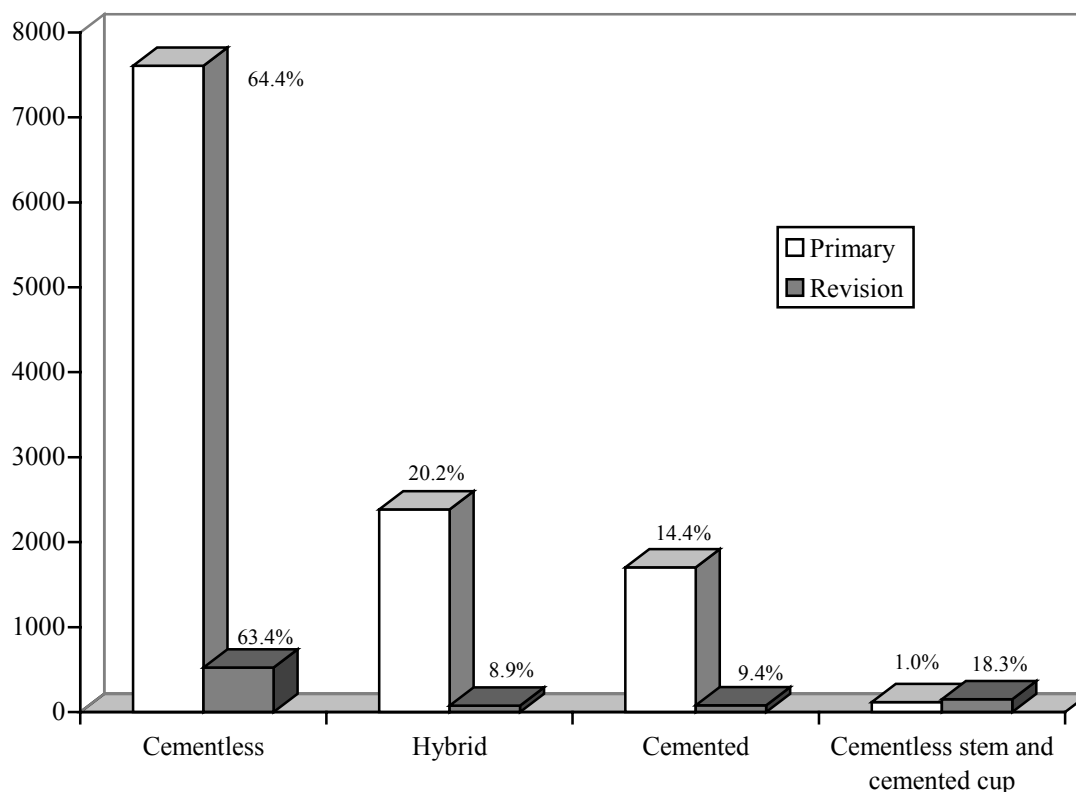
Year operations	Total revision surgery			
	met-pol	cer-pol	cer-cer	met-met
2000	47.0%	34.0%	18.0%	1.0%
2001	48.9%	38.6%	10.9%	1.6%
2002	42.4%	43.5%	11.5%	2.6%

In revision surgery there is a marked increase in the use of ceramic-polyethylene and a clear-cut drop in the use of ceramic-ceramic.

Number of arthroplasty operations on patients admitted between 1st January 2000 and 30th September 2002, according *to type of operation* and *fixation method*.

Fixation method	Primary	Total revision
Cementless prostheses	7.607	524
Hybrid (stem cemented and cementless cup)	2.387	74
Cemented prostheses	1.703	78
Cementless stem and cemented cup	116	151
Total*	11.813	827

* data not supplied in 63 primary operations and 8 revision operations.



Compared to previous years there is an increase in cementless fixation both in primary (60.2 to 64.4%) and revision (61.4 to 63.4%) surgery.

Year operations	Primary surgery			
	Cemented prostheses	Cementless prostheses	Hybrid	Cementless stem and cemented cup
2000	16.1%	59.9%	23.3%	0.7%
2001	14.4%	65.0%	19.6%	1.0%
2002	12.3%	69.6%	17.0%	1.1%

Year operations	Total revision surgery			
	Cemented prostheses	Cementless prostheses	Hybrid	Cementless stem and cemented cup
2000	11.1%	62.9%	10.0%	16.0%
2001	9.8%	63.2%	8.0%	19.0%
2002	6.2%	64.6%	8.7%	20.5%

The following table shows the **type of cement** used in primary surgery with at least one cemented component and in hemiarthroplasty (information recorded in RIPO from 30/09/2001).

Type of cement	Primary	Hemiarthroplasty
SURGICAL SIMPLEX P	32.6%	23.6%
AMPLICEM 3	20.0%	7.4%
CEMEX	15.7%	38.5%
PALACOS R	11.9%	3.8%
CMW 3	5.9%	5.8%
ANTIBIOTIC SIMPLEX	3.7%	0.8%
CEMEX RX	3.3%	9.6%
CEMFIX 3	1.4%	0.1%
CEMEX ISO	1.3%	0.1%
SULCEM 3	1.2%	2.1%
CEMFIX 1	0.7%	0.1%
SULCEM 1	0.7%	0.3%
CMW 1	0.4%	2.5%
AMPLICEM 1	0.3%	0.2%
CEMEX XL	0.3%	3.9%
OTHER	0.6%	1.2%
Total	100.0%	100.0%

Number of arthroplasty operations on patients admitted between 1st January 2000 and 30th September 2002, according *to type of operation* and *bone graft*.

Graft	Primary	Total revision	Cup revision	Stem revision	Total
Not used	11.401	482	495	244	12.622
Acetabular	418	313	330	7	1.068
Femoral	28	7	4	16	55
Both	29	33	11	8	81
Total	11.876	835	840	275	13.826

The most commonly used **surgical approaches** are lateral and postero-lateral.

70% of primary prostheses are implanted by lateral approach, and 24.2% by postero-lateral approach.

55.8% of hemiarthroplasty are implanted by lateral approach and 40% by postero-lateral approach.

6. Antibiotic prophylaxis

List of active principles used in preoperative antibiotic prophylaxis in cases of **primary arthroplasty**.

The number indicates the cases where the active principle was used alone or in combination:

Active principle	Number	Percentage
AMOXYCILLIN	255	2.1 %
AMOXYCILLIN + GENTAMICIN	261	2.2 %
AMPICILLIN	257	2.2 %
CEFAMANDOLE	133	1.1 %
CEFAMANDOLE + GENTAMICIN	112	0.9 %
CEFAMANDOLE + TOBRAMYCIN	107	0.9 %
CEFAZOLIN	2.587	21.8 %
CEFAZOLIN + GENTAMICIN	195	1.6 %
CEFAZOLIN + NETILMICIN	387	3.3 %
CEFAZOLIN + TOBRAMYCIN	1.516	12.8 %
CEFEPIME	298	2.5 %
CEFOTAXIME	431	3.6 %
CEFTAZIDIME	174	1.5 %
CEFTIZOXIME	474	4.0 %
CEFTRIAZONE	823	6.9 %
CEFTRIAZONE + TOBRAMYCIN	101	0.9 %
CEFUROXIME	1.081	9.1 %
CEFUROXIME + TOBRAMYCIN	66	0.6 %
CEFUROXIME + NETILMICIN	28	0.2 %
CIPROFLOXACIN	72	0.6 %
GENTAMICIN	282	2.4 %
PEFLOXACIN	94	0.8 %
TEICOPLANIN	333	2.8 %
TEICOPLANIN + NETILMICIN	265	2.2 %
TOBRAMYCIN	23	0.2 %
VANCOMICIN	329	2.8 %
VANCOMICIN + GENTAMICIN	328	2.8 %
VANCOMICIN + TOBRAMYCIN	108	0.9 %
OTHER	312	2.6 %
UNKNOWN*	444	3.7 %
TOTAL	11.876	100.0%

* In 444 cases, although antibiotic prophylaxis was carried out, the active principle used was not reported to the registry.

In 75% of cases only one active principle was used, in the remaining 25 % two or more were used.

List of active principles used in preoperative antibiotic prophylaxis in cases of **revision surgery**.

The number indicates the cases where the active principle was used alone or in combination:

Active principle	Number	Percentage
AMOXYCILLIN	43	2.1 %
AMOXYCILLIN + GENTAMICIN	41	1.9 %
AMPICILLIN	21	1.1%
CEFAMANDOLE	23	1.2 %
CEFAMANDOLE + GENTAMICIN	22	1.1 %
CEFAMANDOLE + TOBRAMYCIN	25	1.3 %
CEFAZOLIN	475	23.0 %
CEFAZOLIN + GENTAMICIN	17	0.8 %
CEFAZOLIN + NETILMICIN	32	1.5 %
CEFAZOLIN + TOBRAMYCIN	264	12.8 %
CEFEPIME	28	1.3 %
CEFOTAXIME	43	2.0 %
CEFTAZIDIME	8	0.4 %
CEFTIZOXIME	77	3.8 %
CEFTRIAZONE	115	5.6 %
CEFTRIAZONE + TOBRAMYCIN	29	1.5 %
CEFUROXIME	149	7.2 %
CEFUROXIME + TOBRAMYCIN	18	0.9 %
CIPROFLOXACIN	5	0.2 %
GENTAMICIN	31	1.7 %
PEFLOXACIN	6	0.3 %
PIPERACILLIN	4	0.2 %
TEICoplanin	92	4.5 %
TEICoplanin + LEVOFLOXACIN	17	0.8 %
TEICoplanin + NETILMICIN	48	2.2 %
VANCOMICIN	81	3.9 %
VANCOMICIN + GENTAMICIN	99	4.7%
VANCOMICIN + TOBRAMYCIN	41	1.9 %
UNKNOWN	148	7.3 %
OTHER	61	2.8 %
TOTAL	2.063	100%

In 65% of cases only one active principle was used, in the remaining 35% 2 or more were used.

Cefazolin, administered alone or in combination, is used in preoperative prophylaxis in 39.5% of primary arthroplasties and 38.1% of revision operations.

Ceftriaxone, administered alone or in combination, is used in preoperative prophylaxis in 7.8% of primary arthroplasties and 7.1 % of revision operations.

Prophylaxis is performed by **multiple administrations** in 80.6% primary arthroplasties, 82.2 % of hemiarthroplasty, and 81.7% of revision operations.

In the remaining percentages a single administration is used at the moment of induction.

7. Blood transfusion

Percentages of operations performed on patients admitted between 1st January 2000 and 30th September 2002, according *to type of operation and transfusion*.

	None	Autologous	Homologous	Autologous and Homologous	Missing data
Emergency primary	24.1%	2.5%	37.5%	1.0%	34.9%
Elective primary	10.1%	37.6%	12.6%	4.1%	35.6%
Revision	6.8%	21.4%	26.5%	9.8%	35.5%

The analysis can be falsified by a significant percentage of missing data (more than a third). However, it seems evident that homologous blood is used in about one out of five primary operations and one out of three revision operations.

In the following tables the analysis was carried out according to type of operation and healthcare center. The uncertainty in interpreting the information remains, due to the very high percentage of missing data.

Emergency primary					
	None	Autologous	Homologous	Autologous and Homologous	Missing data
AOSP	26.2%	2.4%	31.2%	0.2%	40.0%
Private	3.3%	16.7%	53.3%	0.0%	26.7%
AUSL	24.3%	2.5%	38.0%	4.2%	34.0%
IOR	24.3%	1.7%	48.0%	0.4%	24.9%

Elective primary					
	None	Autologous	Homologous	Autologous and Homologous	Missing data
AOSP	9.2%	40.9%	5.8%	0.4%	43.7%
Private	8.1%	35.8%	15.2%	2.7%	38.1%
AUSL	0.2%	39.9%	12.7%	6.5%	40.7%
IOR	13.9%	48.8%	17.4%	3.5%	16.4%

Revision					
	None	Autologous	Homologous	Autologous and Homologous	Missing data
AOSP	7.0%	34.9%	15.1%	5.8%	37.2%
Private	3.2%	18.5%	29.1%	8.5%	40.7%
AUSL	6.3%	22.5%	22.3%	12.9%	36.0%
IOR	15.3%	20.1%	33.6%	7.0%	24.0%

8. Complications

The rate of complications in prosthetic surgery carried out on patients hospitalized between January 1st 2000 and September 30th 2002.

Complications observed during hospitalization								
Intra-operative			Post-operative local			Post-operative general		
Complication	N.	%	Complication	N.	%	Complication	N.	%
Calcar fracture	64	0.3	Hematoma	175	0.9	Anemia	113	0.6
Diaphyseal fracture	50	0.3	Prosthesis dislocation	110	0.6	Respiration	74	0.4
Anesthesiologic complications	32	0.2	SPE paralysis	39	0.2	Cardiovascular	54	0.3
Other fractures	26	0.1	Thrombophlebitis	35	0.2	Hyperpyrexia	48	0.2
Others	53	0.3	Infection	16	0.1	Collapse	38	0.2
			Crural paralysis	10	0.1	Genito-urinary	30	0.2
			Bed sores	10	0.1	Gastro-intestinal	15	0.1
			Other	43	0.2	Ischemia	7	0.04
						Other	151	0.8
Total	225	1.2	Total	438	2.3	Total	530	2.8

The complications recorded refer only to those that occurred during hospitalization. No variations were observed compared to last year. Among postoperative complications, anemia was interpreted differently by different Centers. To make the data more objective, the information requested from the Centers was integrated with the blood transfusions according to the previous section.

Distribution of complications according to type of operation

	Primary (1.1876)		Revision (2.063)		Hemiartroplasty (5.101)		Total
Intra-operative	117	1.0%	55	2.7%	53	1.0%	225
Post-operative local	283	2.4%	64	3.1%	91	1.8%	438
Post-operative general	234	2.0%	49	2.4%	247	4.8%	530
Death	24	0.2%	7	0.3%	107	2.1%	138

Number of deaths in prosthetic surgery on patients hospitalized between January 1st 2000 and September 30th 2002 (the deaths recorded are those that occurred during hospitalization).

Year 2000			
Type of operation	Deaths	Number of operations	Percentage
Primary	8	4.199	0.2%
Hemiartroplasty	44	1.730	2.5%
Revision	1	676	0.1%
Prosthesis removal	-	35	-

Year 2001			
Type of operation	Deaths	Number of operations	Percentage
Primary	12	4.455	0.3%
Hemiartroplasty*	41	2071	2.0%
Revision	3	799	0.4%
Prosthesis removal	1	43	2.3%

1st January 2000 – 30th Sptember 2002			
Type of operation	Deaths	Number of operations	Percentage
Primary	4	3.222	0.1%
Hemiartroplasty	22	1.300	1.7%
Revision	3	588	0.5%
Prosthesis removal	1	27	3.7%

* 2 deaths occurred during operations to reduce hemiartroplasty displacement, carried out during implant recovery.

9. Duration of hospitalization

	Mean duration	Range duration	Preoperative mean duration	Preoperative duration range	Postoperative mean duration	Postoperative duration range
Primary	12.7	1-112	2.4	1-49	10.4	1-106
Revision	15.5	1-110	3.7	1-84	12.1	1-108
Hemiartroplasty	14.4	1-110	3.7	1-40	11.0	1-101
Prosthesis removal	22.0	6-82	6.3	1-39	16.0	4-73
Total	13.5	1-112	2.9	1-84	10.8	1-108

Postoperative hospitalization equal to 0 days occurs when the patient is transferred to another ward (intensive care).

Total hospitalization equal to 0 days occurs in operations carried out on patients staying in non-orthopedic wards, who return to their ward after surgery.

No variations are observed compared to last year.

The following tables show mean hospitalization divided according to year of surgery.

Elective primary			
	Number of cases	Mean Hospitalization	Range Hospitalization
Year 2000	3810	12.6	1-93
Year 2001	4029	12.4	1-112
Year 2002	2913	12.1	1-78

Emergency primary			
	Number of cases	Mean Hospitalization	Range hospitalization
Year 2000	377	15.7	4-66
Year 2001	420	16.4	4-87
Year 2002	319	15.5	5-46

Hemiartroplasty operations			
	Number of cases	Mean hospitalization	Range hospitalization
Year 2000	1710	14.6	1-96
Year 2001	2028	14.5	1-80
Year 2002	1257	13.9	1-57

Elective primary			
	Median hospitalization	Mean hospitalization	Range hospitalization
AOSP	12.0	12.7	1-55
IOR	12.0	12.7	3-76
AUSL	11.0	11.9	1-112
Private	12.0	13.0	1-107

10. Analysis of survival

The survival curves, calculated by the actuarial method can be constructed with respect to main factors connected to the patient (sex, age, bodyweight, disease), implants (fixation, joint coupling) and most common commercial model used.

In this phase of the study we were able to construct global survival curves, determine failure rates separately for primary prostheses and hemiarthroplasty, for single factors survival curves, calculated by the actuarial method, can be constructed in relationship to the main factors concerning the patient (sex, age, build, disease), the implants (fixation, joint coupling), and for the most commonly marketed models.

In this stage of the study some global survival curves were calculated and only the failure rates for some variables that can influence the outcome of the operation are reported.

The following table shows the number of primary joint arthroplasty operations performed in the period from January 2000 to September 2002 in the first column, the second and third columns show the number of revision operations performed on the same patients. Some revision operations were performed in the same hospital as the primary operation while others were performed at other hospitals in the Emilia-Romagna Region.

At present an indication, albeit partial, can be provided as to the efficacy of the total joint arthroplasty and hemiarthroplasty operations performed at the hospital.

	Number of operations	N. of revisions performed in the same hospital	N. of revisions performed in a different hospital
Primary	11.876	103	11
Hemiarthroplasty	5101	33	8
Total	16.977	136	19

In **9.6%** of the primary total prostheses that are replaced, the patient undergoes revision surgery in a different hospital from the one where the primary operation was performed. With regards to hemiarthroplasty, the percentage is **19.5%**.

The following table shows the *rate of revision* according to type of surgery:

Type of operation	Revision rate	Percentage
Primary	114/11876	1.0%
Hemiarthroplasty	41/5101	0.8%

10.1 Analysis of survival in primary total joint replacement

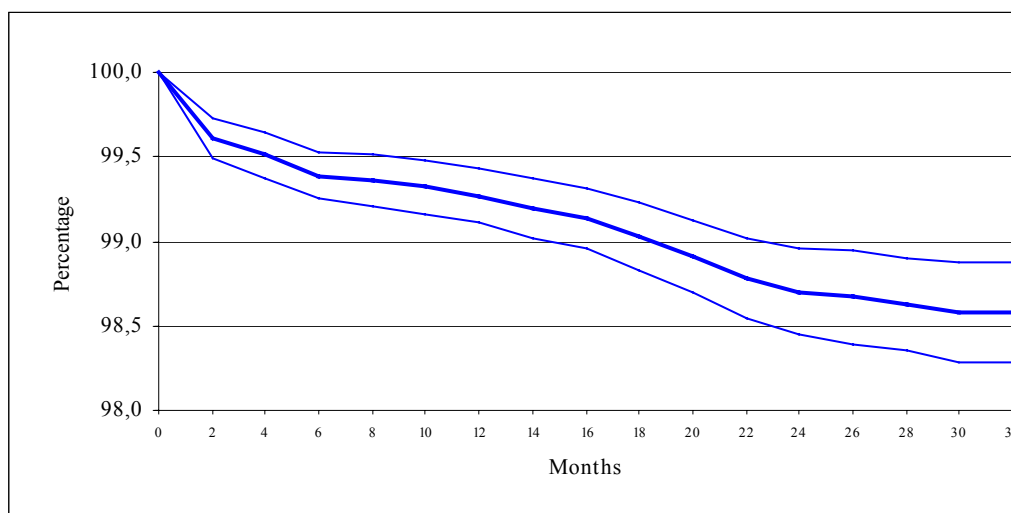
The following table shows the rate of revision in total joint replacement according to *cause of revision*:

Cause of revision	Rate	Percentage
Prosthesis luxation (within 60 days)	31/11876	0.26%
Prosthesis luxation (over 60 days)	15/11876	0.13%
Aseptic loosening of the cup	20/11876	0.17%
Aseptic loosening of the stem	18/11876	0.15%
Septic loosening	9/11876	0.08%
Bone fracture	6/11876	0.05%
Instability cup and/or stem	4/11876	0.03%
Global aseptic loosening	4/11876	0.03%
Breakage of prosthesis	2/11876	0.02%
Femoral diaphysis fracture	1/11876	0.01%
Calcar fracture	1/11876	0.01%
Pathologic fracture	1/11876	0.01%
Trauma	1/11876	0.01%
Insert loosening, head and neck	1/11876	0.01%

Table summarizing total joint arthroplasty operations

Number of arthroprosthesis	Removals
11.876	114

Survival curves



Results in detail

Months	% in site	c.i. at 95%	
2	99.61	99.49	99.73
4	99.51	99.37	99.65
6	99.39	99.25	99.53
12	99.27	99.11	99.43
24	98.7	98.45	98.95
32	98.58	98.29	98.87

The following table shows the rate of revision in total joint arthroplasty according to *patient's age*:

Age range	Number of operations	Removal	Rate	Percentage
<40	342	3	3/342	0.88%
40-49	717	10	10/717	1.40%
50-59	1690	16	16/1.690	0.95%
60-69	3812	39	39/3.812	1.0%
70-79	4320	32	32/4.320	0.74%
Oltre 80	925	14	14/925	1.5%

The following table shows the rate of revision in total joint arthroplasty according to *patient's sex*:

Sex	Number of operations	Removal	Rate	Percentage
Male	4361	43	43/4.361	0.99%
Female	7515	71	71/7.515	0.94%

The following table shows the rate of revision in total joint arthroplasty according to *diagnosis*:

Diagnosis in total joint arthroplasty	Number of operations	Removal	Rate	Percentage
Primary arthritis	7.756	56	56/7.756	0.7%
Sequela of LCA and DCA	1.586	19	19/1.586	1.2%
Femoral neck fracture	1.116	17	17/1.116	1.5%
Necrosis femoral head	621	4	4/621	0.6%
Post traumatic arthritis	273	3	3/273	1.1%
Rheumatic arthritis	190	6	6/190	3.2%
Post traumatic necrosis	186	5	5/186	2.7%
Sequela epifisiolysis	27	-	-	-
Sequela Perthes disease	21	-	-	-
Tumor	20	1	1/20	5.0%
Sequela septic coxitis	14	1	1/14	7.1%
Sequela coxitis TB	10	-	-	-
Sequela Paget's disease	7	-	-	-
Other	41	2	2/41	4.9%

The following table shows the rate of revision in total joint arthroplasty according to *joint coupling*.

Articular coupling	Number of operations	Removal	Rate	Percentage
Metal-polyethylene	4.923	47	47/4.923	0.95%
Ceramic-polyethylene	3.568	35	35/3.568	0.98%
Ceramic-ceramic	2.312	24	24/2.312	1.0%
Metal-metal	852	6	6/852	0.7%
Cerid-polyethylene	125	2	2/125	1.6%

The following table shows the rate of revision in total joint arthroplasty according to *joint coupling* and *cause of revision*

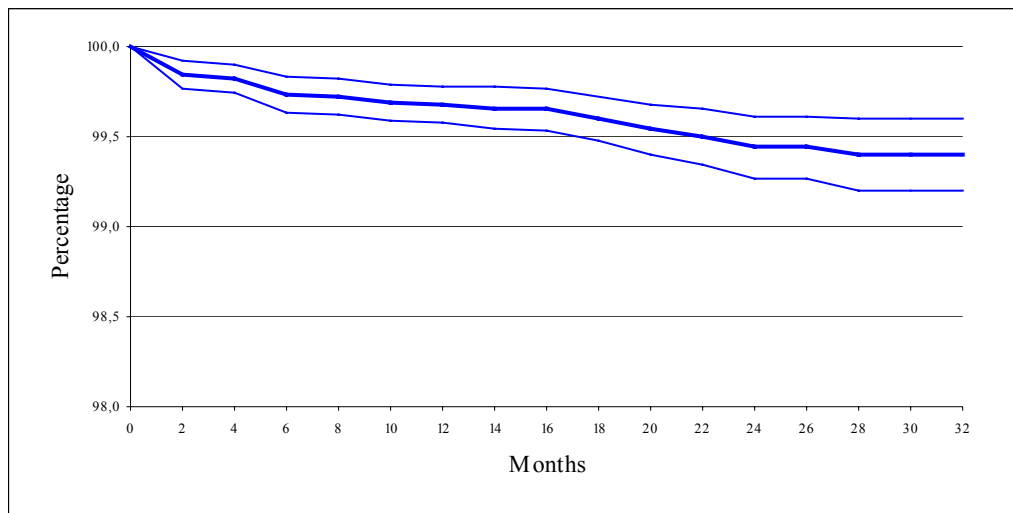
METAL-POLYETHYLENE		
Cause	Rate	Percentage
Prosthesis luxation (within 60 days)	15/4.923	0.3%
Prosthesis luxation (over 60 days)	5/4.923	0.1%
Aseptic loosening of the stem	8/4.923	0.16%
Septic loosening	4/4.923	0.08%
Instability cup and/or stem	3/4.923	0.06%
Global aseptic loosening	3/4.923	0.06%
Aseptic loosening of the cup	9/4.923	0.2%
CERAMIC-POLYETHYLENE		
Cause	Rate	Percentage
Prosthesis luxation (within 60 days)	9/3.568	0.25%
Prosthesis luxation (over 60 days)	7/3.568	0.20%
Aseptic loosening of the cup	7/3.568	0.20%
Septic loosening	4/3.568	0.11%
Aseptic loosening of the stem	3/3.568	0.08%
Bones fracture	2/3.568	0.06%
Instability cup and/or stem	1/3.568	0.03%
Trauma	1/3.568	0.03%
Loosening of the insert, head and neck	1/3.568	0.03%
CERAMIC-CERAMIC		
Cause	Rate	Percentage
Prosthesis luxation (within 60 days)	7/2.312	0.30%
Prosthesis luxation (over 60 days)	2/2.312	0.09%
Aseptic loosening of the cup	3/2.312	0.13%
Aseptic loosening of the stem	3/2.312	0.13%
Bones fracture	3/2.312	0.13%
Septic loosening	1/2.312	0.04%
Aseptic total loosening	1/2.312	0.04%
Breakage of prosthesis	1/2.312	0.04%
Femoral diaphysis fracture	1/2.312	0.04%
Calcar fracture	1/2.312	0.04%
Pathologic fracture	1/2.312	0.04%
METAL-METAL		
Cause	Rate	Percentage
Aseptic loosening of the stem	2/852	0.2%
Prosthesis luxation (over 60 days)	1/852	0.1%
Aseptic loosening of the cup	1/852	0.1%
Bones fracture	1/852	0.1%
Breakage of prosthesis	1/852	0.1%
CERID-POLYETHYLENE		
Cause	Rate	Percentage
Aseptic loosening of the stem	2/125	1.6%

10.1.1 Analysis of cup survival

Summary table: all cup models used

Number of arthroprosthesis	Removals
11.876	48

Survival curve



Results in detail

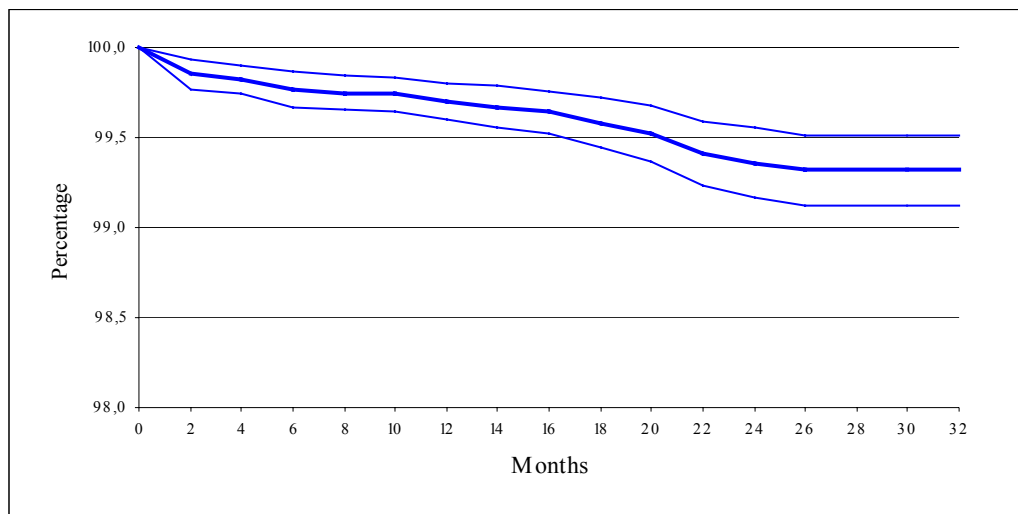
Months	% in site	c.i. at 95%	
2	99.84	99.76	99.92
4	99.82	99.74	99.90
6	99.73	99.63	99.83
12	99.68	99.58	99.78
24	99.44	99.26	99.62
32	99.4	99.20	99.60

10.1.2 Analysis of stem survival

Summary table: all stem models used

Number of arthroprosthesis	Removals
11.876	51

Survival curves



Results in detail

Months	% in site	c.i. at 95%	
2	99.85	99.77	99.93
4	99.82	99.74	99.90
6	99.77	99.67	99.87
12	99.7	99.60	99.80
24	99.36	99.16	99.56
32	99.32	99.12	99.52

10.2 Analysis of hemiarthroplasty survival

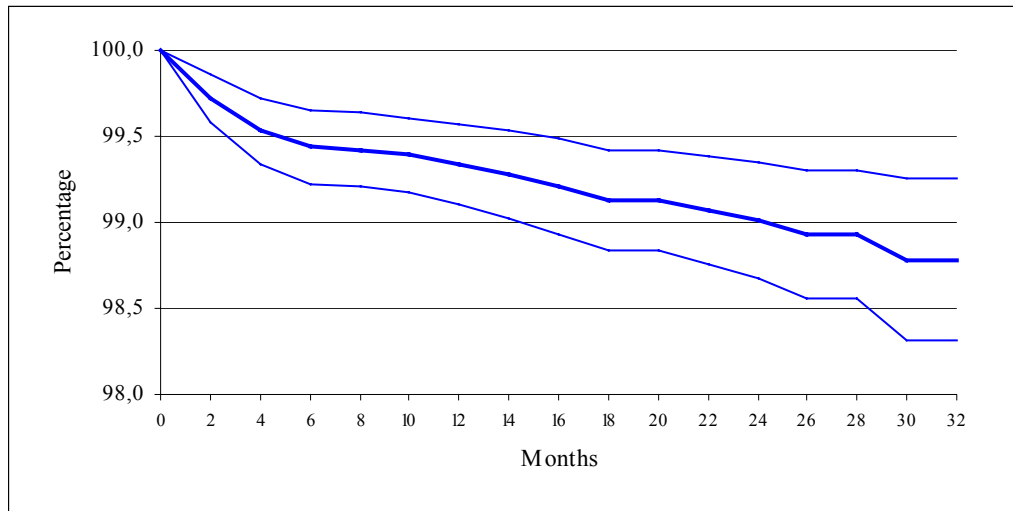
The following table shows the rate of revision in hemiarthroplasty according to *cause of revision*

Cause of revision	Rate	Percentage
Prosthesis luxation (within 60 days)	17/5101	0.39%
Prosthesis luxation (over 60 days)	3/5101	0.06%
Aseptic loosening of the stem	10/5101	0.20%
Acetabular osteitis	6/5101	0.12%
Bones fracture	2/5101	0.04%
Septing loosening	1/5101	0.02%
Recurrence of tumor	1/5101	0.02%
Loosening without pain	1/5101	0.02%

Summary table: *hemiartroplasty* operations

Number of hemiartroplasties	Removals
5.101	41

Survival curves



Results in detail

Months	% in site	c.i. at 95%	
2	99.72	99.58	99.86
4	99.53	99.33	99.73
6	99.44	99.22	99.66
12	99.34	99.10	99.58
24	99.01	98.68	99.34
32	98.78	98.31	99.25

The following table shows the rate of revision in **hemiartroplasty** according to **patient's age at the time of operation**.

Age range	Number of the hemiartroplast y	Removals	Rate	Percentage
<40	7	1	1/7	14.3%
40-49	11	-	-	-
50-59	34	-	-	-
60-69	213	3	3/213	1.4%
70-79	1441	14	14/1441	1.0%
More 80	3360	23	23/3360	0.7%

The following table shows the rate of revision in *hemiartroplasty* according to *patient's sex*

Sex	Number of the hemiartroplast y	Removals	Rate	Percentage
Male	1194	9	9/1194	0.75%
Female	3907	32	32/3907	0.80%

PART TWO: KNEE PROSTHESES

July 2000 – September 2002

1. RIPO support

The following table shows the mean support for RIPO per hospital.

BOLOGNA PROVINCE	January – September 2002		
	N° operations communicated to RIPO	N° operations communicated by S.D.O	% support R.I.P.O.
AZIENDA BOLOGNA CITY			97.8%
Hospital Maggiore	3	9	
Private hospital "Villa Erbosa"	91	90	
Private hospital "Villa Nigrisoli"	74	72	
Private hospital "Villa Torri"	44	44	
Private hospital "Villa Laura"	104	105	
Private hospital "Villa Regina" (not credited)	1	4	
Total	317	324	
Azienda Ospedaliera S. Orsola-Malpighi	14	17	82.3%
Orthopaedic Institutes Rizzoli	400	405	98.7%
AZIENDA BOLOGNA NORTH			100.0%
Hospital Bentivoglio	1	1	
Total	1	1	
AZIENDA BOLOGNA SOUTH			52.4%
Civil hospital Vergato	5	4	
Private hospital "Prof. Nobili"	6	9	
Private hospital "Villa Chiara"	-	8	
Total	11	21	
AZIENDA IMOLA			83.8%
Civil hospital di Imola	26	27	
Castel San Pietro Terme	-	4	
Total	26	31	
FERRARA PROVINCE			55.0%
Stabilimento Ospedaliero di Cento	45	31	
Civil hospital Argenta	64	66	
Civil hospital Comacchio/ Delta	-	87	
Hospital di Bondeno	-	14	
Total	109	198	
Azienda Ospedaliera di Ferrara	12	18	66.6%

FORLÌ-CESENA PROVINCE	January – September 2002		
	N° operations communicated to RIPO	N° operations communicated by S.D.O	% support R.I.P.O.
AZIENDA FORLÌ			100.0%
Hospital "Morgagni-Pierantoni" Forlì	28	27	
Private hospital "Villa Serena" Forlì	-	1	
Total	28	28	
AZIENDA CESENA			90.7%
Hospital "M. Bufalini" Cesena	3	3	
Hospital Cesenatico	-	3	
Private hospital "Malatesta Novello" Cesena	163	161	
Private hospital "S. Lorenzino" Cesena	-	16	
Total	166	183	
MODENA PROVINCE			
AZIENDA MODENA			91.1%
Hospital S. Agostino-Estense	73	68	
Civil hospital Infermi, Carpi	25	25	
Hospital di Finale Emilia	-	-	
Hospital S. Maria Bianca, Mirandola	11	14	
Civil hospital Castelfranco Emilia	-	21	
Civil hospital, Sassuolo	6	8	
Civil hospital, Vignola	31	34	
Hospital, Pavullo	12	12	
Hesperia Hospital	15	14	
Private hospital Prof. Fogliani	63	63	
Total	236	259	
Azienda Ospedaliera Policlinico di Modena	13	36	36.1%
PARMA PROVINCE			
AZIENDA PARMA			94.5%
Civil hospital, Fidenza	32	15	
Hospital Santa Maria, Borgo Val di Taro	59	63	
Hospital San Secondo Parmense	-	23	
Private hospital "Città di Parma"	80	80	
Total	171	181	
Azienda Ospedaliera di Parma	52	58	89.6%
PIACENZA PROVINCE			
AZIENDA PIACENZA			100.0%
Civil hospital, Piacenza	23	22	
Presidio Val Tidone, Castel San Giovanni	42	45	
Presidio Val D'Arda, Fiorenzuola D'Arda	23	21	
Total	88	88	

Regional report R.I.P.O. – 1st July 2000 – 30th September 2002 – Knee

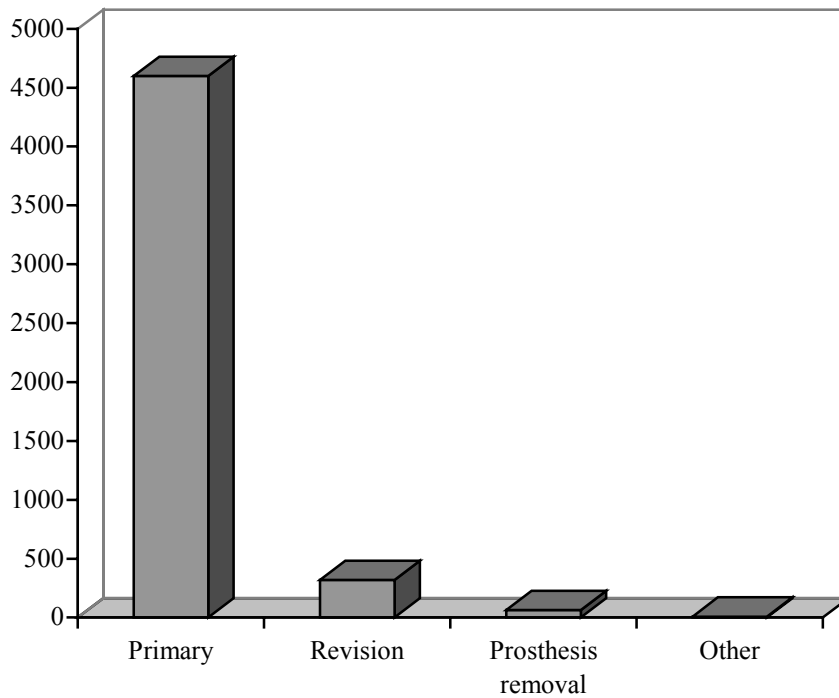
RAVENNA PROVINCE	January – September 2002		
	N° operations communicated to RIPO	N° operations communicated by S.D.O	% support R.I.P.O.
AZIENDA RAVENNA			96.7%
Hospital S. Maria delle Croci, Ravenna	4	5	
Presidio Ospedaliero, Lugo	42	41	
Hospital Infermi, Faenza	7	8	
Private hospital "Domus Nova"	38	38	
Private hospital "S. Francesco"	97	103	
Private hospital "Villa Maria Cecilia"	16	17	
Private hospital "S. Pier Damiano"	88	90	
Total	292	302	
PROVINCE DI REGGIO EMILIA			
AZIENDA REGGIO EMILIA			37.7%
Hospital, Guastalla	15	15	
Hospital Montecchio Emilia	3	3	
Hospital Scandiano	3	3	
Hospital S. Anna, Castelnovo Monti	1	1	
Private hospital "Villa Salus"	21	22	
Private hospital "Villa Verde"(not credited)	0	70	
Total	43	114	
Arcispedale Santa Maria Nuova, Reggio Emilia	9	10	90.0%
RIMINI PROVINCE			
AZIENDA RIMINI			95.8%
Hospital Infermi, Rimini	12	15	
Hospital G. Ceccarini, Riccione	20	20	
Private hospital "Villa Maria"	38	38	
Total	70	73	
TOTAL	2058	2347	87.7%

2. Type of operation

Number of total knee arthroplasty operations performed on patients admitted to hospital between 1st July 2000 and 30 September 2002, according to *type*.

Type of operation	Number	Percentage
Primary	4.599	92.1%
Revision	320	6.4%
Prosthesis removal	63	1.3%
Other (plastic of the rotula, reduction of the hematoma...)	8	0.2%
Total*	4.990	100.0%

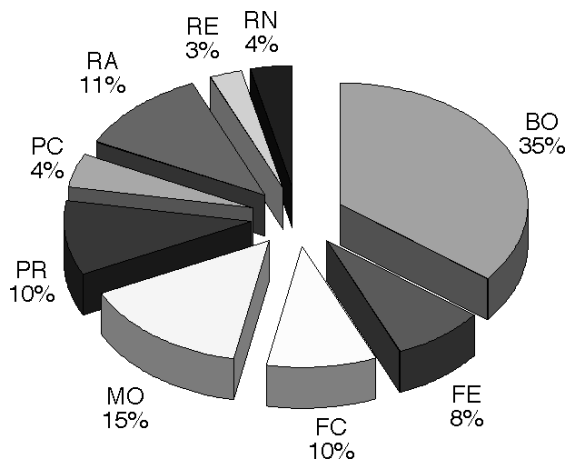
* In 11 cases (0.2%) the information was not reported to RIPO, therefore these operations were excluded from following calculations



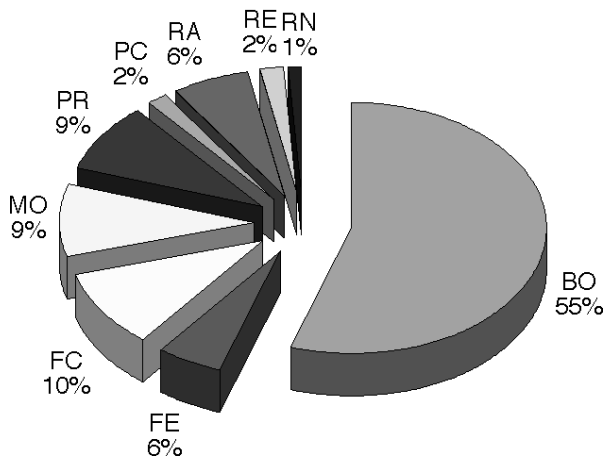
Number of total knee arthroplasty operations performed on patients admitted to hospital between 1st July 2000 and 30 September 2002, according to *type* and *province*.

Province	Primary	Revision	Prosthesis removal	Other	Total
Bologna	1.624	176	53	2	1.855
Ferrara	363	18	1	2	384
Forlì – Cesena	441	32	1	-	474
Modena	665	30	2	2	699
Parma	494	28	-	-	522
Piacenza	195	6	3	-	204
Ravenna	522	20	2	2	546
Reggio Emilia	133	6	-	-	139
Rimini	162	4	1	-	167
Total	4.599	320	63	8	4.990

Percentage distribution of the **primary** operations in the province of Emilia-Romagna:



Percentage distributions of **revision operations** in the province of Emilia-Romagna:



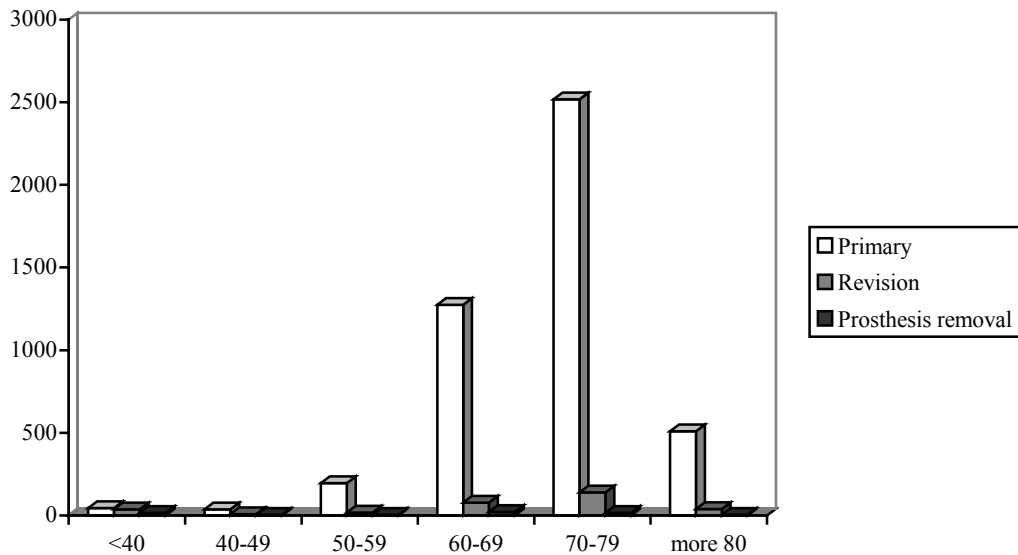
3. Descriptive statistics of patients

3.1. Age

Number of total knee arthroplasty operations performed on patients admitted to hospital between 1st July 2000 and 30 September 2002, according to *type of operation* and *age range* of patients at the time of surgery.

Type of operation	<40		40-49		50-59		60-69		70-79		≥ 80		Total
	N.	%	N.	%	N.	%	N.	%	N.	%	N.	%	
Primary	45	1.0	37	0.8	195	4.3	1274	27.8	2517	55.0	509	11.1	4.577
Revision	37	11.7	7	2.2	17	5.4	78	24.6	139	43.8	39	12.3	317
Prosthesis removal	15	23.8	4	6.3	4	6.3	21	33.3	15	23.8	4	6.3	63
Other	-	-	-	-	1	12.5	1	12.5	5	62.5	1	12.5	8
Total*	97		48		217		1.374		2.676		553		4.965

* In 25 cases (0.5%) the data were not supplied to RIPO



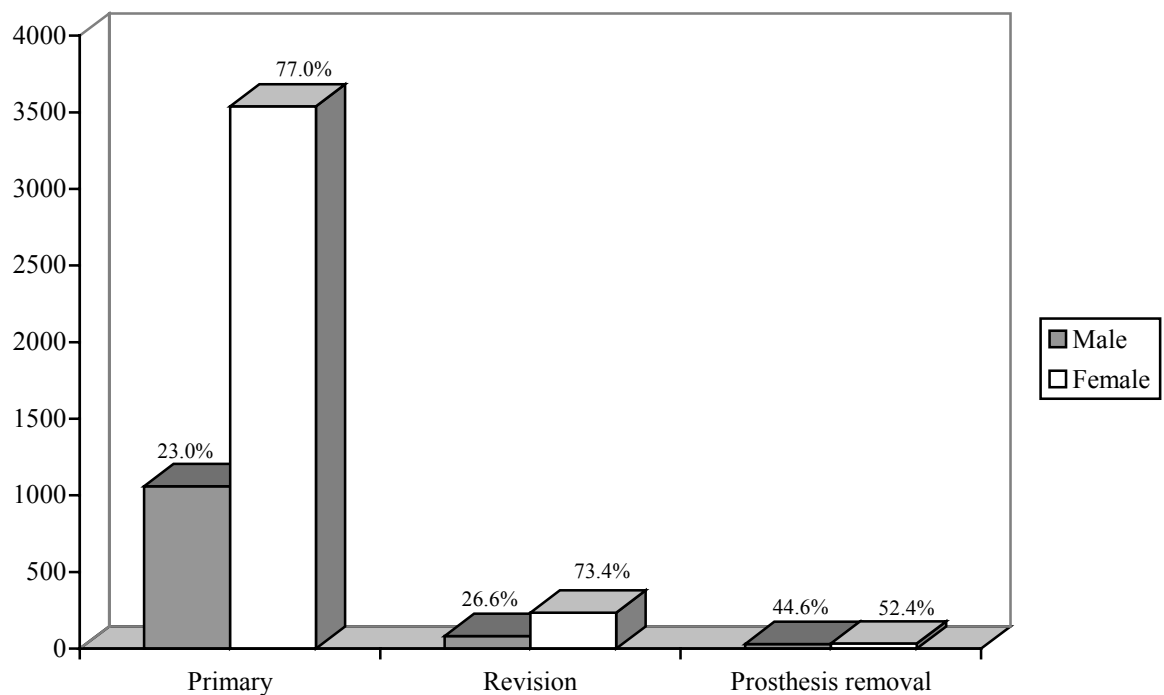
Type of operation	Mean age	Range
Primary	71.2	9-99 years
Revision	65.7	13-90 years
Prosthesis removal	56.9	13-85 years
Other	70.7	9-99 years

Mean age at primary knee surgery was 5 years higher than that observed for primary hip arthroplasty

3.2. Sex

Number of total knee arthroplasty operations performed on patients admitted to hospital between 1st July 2000 and 30 September 2002, according to *type of operation* and patient's *sex*.

Type of operation	Male	Female	Total
Primary	1.060	3.539	4.599
Revision	85	235	320
Prosthesis removal	30	33	63
Other	2	6	8
Total	1.177	3.810	4.990



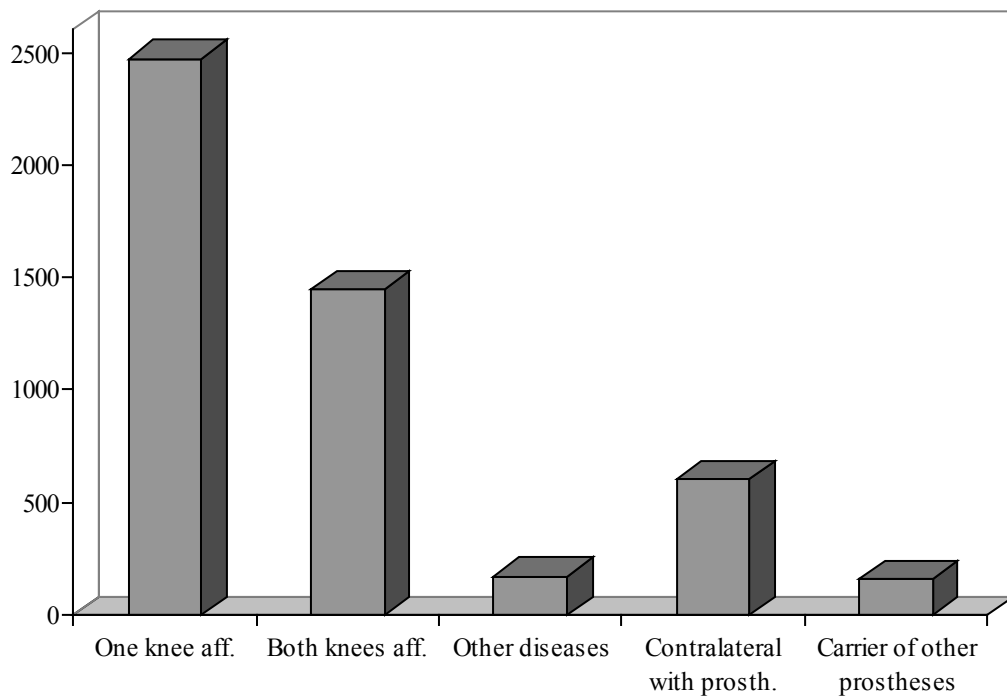
As for hip arthroplasty, the female sex underwent more knee arthroplasty operations. In knee arthroplasty the difference is greater (63.3% for hip, 77% for knee).

3.3. Clinical condition

Number of total knee arthroplasty operations performed on patients admitted to hospital between 1st July 2000 and 30 September 2002, according to *clinical condition* of the patients at the time of surgery.

General status	Number	Percentage
One knee affected	2.472	50.9%
Both knees affected	1.449	29.9%
Other diseases that restrict motor ability	172	3.5%
Contralateral knee with prosthesis	601	12.4%
Carrier of joint prostheses other than that of the knee	160	3.3%
Total*	4.854	100.0%

* In 136 cases (2.7%) the information was not given to RIPO

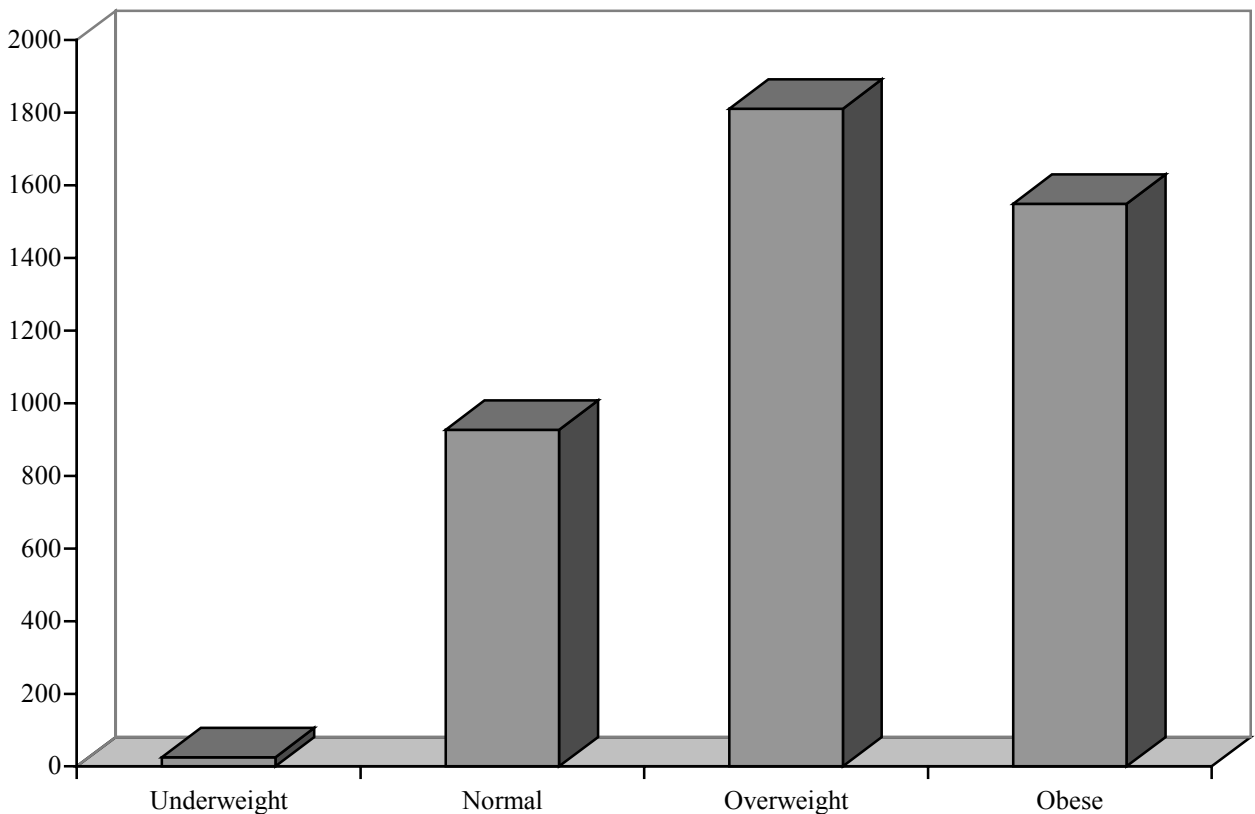


3.4. Body mass index

Number of total knee arthroplasty operations performed on patients admitted to hospital between 1st July 2000 and 30 September 2002, according to *body mass index* at the time of surgery.

Body mass index	Number	Percentage
Underweight (≤ 19)	25	0.6%
Normal (20-25)	927	21.5%
Overweight (26-29)	1.811	42.0%
Obese (≥ 30)	1.549	35.9%
Total*	4.312	100.0%

* In 678 cases (13.6%) the information was not give to RIPO



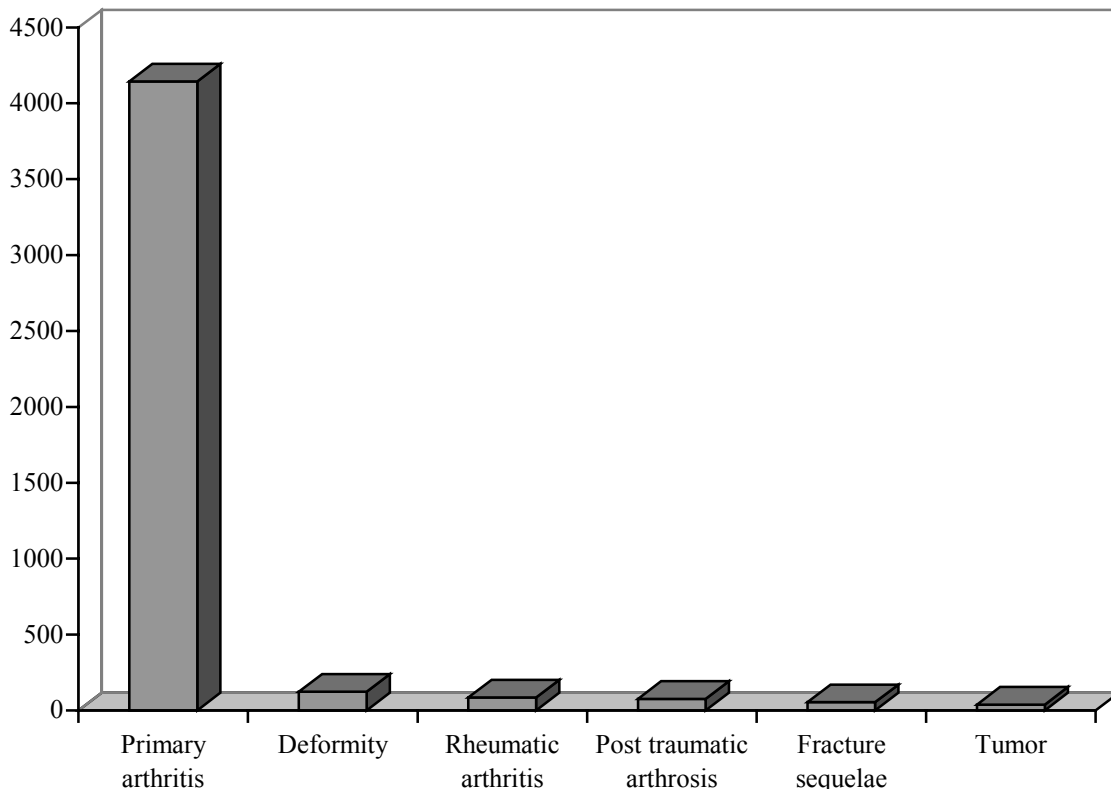
Over 77% of the patients that underwent arthroplasty were either overweight or obese, according to BMI [weight in kg/(height in meters)²]. In hip prosthesis the percentage is 52.4%.

3.5. *Diagnosis according to operation*

Number of total knee arthroplasty operations performed on patients admitted to hospital between 1st July 2000 and 30 September 2002, according to **diagnosis** in primary arthroprosthesis.

Diagnosis in primary arthroplasty	Number	Percentage
Primary arthritis	4.145	90.3%
Deformity	123	2.7%
Rheumatic arthritis	85	1.9%
Post traumatic arthrosis	76	1.7%
Fracture sequelae	54	1.2%
Tumor	38	0.8%
Necrosis	19	0.4%
Post traumatic necrosis	19	0.4%
Osteotomy sequelae	10	0.2%
Septic arthritis sequelae	5	0.1%
Other	15	0.3%
Total*	4.589	100.0%

* 10 results missing, equal to 0.2% of the series of primary operations.



Primary arthritis is the main reason for total knee arthroplasty.

Number of total knee **revision operations** performed on patients admitted to hospital between 1st July 2000 and 30 September 2002, according to *diagnosis*.

Diagnosis in revision surgery	Number	Percentage
Total aseptic loosening	140	44.7%
Septic loosening	49	15.7%
Pain without loosening	31	9.9%
Polyethylene wear	30	9.6%
Aseptic loosening tibial comp.	17	5.4%
Aseptic loosening femoral comp.	12	3.8%
Prosthesis breakage	8	2.6%
Prosthesis luxation	5	1.6%
Bone fracture	4	1.3%
Pathological fracture	2	0.6%
Other	15	4.8%
Total*	313	100.0%

* 7 results missing, equal to 2.2% of the series of revision operations

The rate of septic loosening is very high compared to that of hip arthroplasty. This result will be monitored carefully in future years.

Number of **knee prosthesis removal** performed on patients admitted to hospital between 1st July 2000 and 30 September 2002, according to *diagnosis*.

Diagnosis in prosthesis removal	Number	Percentage
Septic loosening	50	83.3%
Aseptic total loosening	10	16.7%
Total*	60	100.0%

* 3 results missing, equal to 4.8% of the series of explants

4. Antibiotic prophylaxis

List of drugs used in preoperative antibiotic prophylaxis in **knee prosthesis surgery** (information recorded in RIPO from 30/09/2001).

The number indicates the cases where the active ingredient (alone or in combination) was used.

Active principle	Percentage
AMPICILLIN	8.2%
AMPICILLIN + GENTAMICIN	4.4%
CEFAMANDOLE	0.3%
CEFAMANDOLE + GENTAMICIN	0.3%
CEFAZOLIN	18.2%
CEFAZOLIN + GENTAMICIN	1.6%
CEFAZOLIN + TOBRAMICIN	4.4%
CEFEPIME	6.0%
CEFOTAXIME	6.2%
CEFOTAXIME + LEVOFLOXACIN	3.5%
CEFTIZOXIME	0.9%
CEFTRIAZONE	5.8%
CEFTRIAZONE + GENTAMICIN	1.5%
CEFUROXIME	10.4%
CIPROFLOXACIN	1.6%
GENTAMICIN	0.3%
TEICOPLANIN	3.3%
TEICOPLANIN + NETILMICIN	1.7%
VANCOMICIN	2.2%
VANCOMICIN + GENTAMICIN	10.6%
OTHER	8.6%
TOTAL	100.0%

In about 65% of cases only one active ingredient was used, in the remaining 35% 2 or more active ingredients were used.

The active ingredients used in prophylaxis for knee prosthesis surgery are the same as those used in hip prosthesis surgery, although the percentage is different.

5. Type of prosthesis

The following table shows the types of prostheses used for **primary knee arthroplasty** in patients admitted to hospital between July 1st 2000 and September 30th 2002.

<i>Type of Prosthesis</i>	<i>N.</i>	<i>%</i>
NEXGEN – Zimmer	1.156	25.1%
PROFIX – Smith & Nephew	625	13.7%
INTERAX – Stryker Howmedica	360	7.9%
T.A.C.K. – Link	340	7.5%
P.F.C. – DePuy	299	6.5%
OPTETRACK – Exactech	199	4.3%
GENIUS TRICCC – Dedienne Santé	143	3.1%
913 – Cremascoli	120	2.6%
OXFORD (Unicompartmental) – Biomet Merck	116	2.5%
ROTAGLIDE – Corin Medical	109	2.4%
LCS – DePuy	94	2.0%
GENESIS II – Smith & Nephew	92	2.0%
ALLEGRETTO UNI – Protek Sulzer	89	1.9%
NUOVA DURACON II – Stryker Howmedica	84	1.8%
PERFORMANCE – Kirschner Biomet Merck	73	1.6%
ADVANCE – Wright	66	1.4%
ENDO-MODEL – Link	61	1.3%
EFDIOS – CITIEFFE	50	1.1%
HLS (Evolution) – Tornier	47	1.0%
CONSENSUS – Hayes Medical.	36	0.8%
C. K. S. – Stratec Medical	34	0.7%
GENESIS UNI – Smith & Nephew	33	0.7%
CEDIOR – Sulzer	32	0.7%
G. K. S. – Permedica	24	0.5%
UNICIA – Vecteur Orthopedic, Stratec	23	0.5%
MILLER GALANTE UNI – Zimmer	12	0.3%
HLS UNI Evolution – Tornier	12	0.3%
MULTIGEN – Lima	11	0.2%
GENUFITT – Lafitt (femoral component and liner) + EFDIOS – Citieffe (tibial component)	10	0.2%
UNKNOWN	20	0.4%
UNKNOWN – Link	15	0.3%
TOTAL	4.385	95.3%

In the remaining 214 cases (4.7%) **24 different types** of prosthesis were used numbering less than 10 units per type.

The following table shows the types of prostheses used for **knee revision arthroplasty** in patients admitted to hospital between July 1st 2000 and September 30th 2002.

<i>TYPE OF PROSTHESIS</i>	<i>N.</i>	<i>%</i>
ENDO-MODEL – Link	75	23.4%
NEXGEN – Zimmer	65	20.3%
PROFIX – Smith & Nephew	35	10.9%
INTERAX – Stryker Howmedica	25	7.8%
PERFORMANCE – Kirschner Biomet Merck	23	7.2%
C. K. S. – Stratec Medical	13	4.1%
LCS – DePuy	11	3.4%
GENIUS TRICCC – Dedienne Santé	10	3.1%
TOTAL KNEE – Stryker Howmedica	10	3.1%
TC3 – Depuy	10	3.1%
G. K. S. – Permedica	6	1.9%
P.F.C. – DePuy	5	1.6%
T.A.C.K. – Link	4	1.3%
913 – Cremascoli	3	0.9%
CEDIOR – Sulzer	2	0.6%
GENESIS II – Smith & Nephew	2	0.6%
GENUFITT – Lafitt (femoral component and liner) + EFDIOS – Citieffe (tibial component)	2	0.6%
MILLER GALANTE II – Zimmer	2	0.6%
NUOVA DURACON II – Stryker Howmedica	2	0.6%
ROTAGLIDE – Corin Medical	2	0.6%
S-ROM – Johnson & Johnson	2	0.6%
OXFORD (Unicompartmental) – Biomet Merck	2	0.6%
CONSENSUS (PS) – Hayes Medical	1	0.3%
EFDIOS – Citieffe	1	0.3%
HLS REVISION – Tornier	1	0.3%
OPTETRACK – Exactech	1	0.3%
UNKNOWN	5	1.6%
TOTAL	320	100.0%

The joint coupling was metal-polyethylene in nearly all cases. A ceramic-polyethylene coupling was used only in 0.2% of primary operations and 0.3% of revision operations.

The polyethylene tibial insert was mobile in 23.1 % of cases. In some cases, a rotating insert was used in 34 hospitals out of 56 that perform knee prosthesis surgery in Emilia-Romagna.

Percentages of knee joint prostheses used on patient admitted to hospital between 1st July 2000 and 30th September 2002, according to *type of prosthesis implanted*.

Type of prosthesis implanted	Primary prosthesis	Revision
Unicompartmental	9.2%	1.1%
Bicompartmental	85.3%	92.1%
Tricompartmental	5.5%	6.8%
Total	100.0%	100.0%

6. Hospitalization time

	Mean hospitalization	Range	Mean pre-op hospitalization	Range pre-op hospitalization	Mean post-op hospitalization	Range post-op hospitalization
Primary	12.6	1-58	1.6	0-40	10.9	0-56
Revision	14.9	3-73	2.4	0-29	12.5	2-54

Postoperative hospitalization of 0 days occurred when a patient was transferred to another ward (intensive care).

Total hospitalization equal to 3 days occurred when surgery was carried out on patients admitted to non-orthopedic wards, who after surgery continued their stay in the ward of origin. No noteworthy variations were observed compared to last year.

7. Survival analysis

Survival curves, calculated according to the actuarial method, can be constructed in relationship to the patient's main factors (sex, age, build, disease), implants (fixation, joint coupling) and the most commonly used commercial models.

A correct assessment of the survival should be carried out with a group of at least 100 cases in order to present statistically reliable indications.

In this phase of the study reliable survival curves could not be constructed because follow-up was too short, therefore, we only report the number of primary and revision prostheses implanted in the considered period that were reimplanted in the same period. In future years, it will be possible to calculate global, stratified survival curves to determine the influence of single factors in the outcome of surgery.

At present, however, an indication can be provided, albeit partial, about the efficacy of total arthroplasty and revision surgery carried out in the hospital.

The table shows in the first column the number of total arthroplasty operations performed in the period between January 2000 and September 2002, the second and third columns contain the number the number of revision of the same operations. Revision surgery may have been performed at the same hospital where the primary operation was performed or at a different hospital in the Emilia Romagna region.

	Number of operations	Number of revisions in the same hospital	Number of revisions in a different hospital
Primary	4.599	22	3
Revision	320	6	-
Total	4919	28	3

12.0% of revision operations were performed at a hospital in the Emilia-Romagna region that was different from the one where the primary operation was carried out.

Details of revision operations:

Primary prosthesis	Cause of revision	Type of revision	Duration of implant (in days)
Advance – Wright	Pain without loosening	Total revision	247
Butterfly – Permedica	Septic loosening	Total revision	317
Consensus – Hayes Medical.	Aseptic loosening tibial component	Tibial component and lining	505
Duracon – Howmedica	Patella dislocation (?)	Total revision	72
Genius Triccc – Dediennne Sante	Septic loosening	Total revision	189
Genius Triccc – Dediennne Sante	Pain without loosening	Femoral component and lining	219
Interax – Stryker Howmedica	Total aseptic loosening	Total revision in other hospital	161
Interax – Stryker Howmedica	Tibial loosening	Tibial component and lining	422
Knee R.S. System – Cremascoli	Total aseptic loosening	Total revision	252
Nexgen – Zimmer	Lining wear	Only lining	89
Nexgen – Zimmer	Lining loosening	Only lining	119
Nexgen – Zimmer	Femoral component loosening	Femoral component	156
Oxford Unicompartmental – Biomet Merck	Pain without loosening	Total revision	125
Oxford Unicompartmental – Biomet Merck	Bone fracture	Total revision	150
Oxford Unicompartmental – Biomet Merck	Aseptic loosening femoral component	Femoral component and lining	168
Oxford Unicompartmental – Biomet Merck	Pain without loosening	Total revision	339
Oxford Unicompartmental – Biomet Merck	Pain without loosening	Total revision	412
PFC – De Puy	Stiffness	Femoral component and lining	170
PFC – De Puy	Total aseptic loosening	Total revision	348
PFC – De Puy	Septic loosening	Total revision in other hospital	434
Profix – Smith & Nephew	Pain without loosening	Lining and patella	329
Rotaglide – Corin Medical	Total aseptic loosening	Total revision in other hospital	372
Rotaglide – Corin Medical	Aseptic loosening femoral component (?)	Lining and patella	449
T.a.c.k. – Link	Septic loosening	Prosthesis removal	310
Total Stabilizer Knee – Howmedica	Prosthesis dislocation	Total revision	148

Revision rate and type of prosthesis used in primary surgery:

TYPE OF PROSTHESIS	Revision rate	%
OXFORD (Unicompartmental) – Biomet Merck	5/116	4.3%
ROTAGLIDE – Corin Medical	2/109	1.8%
ADVANCE – Wright	1/66	1.5%
GENIUS TRICCC – Dedienne Santé	2/143	1.4%
NUOVA DURACON II – Stryker Howmedica	1/84	1.2%
P.F.C. – DePuy	3/299	1.0%
INTERAX – Stryker Howmedica	2/360	0.56%
NEXGEN – Zimmer	3/1.156	0.3%
T.A.C.K. – Link	1/340	0.29%
PROFIX – Smith & Nephew	1/625	0.16%
913 – Cremascoli	-/120	-
GENESIS II – Smith & Nephew	-/92	-
ALLEGRETTO UNI – Protek Sulzer	-/89	-
PERFORMANCE – Kirschner Biomet Merck	-/73	-
ENDO-MODEL – Link	-/61	-
LCS – DePuy	-/94	-
OPTETRACK – Exactech	-/199	-
OTHER*	4/573	0.7%
TOTAL	25/4.599	0.5%

* The OTHER category includes all types of prostheses with less than 60 cases

Details of revision cases that underwent further revision/prosthesis removal:

Prosthesis	Cause of revision	Type of revision	Duration of implant (in days)
Continuum Knee System PS – Stratec	Septic loosening	Prosthesis removal	224
Genius Triccc – Dedienne Sante	Septic loosening	Prosthesis removal	79
Nexgen – Zimmer	Prosthetic dislocation	Tibial component	84
Nexgen – Zimmer	Total aseptic loosening	Total revision	224
Profix – Smith & Nephew	Septic loosening	Prosthesis removal	161
Profix – Smith & Nephew	Septic loosening (?)	Only insert revision	281

The following table shows the rate of revision and type of operation:

Type of operation	Rate of revision	Percentage
Primary	25/4.599	0.5%
Revision	6/320	1.9%

The following tables show the rate of revision according to *type of operation* and *cause of revision*.

Primary operations

Cause of revision	Rate	Percentage
Pain without loosening	6/4.599	0.1%
Septic loosening	4/4.599	0.09%
Total aseptic loosening	4/4.599	0.09%
Aseptic loosening femoral component	3/4.599	0.07%
Aseptic loosening tibial component	2/4.599	0.04%
Lining loosening	2/4.599	0.04%
Bone fracture	1/4.599	0.02%
Patella dislocation	1/4.599	0.02%
Joint stiffness	1/4.599	0.02%
Prosthesis dislocation	1/4.599	0.02%

Revision operations

Cause of revision	Rate	Percentage
Septic loosening	4/320	1.25%
Total aseptic loosening	1/320	0.3%
Prosthesis dislocation	1/320	0.3%

7.1. Revision of the patella alone

In four patients patella revision was necessary:

Primary prosthesis	Cause of patella revision	Time lapsed from primary surgery (in days)
<i>Genius Triccc – Dediennne Sante</i>	Pain without loosening	97
<i>Genius Triccc – Dediennne Sante</i>	?	238
<i>Genius Triccc – Dediennne Sante</i>	?	238
Multigen – Lima	Pain without loosening	441

RECALL OF PROSTHESES AT RISK

In 2002 and the early months of 2003 three recall procedures were activated by the Italian Health Ministry

1. Devices produced by the Depuy company containing Hylamer polyethylene: liner for the Duraloc cup, monoblock Ogee cup, and the Glene for shoulder prostheses.
2. Epiphyses made of zirconia for hip prostheses manufactured by the Saint Gobain Desmarquest company.
3. Tibial liners made of polyethylene for Interax knee prostheses, size MIDI 1, produced by the Stryker Howmedica company.

1. Hylamer polyethylene, if sterilized by gamma radiation in air may be affected by accelerated wear. Sterilization was performed by this method on some batches made between January 1991 and September 1993. The duration period of sterilization validity is fixed at 5 years; therefore, risk components may have been implanted between 1991 and September 1998.

The Health Department of Emilia-Romagna Regional Council has begun a census at all regional hospitals and has provided operation guidelines.

2. Some batches of epiphyses made of zirconia manufactured by the Desmarquest company were sintered by a novel technique that led to an alarming rate of fractures. They were 6 batches making a total of 4,700 units of which a breakage rate ranging between 0.1 and 33% was observed.

The heads were marketed by several companies, including DePuy, Stryker-Howmedica, Smith & Nephew, Zimmer, SERF and others, from June 1998 to September 2001, when they were taken off the market.

Also in this instance the Department of Health of the Emilia-Romagna Regional Council has begun a census at all regional hospitals. The register reported the use of zirconia heads to each hospital head (limited to the registration period from January 2000).

The Register reports 251 devices implanted, some of which are theoretically at risk.

3. Tibial polyethylene liners for Interax knee prostheses, marketed by the Stryker company, have been withdrawn due to accelerated wear observed only in the MIDI 1 size. Therefore, all batches manufactured before June 2000 have been withdrawn.

The Register has reported the use of these liners to the heads of each hospital.

Altogether, from July 2000 to the time the knee Register began, 85 patients were treated in the region.

Sales figures provided by the Stryker company show that in the period 1992-2000 a total of 1,030 liners were supplied to 12 hospitals and 4 accredited Clinics.

The hospitals involved are checking this information.