

REPORT of R.I.P.O.

(Register of Orthopedic Prosthetic Implantology)

Overall data Emilia-Romagna Region Hip and knee prostheses

1st January 2000 – 31st December 2003

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 and knee arthroplasty carried out in Emilia-Romagna, between 1st January 2000 and 31st December 2003. (http://ripo.cineca.it)

The data include for the hip, besides primary arthroplasty, revision surgery, prosthesis removal and hemiarthroplasty

In section two knee prostheses (both uni and bicompartmental) revisions and prosthesis removal are reported.

As in the past, data from the orthopedic wards was provided on paper forms. Registry staff transferred the data via internet to the databank run by CINECA (Interuniversity Consortium of North-eastern Italy) which was responsible for computer management and security aspects of the data. Statistical analysis was performed by Registry statistics staff.

When forms were missing or lacking important information (patient identification, type of prosthesis implanted), the representative of the hospital was asked to supply it.

In addition, a process of comparison was started between the SDO (Regional Health Department) and RIPO to identify any omissions in sending information to the registry, thus allowing the agencies to fill any gaps. Up to now, the comparison has been made only for 2001. Over the next few months it should be complete.

Likewise, a link has been established with the regional mortality databank to perform correct statistical assessments on patients actually alive.

This report, combined with the report on the data of single units, provides a full picture of regional implantology practice, and offers surgeons a very useful tool for making decisions and informing patients.

Notes on methodology

Elaboration includes data concerning the period 1st January 2000 to 31st December 2003, which arrived before 1st June 2004. The collection of data about the knee started in July 2000.

The identification of the type of prosthesis implanted is reported in detail: the manufacturer's name is reported as it appears on the label, even if the trade mark varies slightly.

The data collected to date has a maximum follow-up of 4 years, therefore, prosthesis survival evaluations can be made.

Survival curves were calculated and plotted according the actuarial method of Kaplan and Meier. The prosthesis is considered to be "surviving" until surgical intervention is needed to replace even one component. Thus, revision surgery represents the end-point. The degree of reliability of the curves may be influenced by the incomplete communication of operations performed in Emilia-Romagna to RIPO; that is why comparison with the SDO databank was made.

Scientific board of RIPO

On March 4th 2004 the Scientific board of RIPO met for the first time to elect its internal chairman.

The board will remain in charge for three years is composed by::

- Dr.ssa Kyriakoula Petropulacos,

Responsabile del Servizio Presidi Ospedalieri – Regione Emilia-Romagna;

- Dr. Salvatore Ferro,

Dirigente Medico del Servizio Presidi Ospedalieri – Regione Emilia-Romagna;

- Dr. Roberto Grilli,

Responsabile Area Governo Clinico – Agenzia Sanitaria Regionale – RER;

- Dr. Andrea Donatini,

Responsabile Area Economia e Salute - Agenzia Sanitaria Regionale - RER;

- Dr. Paolo Costa,

Direttore U.O. Ortopedia e Traumatologia – Az. Osp. di Reggio Emilia;

- Prof. Leo Massari,

Direttore U.O. Ortopedia – Az. Osp. Universitaria di Ferrara;

- Dr Luigi Prosperi,

Direttore U.O. Ortopedia - Ospedale di Bentivoglio - Azienda USL Bologna Nord;

- Dr. Luigi Specchia,

Direttore U.O. Ortopedia - Ospedale di Cento - Az. USL di Ferrara;

- Dr. Aldo Toni,

Dir. 1° Divisione Ortopedia e Traumatologia - Direttore Laboratorio Tecnologia Medica . – II.OO.RR; <u>president</u>

- Dr.ssa Susanna Stea,

R.I.P.O. - II.OO.RR;

- Dr. Enzo Zanini,

Chirurgo Ortopedico - Casa di Cura Villa Erbosa, Bologna;

- Dr.ssa Silvia Cremonini,

Funzionario del Servizio Presidi Ospedalieri – Regione Emilia-Romagna.

Bologna, 20th June 2004

This report has been prepared by Dr. Susanna Stea, Dr. Barbara Bordini, Dr. Manuela De Clerico, with the collaboration of Greta Ghelfi, Elena Nanni, Carolina

Sangiorgi, graphic by Luigi Lena. Supervision by Dr. Aldo Toni

Translation by Keith Smith

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Technological partner for computer management of the database is CINECA of Bologna.

PART ONE: HIP PROSTHESIS

1. RIPO support

1.1 Support for RIPO per hospital in years 2000-2003

Percentage of R.I.P.O. capture calculated versus Schede di Dimissione Ospedaliera

(S.D.O.), according to Agency.

	Year 2000	Year 2001	Year 2002	Year 2003
BOLOGNA PROVINCE	%	%	%	%
BOLOGNA I KOVINCE	support	support	support	support
	R.I.P.O.	R.I.P.O.	R.I.P.O.	R.I.P.O.
Azienda BOLOGNA CITY	77.7%	93.4%	98.6%	95.6%
Azienda Ospedaliera S. Orsola-Malpighi	97.3%	95.6%	82.5%	86.7%
Istituti Ortopedici Rizzoli	102.3%	99.4%	101.9%	99.6%
AZIENDA BOLOGNA NORTH	103.3%	106.0%	102.6%	96.0%
AZIENDA BOLOGNA SOUTH	78.7%	90.0%	93.7%	86.4%
AZIENDA IMOLA	57.6%	93.9%	87.2%	87.1%
FERRARA PROVINCE				
AZIENDA FERRARA	102.2%	96.95	91.7%	79.8%
Azienda Ospedaliera di Ferrara	98.0%	89.2%	91.7%	83.6%
FORLÌ-CESENA PROVINCE				
AZIENDA FORLI'	91.6%	92.5%	82.0%	91.9%
AZIENDA CESENA	100.6%	103.9%	93.7%	87.9%
MODENA PROVINCE				
AZIENDA MODENA	78.2%	92.0%	95.7%	93.8%
Azienda Ospedal. Policlinico di Modena	89.6%	95.9%	89.5%	39.7%
PARMA PROVINCE				
AZIENDA PARMA	73.6%	100.5%	109.6%	102.4%
Azienda Ospedaliera di Parma	75.7%	79.3%	86.2%	91.5%
PIACENZA PROVINCE				
AZIENDA PIACENZA	70.0%	95.8%	105.3%	97.4%
RAVENNA PROVINCE				
AZIENDA RAVENNA	93.3%	100.7%	98.0%	97.1%
REGGIO EMILIA PROVINCE				
AZIENDA REGGIO EMILIA	77.2%	75.5%	81.4%	89.6%
Arcispedale Santa Maria Nuova	104.3%	86.0%	103.8%	72.5%
RIMINI PROVINCE				
AZIENDA RIMINI	101.0%	101.5%	100.0%	91.7%
Total	87.8%	94.3%	95.4%	91.7%

Percentage higher than 100 is possibly due to a mistake in SDO code.

1.2 Percentage of RIPO support year 2003

Percentage of R.I.P.O. capture calculated versus Schede di Dimissione Ospedaliera (S.D.O.), according to Orthopaedic department.

		2003	
BOLOGNA PROVINCE	N° of operations	N° operations	%
BOLOGIVATROVINCE	communicated to	communicated	support to
	RIPO	via S.D.O.	R.I.P.O.
Azienda BOLOGNA CITY			
Hospital Maggiore ,Bellaria	151	157	
Private hospital "Villa Erbosa"	79	87	
Private hospital "Villa Nigrisoli"	131	132	95.6%
Private hospital "Villa Torri"	159	169	73.0 /0
Private hospital "Villa Laura"	114	116	
Private hospital "Villa Regina" (not cred.)	23	26	
Total	657	687	
Azienda Ospedaliera S. Orsola-Malpighi	241	278	86.7%
Istituti Ortopedici Rizzoli	1425	1431	99.6%
AZIENDA BOLOGNA NORTH			
Hospital Bentivoglio, Budrio, San Giovani in Pers.	96	100	96.0%
Total	96	100	
AZIENDA BOLOGNA SOUTH			
Civil hospital Vergato	46	61	
Private hospital "Prof. Nobili"	18	18	86.4%
Private hospital "Villa Chiara"	31	31	
Total	95	110	
AZIENDA IMOLA			
Civil hospital Imola, Castel San Pietro	251	288	87.1%
Total	251	288	07.17,0
EEDDA DA DOUWLOE			
FERRARA PROVINCE Stabilimento Ospedaliero di Cento, Bondeno	206	212	
Civil hospital Argenta	199	211	
Civil hospital Comacchio/ Delta	29	121	79.8%
Total	434	544	
Azienda Ospedaliera di Ferrara	183	219	83.6%

No of operations communicated to multimizated to RIPO			2003	
Communicated to Communicated via S.D.O.	EODLÌ CESENA DDOVINCE	N° of operations	N° operations	%
RIPO Via S.D.O. R.I.P.O.	FORLI-CESENA PROVINCE			support to
Hospital "Morgagni-Pierantoni" Forli 141 158 Forlimpopoli, Santa Sofia 102.4%*		RIPO	via S.D.O.	
Private hospital "Villa Serena" Forlì 64 65	AZIENDA FORLI'			
Private hospital "Villa Serena" Forli	Hospital "Morgagni-Pierantoni" Forlì,	141	158	
Total 205 223				91.9%
AZIENDA CESENA Hospital "M. Bufalini" Cesena, Bagno di Romagna, Cesenatico Private hospital "Malatesta Novello" Cesena 204 204 204 204 204 204 204 204 204 204 205	Private hospital "Villa Serena" Forlì	64	65	
Hospital "M. Bufalini" Cesena, Bagno di Romagna, Cesenatico	Tota	205	223	
Hospital "M. Bufalini" Cesena, Bagno di Romagna, Cesenatico	AZIENDA CESENA			
St. 99% St.		164	214	
Private hospital "Malatesta Novello" Cesena 204 204 204 204 204 204 204 204 204 204 204 204 204 204 204 204 204 205				0= 00/
Private hospital "S. Lorenzino" Cesena 3 4		204	204	87.9%
MODENA PROVINCE	•	3	4	
MODENA PROVINCE	<u> </u>	371	422	
AZIENDA MODENA Hospital S. Agostino-Estense 346 336 Civil hospital Infermi, Carpi 198 193 Hospital Finale Emilia - 6 6 Hospital Finale Emilia 15 89 Civil hospital Castelfranco Emilia 15 89 Civil hospital, Sassuolo 77 96 93.8% Civil hospital, Sassuolo 77 96 93.8% Civil hospital, Vignola 222 210 Hospital, Pavullo 79 81 Hesperia Hospital 35 33 Private hospital "Prof. Fogliani" 25 25 25 Total 1106 1179				
Hospital S. Agostino-Estense 346 336 Civil hospital Infermi, Carpi 198 193 Hospital Finale Emilia - 6 6 Hospital S. Maria Bianca, Mirandola 109 110 Civil hospital Castelfranco Emilia 15 89 Civil hospital, Sassuolo 77 96 93.8% Civil hospital, Vignola 222 210 Hospital, Pavullo 79 81 Hesperia Hospital "Prof. Fogliani" 25 25 25 25 Total 1106 1179	MODENA PROVINCE			
198 193 193 194 195				
Hospital Finale Emilia	· · ·	346	336	
Hospital S. Maria Bianca, Mirandola 109		198	193	
15 89 23.8% 25 210 205 25 25 25 25 25 25	1	-	6	
Parma Private hospital, Fidenza San Secondo Parmense 108 100	Hospital S. Maria Bianca, Mirandola	109	110	
Civil hospital, Vignola 222 210 Hospital, Pavullo 79 81 Hesperia Hospital 35 33 Private hospital "Prof. Fogliani" 25 25 Total 1106 1179 Azienda Ospedaliera Policlinico di Modena 56 141 39.7% PARMA PROVINCE	Civil hospital Castelfranco Emilia	15	89	
Hospital, Pavullo	Civil hospital, Sassuolo	77	96	93.8%
Hesperia Hospital 35 33 25 25 25 25 25 25	Civil hospital, Vignola	222	210	
Private hospital "Prof. Fogliani" 25 25	Hospital, Pavullo	79	81	
Total 1106 1179	Hesperia Hospital	35	33	
Azienda Ospedaliera Policlinico di Modena 56	Private hospital "Prof. Fogliani"	25	25	
PARMA PROVINCE AZIENDA PARMA 100 Civil hospital, Fidenza, San Secondo Parmense 108 100 Hospital Santa Maria, Borgo Val di Taro 60 63 102.4%* Private hospital "Città di Parma" 42 42 42 Azienda Ospedaliera di Parma 444 485 91.5% PIACENZA PROVINCE AZIENDA PIACENZA Civil hospital, Piacenza 225 241 Presidio Val Tidone, Castel San Giovanni 78 73 97.4% Presidio Val D'Arda, Fiorenzuola D'Arda , Cortemaggiore 114 114 114	Tota	1106	1179	
PARMA PROVINCE AZIENDA PARMA Civil hospital, Fidenza, San Secondo Parmense 108 100 Hospital Santa Maria, Borgo Val di Taro 60 63 Private hospital "Città di Parma" 42 42 Total 210 205 Azienda Ospedaliera di Parma 444 485 91.5% PIACENZA PROVINCE AZIENDA PIACENZA Civil hospital, Piacenza 225 241 Presidio Val Tidone, Castel San Giovanni 78 73 Presidio Val D'Arda, Fiorenzuola D'Arda , Cortemaggiore 114 114	Azienda Ospedaliera Policlinico di Modena	56	141	39 7%
AZIENDA PARMA	2 1710 4011		111	• • • • • • • • • • • • • • • • • • • •
Civil hospital, Fidenza , San Secondo Parmense 108 100 Hospital Santa Maria, Borgo Val di Taro 60 63 102.4%*				
Hospital Santa Maria, Borgo Val di Taro Private hospital "Città di Parma" 42 42 Total Azienda Ospedaliera di Parma 444 485 PIACENZA PROVINCE AZIENDA PIACENZA Civil hospital, Piacenza Presidio Val Tidone, Castel San Giovanni Presidio Val D'Arda, Fiorenzuola D'Arda, Cortemaggiore 102.4%* 44 485 91.5% 97.4%		100	100	
Private hospital "Città di Parma" 42 42 42 Total 210 205 Azienda Ospedaliera di Parma 444 485 91.5% PIACENZA PROVINCE AZIENDA PIACENZA Civil hospital, Piacenza Presidio Val Tidone, Castel San Giovanni Presidio Val D'Arda, Fiorenzuola D'Arda, Cortemaggiore 225 97.4% 114	• • •			100 10/1
Total 210 205 Azienda Ospedaliera di Parma 444 485 91.5% PIACENZA PROVINCE AZIENDA PIACENZA Civil hospital, Piacenza 225 241 Presidio Val Tidone, Castel San Giovanni 78 73 Presidio Val D'Arda, Fiorenzuola D'Arda, Cortemaggiore 114 114	*	+		102.4%*
Azienda Ospedaliera di Parma 444 485 91.5% PIACENZA PROVINCE AZIENDA PIACENZA Civil hospital, Piacenza Presidio Val Tidone, Castel San Giovanni Presidio Val D'Arda, Fiorenzuola D'Arda, Cortemaggiore 444 485 91.5% 91.5%	1			
PIACENZA PROVINCE AZIENDA PIACENZA Civil hospital, Piacenza Presidio Val Tidone, Castel San Giovanni Presidio Val D'Arda, Fiorenzuola D'Arda, Cortemaggiore 225 241 78 73 97.4%	Tota	210	205	
PIACENZA PROVINCE AZIENDA PIACENZA Civil hospital, Piacenza Presidio Val Tidone, Castel San Giovanni Presidio Val D'Arda, Fiorenzuola D'Arda, Cortemaggiore 225 241 78 73 97.4% 114	Azienda Ospedaliera di Parma	444	485	91.5%
AZIENDA PIACENZA Civil hospital, Piacenza Presidio Val Tidone, Castel San Giovanni Presidio Val D'Arda, Fiorenzuola D'Arda, Cortemaggiore 225 241 78 73 97.4%	•		<u> </u>	
Civil hospital, Piacenza Presidio Val Tidone, Castel San Giovanni Presidio Val D'Arda, Fiorenzuola D'Arda, Cortemaggiore 225 73 97.4%				
Presidio Val Tidone, Castel San Giovanni 78 73 Presidio Val D'Arda, Fiorenzuola D'Arda, 114 Cortemaggiore 114	AZIENDA PIACENZA			
Presidio Val D'Arda, Fiorenzuola D'Arda , 114 114	Civil hospital, Piacenza	225	241	
Presidio Val D'Arda, Fiorenzuola D'Arda , 114 114 Cortemaggiore	Presidio Val Tidone, Castel San Giovanni	78	73	97 4%
**		114	114	∕1 • ₹/U
Total 417 428		1 417	428	

		2003	
RAVENNA PROVINCE	N° of operations	N° operations	%
RAVERNATROVINCE	communicated to	communicated	support to
	RIPO	via S.D.O.	R.I.P.O.
AZIENDA RAVENNA			
Hospital S. Maria delle Croci, Ravenna	128	135	
Presidio Ospedaliero, Lugo	248	252	
Hospital Infermi, Faenza	89	101	
Private hospital "Domus Nova"	19	19	97.1%
Private hospital "S. Francesco"	123	126	
Private hospital "Villa Maria Cecilia"	48	48	
Private hospital "S. Pier Damiano"	136	134	
Total	791	815	
REGGIO EMILIA PROVINCE			
AZIENDA REGGIO EMILIA			
Hospital, Guastalla	97	95	
Hospital S. Sebastiano, Correggio	-	5	
Hospital Montecchio Emilia	62	64	
Hospital Scandiano	69	68	89.6%
Hospital S. Anna, Castelnovo Monti	81	76	
Private hospital "Villa Salus"	80	80	
Private hospital "Villa Verde"(non accred)	-	46	
Total	389	434	
Arcispedale Santa Maria Nuova, Reggio Emilia	187	258	72.5%
DIMINI DDOVINCE			
RIMINI PROVINCE AZIENDA RIMINI			
Hospital Infermi, Rimini, Sant Arcangelo	119	141	
Hospital G. Ceccarini, Riccione,	164	167	
Cattolica, Cesenatico	104	107	91.7%
Private hospital "Sol et Salus"	69	75	22770
Private hospital "Villa Maria"	3	3	
Total	_	386	
1000		230	
TOTAL	7913	8633	91.7%

16 operations performed in two 'non accreditated' private hospitals of Bologna (Villalba and Villa Toniolo)are not here reported.

1.3 Ratio public/private treatment

Percentage of primary arthroprostheses, hemiarthroplasties and revisions of the hip performed in public hospitals.

	% of operations performed in public hospitals (AUSL, AOSP, IRCCS)		
Year of surgery	Primary arthroprosthesis	Hemiarthroplasty	Revision
2000	77.0%	97.0%	78.0%
2001	81.0%	97.3%	77.0%
2002	78.0%	97.5%	79.0%
2003	76.0%	98.5%	78.0%

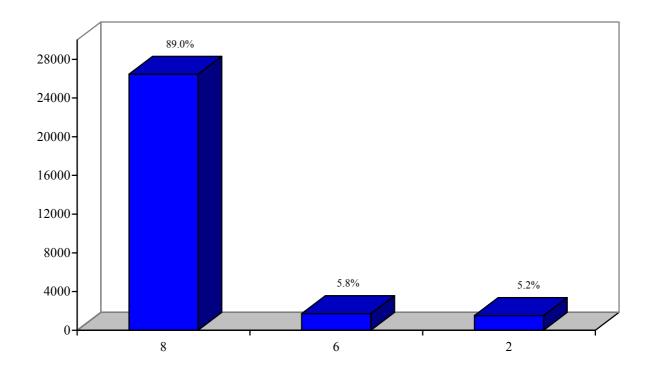
More than $\frac{3}{4}$ of THA (total hip arthroplasties) and nearly all hemiarthroplasties are performed in public hospitals.

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 31st December 2003, according to **quality** of data.

Quality	Number operations	Percentage
8	26.462	89.0%
6	1.730	5.8%
2	1.527	5.2%
Total	29.719	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 2003 this percentage was much higher, 98%.

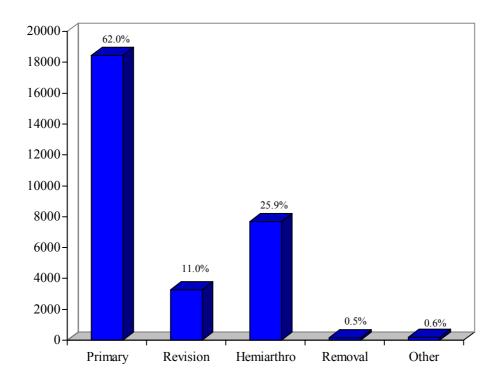
There are still, in isolated cases, some difficulties due to inaccurate reporting of data.

3. Type of operation

Number of <u>hip operations</u> carried out on patients with admission date between 1^{st} January 2000 and 31^{st} December 2003, according to **type**.

Type of operation	Number of operations	Percentage
Primary THA	18.435	62.0%
Revision*	3.271	11.0%
Hemiarthroplasty	7.679	25.9%
Prosthesis removal	156	0.5%
Other**	178	0.6%
Total	29.719	100.0%

- * 1278 total revisions, 1325 cup revisions, 471 stem revisions, 180 head revisions 18 hemiarthroplasty revisions.
- ** Including 88 luxation reductions, 37 debridements, 7 hematoma drains, 6 ossification removals, 5 fixation device removals, and 8 partial prosthesis removals.



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

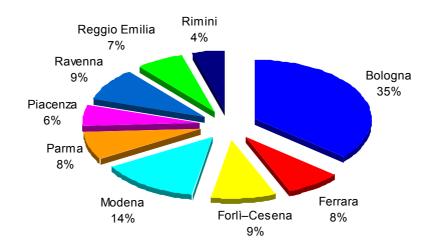
The percentage distribution of primary total arthroplasties remained constant throughout the four years.

3.1 Number of operations according to province

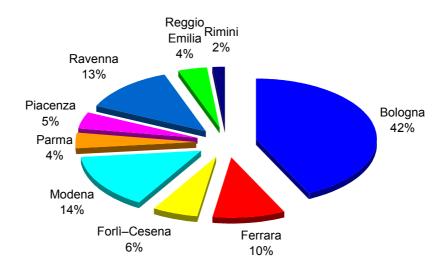
Number of <u>hip operations</u> operations carried out on patients with admission date between 1st January 2000 and 31st December 2003, according to **type** and **province**.

Province	Primary	Revision	Hemiarthroplasty	Prosthesis removal	Other	Total
Bologna	6.671	1.397	1.865	119	122	10.174
Ferrara	1.426	324	733	7	5	2.495
Forlì-Cesena	1.633	200	511	2	4	2.350
Modena	2.528	481	1.212	6	13	4.240
Parma	1.428	130	635	3	3	2.199
Piacenza	1.044	152	501	9	13	1.719
Ravenna	1.673	409	925	4	11	3.022
Reggio Emilia	1.236	119	865	5	4	2.229
Rimini	796	59	432	1	3	1.291
Totale	18.435	3.271	7.679	156	178	29.719

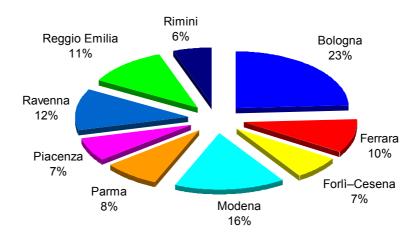
Percentage distribution of **primary arthroplasty operations** in the provinces of Emilia Romagna:



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.

Number of THA performed in Emilia Romagna is 105/100.000 inhabitants; the value is appropriate to satisfy the request of population.

3.2 Passive and active movement

Number of THA and TKA operations performed in the Emilia-Romagna region on patients according to their origin from outside the Emilia-Romagna region.

Region of residence	Primary THA	Primary TKA
Piemonte	29	21
Lombardia	37	67
Veneto	102	56
Friuli	13	7
Liguria	30	19
Marche	140	177
Toscana	101	69
Umbria	67	53
Lazio	73	32
Campania	95	81
Abruzzo	59	36
Molise	16	12
Basilicata	30	20
Puglia	154	171
Calabria	55	58
Sicilia	152	131
Sardegna	24	8
Other regions and	79	46
abroad		
	1256	1064
Total	(that is 23% of operations performed in Emilia-Romagna)	(that is 31% of operations performed in Emilia-Romagna)

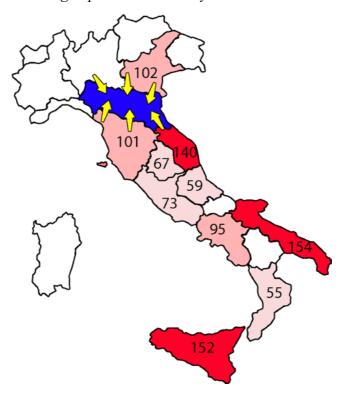
Source: data bank S.D.O. 2003

Movement of Emilia-Romagna residents to other regions

Region of residence	Primary THA	Primary TKA
Lombardia	191	183
Veneto	48	79
Liguria	30	4
Marche	23	18
Other Regions	38	20
Total	330 (equal to 7.7% of operations performed on Emilia-Romagna residents)	304 (equal to 12% of operations performed on Emilia-Romagna residents)

Source: data bank S.D.O. 2003

Origin of non-Emilia-Romagna patients treated by THA in Emilia-Romagna



Movement of Emilia-Romagna residents to other regions



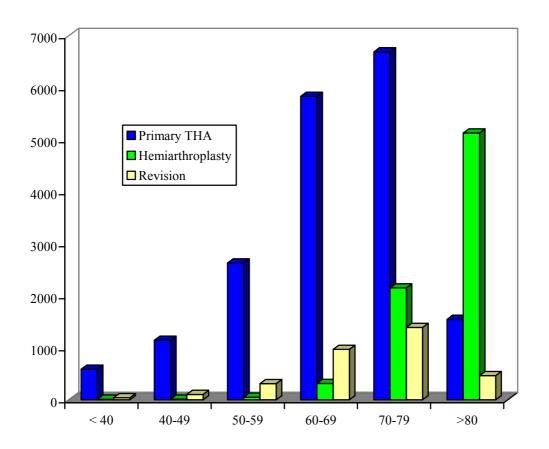
4. Descriptive statistics of patients

4.1. Age

Number of <u>hip operations</u> carried out on patients with admission date between 1^{st} January 2000 and 31^{st} December 2003, according to **type of operation** and **age group** of patients at the time of surgery.

Type of operation	<4	10	40-4	19	50-	59	60-	60-69 70-		·79 ≥ 80		Total	
	N.	%	N.	%	N.	%	N.	%	N.	%	N.	%	1 Otal
Primary THA	587	3.1	1143	6.2	2629	14.3	5832	31.7	6686	36.3	1545	8.4	18422
Hemiarthropl.	10	0.1	12	0.2	48	0.6	312	4.1	2150	28.1	5128	66.9	7660
Revision	39	1.1	102	3.1	310	9.5	968	29.6	1389	42.5	463	14.2	3271
Prosthesis removal	1	0.6	8	5.1	11	7.1	48	30.8	66	42.3	22	14.1	156
Other	11	6.1	6	3.4	26	14.6	53	29.8	51	28.7	31	17.4	178
Total*	64	8	127	1	30	24	72	13	103	342	71	89	29687

^{*} In 32 cases (0.1%) 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 90 treated by hemiarthroplasty was stable throughout the four-year analysis of the register and now is set at 17%

The percentage of patients under 50 treated by arthroplasty was also stable (6.5%).

Mean age at surgery, according to type of operation

Type of operation	Mean age	Range
Primary THA	66.2	14 -100 years
Revision	69.6	22 - 100 years
Hemiarthroplasty	82.4	23 -104 years
Prosthesis removal	69.8	41 - 96 years
Other	67.1	20 – 96 years
General	70.8	14 -100 years

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

Mean age of patients treated with THA due to coxarthrosis according to the year of surgery

	Primary arthroplasty for coxarthrosis				
	Mean age	Range			
Year 2000	63.9	30 – 84 years			
Year 2001	68.7	26 – 100 years			
Year 2002	68.8	16 – 99 years			
Year 2003	69.0	34 – 100 years			

Mean age of patients treated with hemiarthroplasty due to fracture according to the year of surgery

C ,	Hemiarthroplasty due to fracture				
	Mean age	Range			
Year 2000	82.4	32 – 104 years			
Year 2001	82.4	39 – 101 years			
Year 2002	82.6	27 – 102 years			
Year 2003	82.8	53 – 102 years			

In both cases data are slightly increasing

Type of prosthesis implanted to treat femoral neck fracture

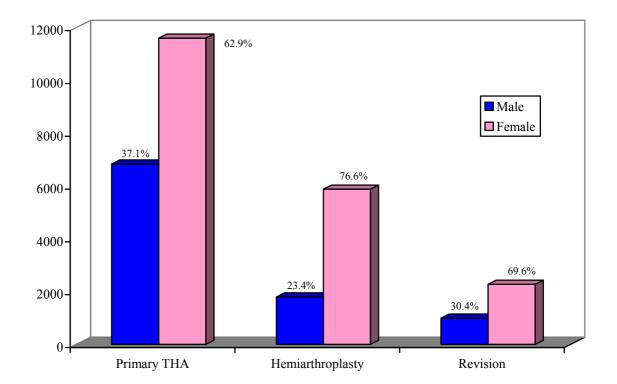
	Prosthesis due to femoral neck fracture			
	Mean age	Range		
Arthroprosthesis	70.5	19 – 100 years		
Hemiarthroplasty	82.5	27 – 104 years		

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

4.2. Sex

Number of <u>hip operations</u> carried out on patients with admission date between 1st January 2000 and 31st December 2003, according to *type of operation* and *sex* of patient.

Type of operation	Male	Female	Total
Primary THA	6.834	11.601	18.435
Hemiarthroplasty	1.797	5.882	7.679
Revision	994	2277	3.271
Prosthesis removal	58	98	156
Other	71	107	178
Total	9.754	19.965	29.719



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

This datum also appears to be stable: in the four years of the register, women have accounted for 68.1%, 67.3% , 67.5% and 66.7%of all patients undergoing hip arthroplasty.

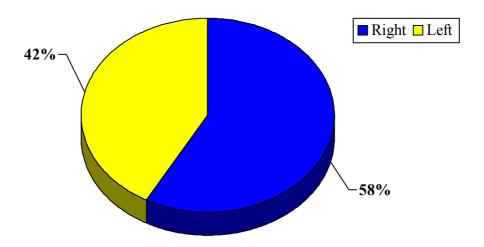
Regarding only *hemiarthroplasty*, the percentage of women was 77.9% in 2000, 76.2% in 2001, 75.5% in 2002, and 76.8% in 2003.

Concerning *primary arthroplasty* the female sex accounted for 64.0% of cases in 2000, 62.4% in 2001, 63.7% in 2002 and 62.6% in 2003.

4.3. Side of surgery

Coxarthrosis more often affects right hip (58%). The percentage has been calculated on patients wearing only one implant.

Percentage distribution of primary THA due to coxarthrosis, according to side

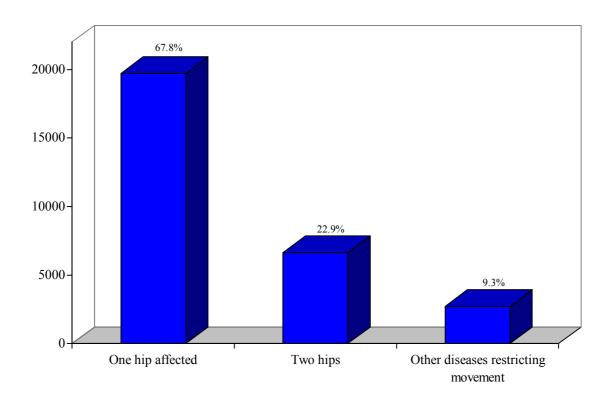


4.4. Clinical condition

Number of <u>arthroplasty operations</u> carried out on patients with admission date between 1^{st} January 2000 and 31^{st} December 2003, according to **clinical condition** of patients at the time of surgery

Clinical condition	Number	Percentage
One hip affected	19.720	67.8%
Two hips affected	6.644	22.9%
Other diseases restricting movement	2.716	9.3%
Total*	29.080*	100.0%

^{* 639 (2.2%)} data are missing



Percentages are similar to previous years.

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	69.9%	62.6%	64.8%
Two hips affected	19.4%	31.7%	28.2%
Other diseases restricting movement	10.7%	5.7%	7.0%
Total	100.0%	100.0%	100.0%

4.5 Bilateral arthroplasty

In the period of registry observation (4 years) 1,277 patients underwent bilateral operations. About 7% of this group of patients chose to undergo the second operation at a different hospital from where the first one was performed.

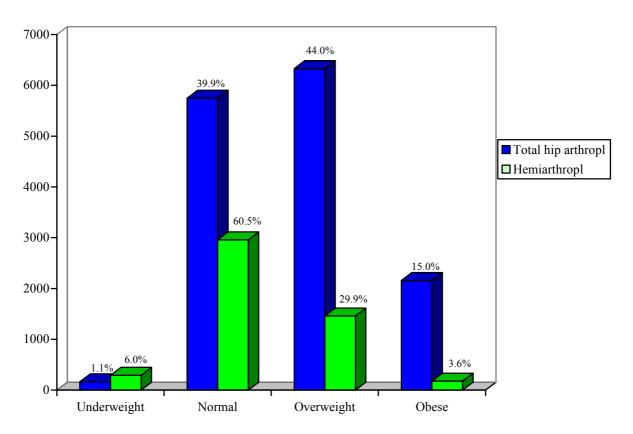
In bilateral operations, it was observed that the first hip to be treated was the right one in 53% of cases.

4.6. Body mass index (BMI)

Number of <u>arthroplasty operations</u> carried out on patients with admission date between I^{st} January 2000 and 31st December 2003, according to **body mass index** of patients at the time of surgery.

Body Mass Index	Primary THA	Hemiarthroplasty
Underweight (≤ 19)	173	306
Normal (20-25)	6.061	3.097
Overweight (26-29)	6.676	1.528
Obese (≥ 30)	2.276	185
Total*	15.186	5.116

* 5812 (22.3%) are missing



Overweight and obesity, calculated according to BMI [weight in kg/(height in meters)²], are characteristics found in more than 60% of patients undergoing hip arthroplasty.

Elderly patients undergoing hemiarthoplasty are overweight or obese only in 33% of cases. In this group scarce nutrition is more common. Difference between the two groups is significant (Chi square test)

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.

4.7 Pathology in primary THA and hemiarthroplasty

Number of <u>primary total hip arthroplasty</u> operations carried out on patients with admission date between 1st January 2000 and 31st December 2003, according to **diagnosis**.

Diagnosis in primary arthroplasty	Number	Percentage
Primary arthritis**	12.089	65.8%
Sequelae of LCA and DCA	2.390	13.0%
Femoral neck fracture	1.608	8.8%
Femoral head necrosis (idiopathic, due to dialysis, due to steroids)	985	5.4%
Post traumatic arthritis	459	2.5%
Post traumatic necrosis	270	1.5%
Rheumatic arthritis	259	1.4%
Femoral neck fracture sequelae	69	0.4%
Epiphysiolysis sequelae	45	0.2%
Perthes disease sequelae	40	0.2%
Tumor	36	0.2%
Septic coxitis sequelae	26	0.1%
Paget's disease sequelae	16	0.1%
TBC coxitis sequelae	15	0.1%
Other	62	0.3%
Total*	18.369	100.0%

^{*66} data missing, equal to 0.4% of the series

Percentage distribution of diseases leading to THA according to year of operation

Diagnosis in primary arthroplasty	Percentage					
Diagnosis in primary arthropiasty	Year 2000	Year 2001	Year 2002	Year 2003		
Primary arthritis	66.8%	65.1%	63.6%	67.4%		
Sequelae of LCA and DCA	13.5%	13.3%	13.1%	12.0%		
Femoral neck fracture	9.0%	9.1%	9.3%	8.0%		
Femoral head necrosis idiopathic	4.8%	5.3%	5.0%	5.3%		
Post traumatic arthritis	2.1%	2.1%	2.7%	2.0%		
Post traumatic necrosis	1.3%	1.5%	2.0%	1.3%		
Rheumatic arthritis	1.4%	1.6%	1.4%	1.2%		
Other	1.1%	2.0%	2.9%	2.8%		

Percentage distribution is similar over the four years

^{**} in 428 cases (2.3% of the total) patients are younger than 50 years or older than 95 Prostheses for bone tumor resection are not registered by R.I.P.O.

Percentage distribution of diagnosis in THA, according to type of healthcare center

Diagnosis in primary arthroplasty	Percentage					
Diagnosis in primary artificiality	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%		

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.

Number of <u>hemiarthroplasty</u> carried out on patients admitted to hospital between 1^{st} January 2000 and 31^{st} December 2003, according to **diagnosis**.

Diagnosis in hemiarthroplasty	Number	Percentage
Femoral neck fracture	7.477	97.9%
Tumor, pathological fracture	69	0.9%
Primary arthritis*	33	0.4%
Post traumatic arthritis*	12	0.2%
Sequelae femoral neck fracture	24	0.3%
Other	23	0.3%
Total**	7.638	100.0%

^{*} data not fully reliable

Almost all hemiarthroplasty were implanted in the treatment of femoral neck fractures or their sequelae(fracture fixation device loosening, pseudoarthrosis..). The treatment of primitive or secondary coxarthritis seems unlikely.

^{** 41} data missing, equal to 0.5% of the series.

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

Type of anomation		Percentage			
Type of operation	AOSP	Private	AUSL	I.O.R	
Primary THA	12.3%	36.6%	17.6%	31.6%	
Hemiarthroplasty	87.7%	63.4%	82.4%	68.4%	
Patients mean age	80.4 yrs	78.2 yrs	80.5 yrs	79.8 yrs	

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.

4.8 Causes for revision

Number of <u>revision operations</u> carried out on patients admitted between 1st January 2000 and 31 December 2003, according to **diagnosis**.

In the Table all revisions performed in the Region, without taking care of site and date of primary implant are reported. No indication of follow-up time is in theses data.

Diagnosis in revision surgery	Number	Percentage
Cup aseptic loosening	1.042	32.1%
Total aseptic loosening	1.031	31.7%
Stem aseptic loosening	356	11.0%
Prosthesis luxation	216	6.6%
Prosthesis removal	86	2.6%
Hemiarthroplasty stem loosening	75	2.3%
Bone fracture	63	1.9%
Hemiarthroplasty luxation	55	1.7%
Septic loosening	52	1.6%
Prosthesis breakage **	49	1.5%
Pain without loosening	45	1.4%
Acetabular osteitis	41	1.3%
Polyethylene wear	36	1.1%
Pain without hemiarthroplasty loosening	12	0.4%
Other (ossifications, trauma, fracture)	92	2.8%
Total*	3.251	100.0%

^{*20} 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 74% of revisions carried out in the region.

Septic loosening, although limited to 1.6%, 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.

^{** 8} cup fracture, 11 stem farcture, 6 head fracture, 11 insert fracture

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.

5.1 Cups used in *primary surgery*

TYPE OF CUP	NUMBER	%
ANCA FIT – Cremascoli	4436	24.1%
CLS – Sulzer	1976	10.7%
FITMORE – Sulzer	1023	5.5%
ABG II – Howmedica	959	5.2%
STANDARD CUP – Sulzer	929	5.0%
DUOFIT PSF – Samo	894	4.8%
MULLER – Cremascoli	731	4.0%
TRILOGY- Zimmer	657	3.6%
REFLECTION – Smith & Nephew	644	3.5%
CONTEMPORARY – Howmedica	344	1.9%
ABG – Howmedica	334	1.8%
MULLER – Samo	321	1.7%
ELLIPTICAL CUP – Stratec	316	1.7%
ZCA – Zimmer	296	1.6%
MULLER – Sulzer	288	1.6%
BICON-PLUS - Endoplus	190	1.0%
SPH CONTACT – Lima	174	0.9%
MULLER – Smith & Nephew	174	0.9%
OSTEOLOCK – Howmedica	170	0.9%
SECUR-FIT – Osteonic	168	0.9%
INTERSEAL – Wright	161	0.9%
HILOCK LINE – Symbios	160	0.9%
DURALOC – DePuy	154	0.8%
METASUL STAR CUP – Sulzer	146	0.8%
ALBI – Cremascoli	145	0.8%
CFP – Link	143	0.8%
MARBURG – Allopro Sulzer	131	0.7%
EASY – Hit Medica	130	0.7%
MULLER- Lima	98	0.5%
FITEK – Sulzer	79	0.4%
MBA – Groupe Lépine	74	0.4%
SPH PEG – Lima	71	0.4%
DURALOC SECTOR – Depuy	65	0.4%
MC MINN – Link	58	0.3%
TRILOGY AB – Zimmer	54	0.3%
S II – Link	53	0.3%
DURALOC OPTION – Depuy	52	0.3%
SURFACE PROSTHESIS – Birmingham	98	0.5%
UNKNOWN	77	0.4%
TOTAL	16973	92.1%

The remaining 1462 cups (7.9%) were of 55 different types, with less than 50 per type. On the whole, 94 different types of cups were used in primary operations.

5.2 Cups used in total revision surgery

TYPE OF CUP	NUMBER	%
ANCA FIT – Cremascoli	226	17.7%
STANDARD CUP – Sulzer	131	10.3%
MULLER – Sulzer	88	6.9%
CONTEMPORARY – Howmedica	72	5.6%
TRILOGY-Zimmer	61	4.8%
OSTEOLOCK – Howmedica	47	3.7%
MULLER – Cremascoli	45	3.5%
MC MINN – Link	43	3.4%
LOR – Allopro Sulzer	41	3.2%
MULLER – Samo	35	2.7%
CLS – Sulzer	33	2.6%
PROCOTYL-E - Cremascoli	32	2.5%
FITMORE – Sulzer	28	2.2%
SECUR-FIT – Osteonic	25	2.0%
HAC CERAFIT CUP – Ceraver Osteal	22	1.7%
CONICAL SCREW CUP – Protek	21	1.6%
DUOFIT PSF – Samo	20	1.6%
ZCA – Zimmer	19	1.5%
MULLER – Lima	18	1.4%
CCB – Mathys	17	1.3%
DURALOC – De Puy	16	1.3%
ARTHOPOR II – Johnson & Johnson	15	1.2%
TOTAL	1055	82.6%

The remaining 223 cups (17.4%) were of 40 different types, with less than 15 per type.

On the whole, 62 different types of cups were used in total revision surgery.

5.3 Stems used in primary surgery

TYPE OF STEM	NUMBER	%
ANCA FIT – Cremascoli	2844	15.4%
CLS – Sulzer	2019	11.0%
CONUS – Sulzer	1648	8.9%
ABGII – Howmedica	822	4.5%
ABG – Howmedica	607	3.3%
EXETER – Howmedica	487	2.6%
SPECTRON – Smith & Nephew	473	2.6%
JVC Cremascoli	443	2.4%
VERSYS FIBER METAL TAPER – Zimmer	425	2.3%
MRL – Cremascoli	423	2.3%
P507 Samo	374	2.0%
VERSYS CEMENTED – Zimmer	365	2.0%
SL PLUS – Endoplus	310	1.7%
LC – Samo	285	1.5%
AD – Samo	283	1.5%
AHS – Cremascoli	268	1.5%
ANCA-FIT CLU – Cremascoli	262	1.4%
BASIS – Smith & Nephew	246	1.3%
DEFINITION – Howmedica	246	1.3%
PROXILOCK FT – Stratec	246	1.3%
EHS – Cremascoli	221	1.2%
PROFEMUR Z – Cremascoli	211	1.1%
SYNERGY – Smith & Nephew	206	1.1%
DUOFIT RKT – Samo	202	1.1%
STEM – Cremascoli	201	1.1%
ULTIMA – Johnson & Johnson	200	1.1%
C2 – Lima	186	1.0%
LUBINUS SP2 – Link	182	1.0%
G3 – Citieffe	177	1.0%
CORAIL – Depuy	170	0.9%
MS 30 – Protek Sulzer	167	0.9%
CFP – Link	155	0.8%
C STEM – Depuy	150	0.8%
CITATION – Howmedica	127	0.7%
EASY – Hitmedica	125	0.7%
PPF – Biomet	121	0.7%
ALLOCLASSIC SL – Allopro Sulzer	115	0.6%
ANCA – Cremascoli	111	0.6%
SPS – Symbios	93	0.5%
PROFEMUR – Cremascoli	84	0.5%
BHS – Smith and Nephew	83	0.5%
AC – Howmedica	73	0.4%
IMAGE – Smith & Nephew	73	0.4%
CBC – Mathys	70	0.4%
CDC - Mainys	/ U	0.470

(continues)

TYPE OF STEM	NUMBER	%
MERIDIAN – Howmedica	67	0.4%
S. ROM – Johnson & Johnson	67	0.4%
PERFECTA – Wright	65	0.4%
TAPERLOC – Biomet Merck	65	0.4%
FULLFIX – Mathys	62	0.3%
VERSYS CEMENTED LD – Zimmer	56	0.3%
SL – Lima	54	0.3%
SL REVISION – Sulzer	54	0.3%
MBA – Groupe Lépine	51	0.3%
Surface prosthesis – Birmingham	98	0.5%
UNKNOWN	99	0.5%
TOTAL	17317	93.9%

The remaining 1118 stems (6.1%) were of 55 different types, with less than 50 per type. On the whole 110 different types of stem were used in primary surgery.

5.4 Stems used in total revision surgery

TYPE OF STEM	NUMBER	%
PROFEMUR – Cremascoli	326	25.5%
SL REVISION – Sulzer	250	19.6%
S.ROM – Johnson & Johnson	69	5.4%
RESTORATION T3 – Howmedica	60	4.7%
AnCA FIT - Cremascoli	46	3.6%
CONUS - Sulzer	43	3.4%
ZMR – Zimmer	34	2.7%
MP RECONSTRUCTION – Link	29	2.3%
AnCA – Cremascoli	27	2.1%
EXETER - Howmedica	26	2.0%
CLS – Sulzer	23	1.8%
CONELOCK REVISION – Stratec	23	1.8%
AD – Samo	22	1.7%
MP RECONSTRUCTION PROSTHESIS – Link	21	1.6%
CBK – Mathys	20	1.6%
JVC – Cremascoli	19	1.5%
C2 – Lima	16	1.3%
AnCA-FIT CLU – Cremascoli	12	0.9%
TOTAL	1066	83.4%

The remaining 212 stems (16.6%) were of 39 different types, with less than 10 per type.

On the whole 60 different types of stems were used in primary surgery.

It should be pointed out that in 7.3% of primary operations heads and stems manufactured by different companies were implanted in the same operations.

5.5 Number of different types of implants

Number of <u>different types</u> of cups and stems implanted in primary surgery, according to

year of operation.

Voor of anaration	Primary surgery	
Year of operation	Stems	Cups
2000	93	87
2001	98	92
2002	94	90
2003	110	94

Number of <u>different types</u> of cups and stems implanted in revision surgery, according to

year of operation.

Voor of operation	Total revision surgery	
Year of operation	Stems	Cups
2000	48	58
2001	55	64
2002	48	59
2003	60	62

Data are dispersed. The efficacy of single devices implanted in few cases will be difficult to ascertain.

Types have not been considered different when only change of trade-marked occurred (eg. Sulzer-Centerpulse, or Johnson & Johnson-Depuy)

5.6 Modular neck

Nearly 1/4 of stems implanted in primary surgery have modular neck.

ANCA-fit stem by Cremascoli, the more common stem in the region, short necks are used in 2/3 of operations.

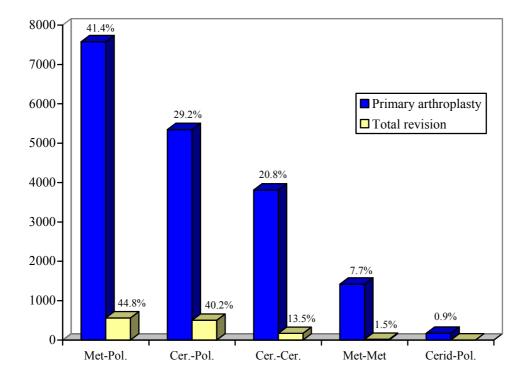
Straight neck is implanted in 40% of operations, anti-retro versus inn 41% and varus-valgus in 17%.

5.7 Articular coupling and head diameter

Number of <u>primary total hip arthroplasty</u> operations carried out on patients with admission date between 1st January 2000 and 31 December 2003, according to **type of operation and articular coupling**.

Articular coupling	Total hip arthroplasty Total rev	
Metal-polyethylene	7.578	562
Ceramic- polyethylene	5.346	503
Ceramic-ceramic	3.811	169
Metal-metal	1.420	19
Cerid- polyethylene	170	0
Total*	18.325	1.253

^{* 110} missing data for primary and 25 for revision



Percentage of total hip arthroplasty according to articular coupling during the years

Year of operation	Primary THA			
Tear or operation	met-pol	cer-pol	cer-cer	met-met
2000	45.2%	29.3%	18.5%	7.1%
2001	40.4%	31.6%	20.3%	7.6%
2002	39.3%	30.5%	22.3%	7.9%
2003	42.0%	28.4%	20.8%	8.8%

Percentage of revision surgery according to articular coupling during the years

Year of operation	Total revision surgery				
rear or operation	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	42.9%	42.9%	12.2%	2.0%	
2003	42.0%	45.2%	11.7%	1.1%	

Cer-pol is slightly increasing whilst cer-cer is decreasing

Percentage of elective THA according to articular coupling and class age

Age classes		Elective THA				
Age classes	met-pol	cer-pol	cer-cer	met-met		
<40	21.2%	9.6%	26.9%	42.3%		
40-49	16.6%	12.8%	42.5%	28.1%		
50-59	23.4%	19.8%	37.2%	19.6%		
60-69	40.0%	28.4%	24.3%	7.3%		
70-79	52.5%	35.5%	10.9%	1.1%		
> 80	66.0%	29.8%	4.1%	0.1%		

Head diameter

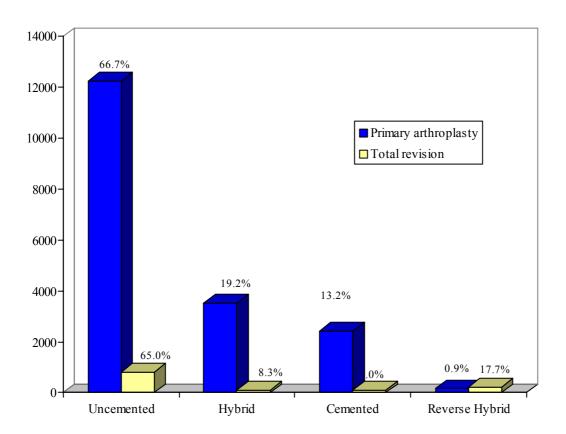
Head diameter is almost always 28 mm, no matter what the material is. Few metal Metasul heads have a greater diameter, up to 38 mm.

5.8 Prosthesis fixation

Number of <u>hip arthroplasty operations</u> on patients admitted between 1st January 2000 and 31st December 2003, according to type of operation and fixation method.

Fixation method	Primary THA	Total revision
Uncemented	12.247	818
Hybrid (stem cemented and cementless cup)	3.519	104
Cemented prostheses	2.428	114
Cementless stem and cemented cup	159	223
Total*	18.353	1.259

^{*} data not supplied in 82 primary operations and 19 revision operations



Percentage of total hip arhroplasties according to fixation, during the years

	Primary surgery			
Year operations	Cemented prostheses	Cementless prostheses	Hybrid	Cementless stem and cemented cup
2000	15.8%	60.4%	23.0%	0.8%
2001	14.4%	65.3%	19.4%	0.8%
2002	12.0%	70.1%	16.9%	1.1%
2003	11.4%	71.3%	16.5%	0.9%

Percentage of total revision surgery according to fixation, during the years

	Total revision surgery			
Year operations	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	7.5%	65.8%	8.2%	18.5%
2003	7.3%	69.1%	6.5%	17.1%

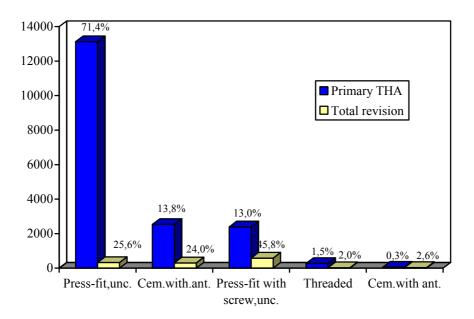
An increase of uncemented fixation can be observed either for primary and for revision surgery.

5.9 Cup fixation

Number of <u>hip operations</u> carried out on patients admitted between 1^{st} January 2000 and 31^{st} December 2003, according to **type of operation and cup fixation**

Cup fixation	Primary THA	Total revision
Press-fit, uncemented	13.128	325
Cemented without antibiotic	2.535	304
Press fit with screw, uncemented	2.392	581
Threaded	273	25
Cemented with antibiotic	54	34
Total*	18.382	1.269

^{* 53}missing data for THA and 9 for revision

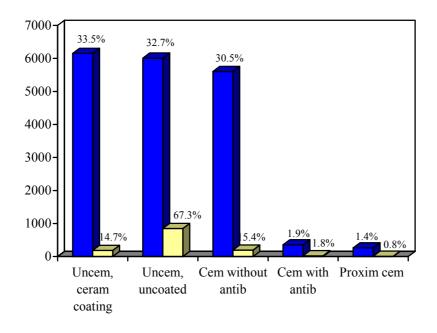


5.10 Stem fixation

Number of <u>hip operations</u> carried out on patients admitted between 1^{st} January 2000 and 31^{st} December 2003, according to **type of operation and stem fixation**

Cup fixation	Primary THA	Total revision
Uncemented, HA coated	6.150	186
Uncemented, no ceramic coating	6.007	850
Cemented without antibiotic	5.604	195
Cemented with antibiotic	354	23
Proximally cemented	262	9
Total*	18.377	1263

^{* 51} missing data for THA and 15 for revision



■ Primary THA
■ Total revision

5.11 Bone cement

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 THA	Hemiarthroplasty
SURGICAL SIMPLEX P	32.2%	23.7%
AMPLICEM 3	15.2%	6.3%
CEMEX	19.1%	38.5%
PALACOS R	12.3%	4.4%
CMW 3	4.8%	6.5%
ANTIBIOTIC SIMPLEX	4.6%	2.2%
CEMEX RX	3.4%	9.0%
CEMFIX 3	2.4%	0.2%
CEMEX ISO	0.9%	0.4%
SULCEM 3	1.6%	2.2%
CEMFIX 1	0.5%	0.1%
SULCEM 1	0.4%	0.2%
CMW 1	0.7%	1.7%
AMPLICEM 1	0.7%	1.3%
CEMEX XL	0.3%	1.6%
Other	0.9%	1.7%
Total	100.0%	100.0%

Bone cement preparation for stem fixation is done under vacuum in 51.7% of cases

The stem is cemented in 78.2% of cases under pressure with applicator, in 20.1% manually, and in the remaining 1.7% by aspiration system.

5.12 Surgical techniques

(surgical approach, bone graft, reinforcement rings)

The most commonly used *surgical approaches* are lateral and postero-lateral. 70.0% of <u>THA</u> is implanted through lateral approach, 26.0% through postero-lateral. Minimally invasive approach is used in 0.07% of operations.

56.1% of hemiarthroplasties is implanted through lateral approach, 40.4% through postero-lateral

Number of hip arthroplasty operations on patients admitted between 1st January 2000

and 31st December 2003, according to type of operation and bone graft.

Graft	Primary THA	Total revision	Cup revision	Stem revision	Total
Not used	17.562	702	743	417	19.424
Acetabular	688	496	545	12	1.741
Femoral	125	19	5	27	176
Both	60	61	23	8	152
Total	18.435	1.278	1.316	464	21.493

In 15.6% of revision surgery of cups, **reinforcement ring** were uses. More commonly used are MULLER – Sulzer (67.6%) and Burch-Schneider – Sulzer (23.6% of cases).

6. Types of hemiarthroplasty

6.1 Stem and head

Type of hemiarthroplasty		
(head + stem)	<i>N</i> .	%
SPERI-LOCK + SL -Hit Medica	707	9.2%
SPERI–LOCK + SL STREAKES – Hit Medica	90	1.2%
SPERI–LOCK + SPERI–SYSTEM II – Hit Medica	664	8.6%
TESTA BIARTICOLARE + SL –Lima	423	5.5%
ULTIMA + ULTIMA LX – Johnson & Johnson	312	4.1%
ULTIMA + ULTIMA STRAIGHT – Johnson & Johnson	97	1.3%
CENTRAX + HIP FRACTURE – Howmedica	288	3.8%
CUPOLA SEM + STELO SEM – D.M.O.	61	0.8%
CUPOLA SEM + STELO SEM II – D.M.O.	258	3.4%
CUPOLA BIPOLARE + CCA Mathys	269	3.5%
RETENTIVE MOBILE CUP – Cedior + ORTHO–FIT – Allopro	205	2.7%
MODULAR BIPOLAR + STANDARD STRAIGHT – Protek	288	3.8%
C1 + AB – Citieffe	397	5.2%
BICENTRIC + RELIANCE Howmedica	190	2.5%
CUPOLA MOBILE BIARTICOLARE + SL – Permedica	299	3.9%
CUPOLA MOBILE + AHS – Cremascoli	225	2.9%
TESTA ELLITTICA + LC –Samo	160	2.1%
TESTA BIPOLARE + SL – Amplimedical	152	2.0%
SPERI-LOCK – Hit Medica + MRL – Cremascoli	107	1.4%
CUPOLA MOBILE + MRL – Cremascoli	127	1.7%
CENTRAX + EXETER – Howmedica	120	1.6%
CUPOLA MOBILE + JVC – Cremascoli	108	1.4%
CUPOLA MOBILE – Cremascoli + VERSYS – Zimmer	127	1.7%
CUPOLA MOBILE TEKNO–FIN +STANDARD STRAIGHT – Protek	143	1.9%
C1 – Citieffe + DEON – Bioimpianti	75	1.0%
TESTA BIARTICOLARE – Lima + SL –Hit Medica	58	0.8%
C1 – Citieffe + VERSYS – Zimmer	88	1.1%
RETENTIVE MOBILE CUP – Cedior + METABLOC – Protek	58	0.8%
JANUS + FIN – Bioimpianti	134	1.7%
JANUS Bioimpianti + SPERI–SYSTEM II – Hit Medica	54	0.7%
TESTA BIARTICOLARE – Lima + ALBI PTC – Cremascoli	135	1.8%
BICONTACT AESCULAP + BICONTACT AESCULAP	129	1.7%
BI-POLAR + PPF - Biomet Merck	31	0.4%
UHR – Osteonics + Exeter – Howmedica	31	0.4%
UHR + ACCOLADE – Osteonics	106	1.4%
TESTA BIARTICOLARE + DUOFIT CKA Samo	66	0.9%
TESTA BIARTICOLARE LOCK – Lima + LOGICA LIMA	145	1.9%
CENTRAX + DEFINITION – Howmedica	35	0.5%
Unknown	78	1.0%
TOTAL	7040	91.7%

In the remaining 639 cases (8.3%) 40 different types of prosthesis were used numbering less than 30 units per type.

It should be pointed out that in 19.5% of hemiarthoplasty **heads and stems manufactured by different companies** were implanted in the same operations. In 5.9% head **and stems manufactured by different companies** were implanted in the same operations.

6.2 Other characteristics of hemiarthroplasties

Number of surgeries according to head type

Head type	N.	%
Preassembled bipolar head	6.940	91.0%
Bipolar head to be assembled in the operating	462	6.1%
Monopolar head	224	2.9%
Total*	7.626	100.0%

^{*53} missing cases, equal to 0.7%

The most commonly used heads are biarticular, pre-assembled and ready for implantation. Two components to be assembled during surgery are very rarely used.

In 94.8% of cases the stem of the hemiarthroplasties was cemented and the stem had a modular neck in only 3.5% of cases.

In 2.2% of cases the hemiarthroplasties had a ceramic head, all the other heads were metal.

6.8% of the metal heads had collars.

7. Antibiotic prophylaxis

7.1 Antibiotic prophylaxis in primary surgery

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
AMOXICILLIN	302	1.6%
AMOXICILLIN + GENTAMICIN	326	1.8%
AMPICILLIN	298	1.6%
AMPICILLIN + SULBACTAM	135	0.7%
AMPICILLINA+ GENTAMICIN	62	0.3%
CEFAMANDOL	169	0.9%
CEFAMANDOL + GENTAMICIN	141	0.8%
CEFAMANDOL + TOBRAMICIN	164	0.9%
CEFAZOLIN	4561	24.7%
CEFAZOLIN + GENTAMICIN	365	2.0%
CEFAZOLIN + NETILMICIN	399	2.2%
CEFAZOLIN + TOBRAMICIN	2682	14.5%
CEFEPIME	339	1.8%
CEFOTAXIME	593	3.2%
CEFTAZIDIM	186	1.0%
CEFTIZOXIME	669	3.6%
CEFTRIAXONE	1134	6.2%
CEFTRIAXONE + TOBRAMICIN	161	0.9%
CEFUROXIME	1690	9.2%
CEFUROXIME + TOBRAMICIN	73	0.4%
CEFUROXIME + NETILMICIN	28	0.2%
CIPROFLOXACINE	188	1.0%
GENTAMICIN	409	2.2%
PEFLOXACIN	139	0.8%
TEICOPLANIN	753	4.1%
TEICOPLANIN + NETILMICIN	275	1.5%
TOBRAMICIN	29	0.2%
VANCOMICIN	449	2.4%
VANCOMICIN + GENTAMICIN	537	2.9%
VANCOMICIN + TOBRAMICIN	133	0.7%
Other	545	3.0%
Unknown*	501	2.7%
TOTAL	18.435	100.0%

^{*} In 501 cases, although antibiotic prophylaxis was carried out, the active principle used was not reported to the registry.

In 67.4% of cases only one active principle was used, in the remaining 32.6 % two or more were used.

7.2 Antibiotic prophylaxis in revision surgery

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
AMOXICILLIN	44	1.3%
AMOXICILLIN + GENTAMICIN	49	1.5%
AMPICILLIN	24	0.7%
CEFAMANDOLE	28	0.9%
CEFAMANDOLE + GENTAMICIN	25	0.8%
CEFAMANDOLE + TOBRAMICIN	38	1.2%
CEFAZOLIN	754	23.0%
CEFAZOLIN + GENTAMICIN	39	1.2%
CEFAZOLIN + NETILMICIN	32	1.0%
CEFAZOLIN + TOBRAMICIN	495	15.1%
CEFEPIME	29	0.9%
CEFOTAXIME	57	1.7%
CEFTAZIDIME	12	0.4%
CEFTIZOXIME	152	4.6%
CEFTRIAXONE	142	4.3%
CEFTRIAXONE + TOBRAMICIN	29	0.9%
CEFUROXIMA	251	7.7%
CEFUROXIMA + TOBRAMICINA	34	1.0%
CIPROFLOXACINE	10	0.3%
GENTAMICIN	49	1.5%
PEFLOXACIN	6	0.2%
PIPERACILLIN	12	0.4%
TEICOPLANIN	172	5.3%
TEICOPLANIN + LEVOFLOXACINA	40	1.2%
TEICOPLANIN + NETILMICIN	51	1.6%
VANCOMICIN	130	4.0%
VANCOMICIN + GENTAMICIN	162	4.9%
VANCOMICIN + TOBRAMICIN	51	1.5%
Unknown	205	6.3%
Other	149	4.6%
TOTAL	3.271	100.0%

In 60.7% of cases only one active principle was used, in the remaining 39.3% 2 or more were used.

Prophylaxis is performed by **multiple administrations** in 81.5% primary arthroplasties, 80.9% of hemiarthroplasty, and 84.0% of revision operations.

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

8. Blood transfusion

Percentages of operations performed on patients admitted between 1st January 2000 and

31st December 2003 according to type of operation and transfusion.

	None	Autologus (recovery)	Autologus (predeposit)	Homologous	Autologous and Homologous	Missing data
Emergency primary	31.0%	3.7%	-	49.2%	1.6%	14.5%
Elective primary	13.8%	9.0%	44.9%	13.8%	7.7%	10.8%
Revision	8.5%	5.2%	26.3%	34.2%	14.5%	11.3%

Nearly half elective primary operations are supported by predeposited blood.

In the following tabs, the analysis has been performed according to type of operation and and healthcare structure. The quote of missing data is still quite high.

Emergency primary								
None Autologus (recovery) Autologus (predeposit) Homologous Autologus Homologous								
AOSP	30.8%	3.3%	48.8%	0.1%	17.0%			
Private	10.1%	18.8%	53.6%	5.8%	11.7%			
AUSL	32.6%	3.8%	46.6%	2.1%	14.9%			
IOR	19.6%	1.0%	70.7%	0.3%	8.4%			

Elective primary								
	None Autologus (recovery) Autologus (predeposit) Homologous Autologous and homologous data							
AOSP	11.7%	9.5%	55.2%	7.8%	2.5%	13.3%		
Private	9.9%	25.0%	30.1%	13.5%	7.6%	13.9%		
AUSL	17.8%	8.6%	40.1%	12.8%	8.9%	11.8%		
IOR	17.1%	1.2%	52.2%	16.7	6.6%	6.2%		

Revision surgery							
None Autologus (recovery) Autologus (predeposit) Homologous Autologous and Homologous							
AOSP	9.9%	7.2%	39.7%	19.8%	6.8%	16.6%	
Private	8.1%	13.0%	14.6%	29.2%	14.2%	20.9%	
AUSL	9.6%	6.2%	27.2%	28.3%	17.7%	11.0%	
IOR	9.5%	1.6%	26.0%	42.2%	13.6%	7.10%	

9. Complications occurred during hospitalization.

The rate of complications in prosthetic surgery carried out on patients hospitalized between January 1^{st} 2000 and December 31st 2003.

Data are not compared to SDO

	Data are not compared to 550								
Complications observed during hospitalization									
Intra-ope	Intra-operative			Post-operative local			Post-operative general		
Complication	N.	%*	Complication	N.	%	Complication	N.	%	
Calcar fracture	109	0.4	Hematoma	258	0.9	Anemia	271	0.9	
Diaphyseal fracture	122	0.4	Prosthesis dislocation	178	0.6	Respiration	101	0.34	
Anesthesiologic complications	63	0.2	SPE paralysis	71	0.24	Cardiovascular	81	0.27	
Other fractures	41	0.14	Thrombophlebitis	59	0.2	Hyperpyrexia	127	0.43	
Others	36	0.12	Infection	37	0.12	Collapse	67	0.23	
			Crural paralysis	21	0.07	Genito-urinary	125	0.42	
			Hemorragies	39	0.13	Gastro-intestinal	76	0.26	
			Bed sores	30	0.1	Embolism	64	0.22	
			Other	35	0.1	Cerebral ischemia	21	0.07	
						Confusion	31	0.1	
						Other	63	0.2	
Total	371	1.3	Total	728	2.4	Total	1.027	3.5	

^{*} The percentage has been calculated on the total number of operations

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

	Prin TI (184	_		ision 71)	pla	arthro sty 579)	rem	thesis oval 56)	Tot.
Intra-operative	197	1.1	92	2.8	80	1.0	2	1.3	371
Post-operative	454	2.5	120	3.7	150	2.0	4	2.6	728
local									
Post-operative	478	2.6	107	3.3	441	5.7	1	0.6	1027
general									
Death	49	0.3	21	0.6	246	3.2	1	0.6	317

10. Deaths during hospitalisation

Number of deaths in prosthetic surgery on patients hospitalized between January 1st 2000 and December 31st 2003

(the deaths recorded are those that occurred during hospitalization).

Year 2000					
Type of operation	Deaths	Number of operations	Percentage		
Primary THA	14	4.257	0.3%		
Hemiarthroplasty	54	1.731	3.1%		
Revision	1	718	0.1%		
Prosthesis removal	-	36	-		

Year 2001					
Type of operation	Deaths	Number of operations	Percentage		
Primary THA	15	4.542	0.3%		
Hemiarthroplasty	73	2.114	3.5%		
Revision	8	846	0.9%		
Prosthesis removal	1	45	2.2%		

Year 2002*					
Type of operation	Deaths	Number of operations	Percentage		
Primary THA	6	4.655	0.1%		
Hemiarthroplasty	34	1.904	1.8%		
Revision	5	851	0.6%		
Prosthesis removal	-	40	-		

Year 2003					
Type of operation	Deaths	Number of operations	Percentage		
Primary THA	14	4.981	0.3%		
Hemiarthroplasty	85	1.930	4.4%		
Revision	7	856	0.8%		
Prosthesis removal	=	35	-		

^{*}Crosschecking is still in progress for 2002. An underestimation is evident.

It should be pointed out that for 2000-2001 and 2003 crosschecking was performed for mortality data that was reported to RIPO compared to those of the Regional databanks. It was found that only a third of the deaths that occurred during hospitalization were reported on the RIPO forms, probably due to the fact that a patient dies only rarely in the orthopedic ward; more often death occurs in intensive care units.

10.1 Deaths in the first 30 and 180 days

Deaths in the first 30 days after surgery

Through the regional mortality databank it was possible to determine the death rate in patients in the first **30 days** after discharge. The table shows the total number of deaths, including also those of the above table of deaths during hospitalization concerning only patients treated in 2001.

1 st January 2001 – 31 st December 2001					
Type of operation	Deaths	Number of operations	Percentage		
Primary THA	20	4.542	0.4%		
Hemiarthroplasty*	107	2.114	5.1%		
Revision	9	846	1.1%		
Prosthesis removal	2	45	4.4%		

Mortality after 180 days

Through the regional mortality databank it was possible to determine the death rate in patients in the first **6 months** after discharge. The table shows the total number of deaths, including also those of the above table of deaths during hospitalization concerning only patients treated in 2001.

1 st January 2001 – 31 st December 2001					
Type of operation	Deaths	Number of operations	Percentage		
Primary THA	25	4.542	0.6%		
Hemiarthroplasty*	148	2.114	7.0%		
Revision	10	846	1.2%		
Prosthesis removal	3	45	6.7%		

^{*}Number of deaths observed for patients treated with hemiarthroplasties is in line with the mortality rate expected for a population of over-80-year-olds.

11. Duration of hospitalization

Preoperative hospitalization is the difference between date of surgery and date of admittance. Postoperative hospitalization is the difference between the date of discharge and the date of surgery.

	Mean luration	Range duration	Preoperative mean duration	Preoperative duration range	Postoperative mean duration	Postoperative duration range
Primary	12.6	0-134	2.2	0-78	10.5	0-131
Revision	15.7	1-129	3.5	0-84	12.3	0-111
Hemiarthropl	14.5	0-217	3.6	0-68	10.9	0-149
Prosthesis	23	6-99	5.4	0-50	16.6	0-98
removal						
Total	13.5	0-217	2.7	0-84	10.8	0-149

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 THA				
	Number of cases	Mean hospitalization	Range hospitalization		
Year 2000	3880	12.6	1-93		
Year 2001	4137	12.4	1-114		
Year 2002	4234	12.3	1-78		
Year 2003	4273	11.9	1-134		

	Emergency primaryTHA				
	Number of cases	Mean hospitalization	Range hospitalization		
Year 2000	377	15.7	4-66		
Year 2001	405	16.5	4-87		
Year 2002	421	16.0	4-112		
Year 2003	371	16.2	2-68		

	Hemiarthroplasty operations				
	Number of cases	Mean hospitalization	Range hospitalization		
Year 2000	1731	14.7	1-110		
Year 2001	2113	14.6	1-80		
Year 2002	1903	14.0	1-86		
Year 2003	1917	14.6	1-217		

	Elective primary THA				
	MedianMeanRangehospitalizationhospitalizationhospitalization				
AOSP	12	12.5	1-114		
IOR	12	12.7	3-76		
AUSL	11	11.9	1-134		
Private	12	12.7	1-107		

There is no significant differences among structures

12. Analysis of survival of primary surgery

12.1 Cox multivariate analysis

The Cox multivariate analysis identifies any variables that are independent from each other that can influence the event, in our case the removal of at least one prosthesis component.

Other variables that might influence the outcome of surgery, such as the method of fixing the prosthesis, or joint coupling, were not introduced into the analysis because they were not independent (for example, prosthesis fixation depends on the patient's age).

All primary hip arthroplasties performed in the region between 2000 and 2003 were analyzed.

Cox proportional risk m Variables	odel	
Dependent: Follow-	ир	
Independent: Age, se	ex and diagnosis.	
Number of valid observati Non revised: 18198	ons: 18435 (no exclusions) Revised: 237	
Chi-square: 20.48	p=0.0087	
Variable	Significance (p)	
Sex	NS	
	(0.38)	
Age	NS	
	(0.20)	
Diagnosis	S	
	(0.0001)	

The chi-square test, used to test globally the model applied, was significant, which suggested that, on the whole, the variables inserted in the model influenced the outcome of prosthetic surgery. The effect of each variable was compared to the others when equal. For example sex, when age and diagnosis were equal, did not influence the risk of failure, thus age, when sex and diagnosis were equal, did not influence the outcome.

The only variable in the model that influences significantly the outcome of surgery is preoperative diagnosis.

At this point we tested how it acts, either by reducing or increasing the risk.

The rate of relative risk was expressed with respect to the risk rate presented by the patients affected by coxarthrosis. A relative risk rate below 1 indicated a reduced risk of prosthesis loosening.

Conversely, a relative risk rate above 1 indicated an increased risk of prosthesis loosening.

To analyze the influence of the disease, the patients were divided into 6 groups:

- coxarthrosis,
- rheumatic arthritis (rheumatoid arthritis, psoriasis, rhizomelic spondylitis)
- femoral fractures and their consequences (necrosis and post-traumatic arthrosis)
- idiopathic necrosis of the femoral head
- sequelae of congenital and infantile diseases (LCA, DCA, Perthes, epiphysiolysis)
- "others" that include sequelae of septic coxitis, coxitis from TBC, ankylosis, and metastases.

The following table shows a significant increase in risk in the case of patients treated by arthroplasty due to femoral fracture, or after "other" diseases or rheumatic arthritis. In patients affected by rheumatic arthritis the risk was 2.58 times greater than in patients of the same sex and age treated for coxarthrosis. In patients affected by "other" diseases or treated by arthroplasty due to femoral fracture the risk was respectively 4.08 and 1.48 times greater than in patients of the same age and sex treated for coxarthrosis.

Conversely, in patients treated by arthroplasty due to cephalic necrosis, or to correct sequelae of congenital and infantile diseases the risk of loosening was not significantly higher than in patients treated for coxarthrosis.

Variable	Relative risk rate	Confidence Interval 95%		Significance (p)
Diagnosis				
Others (sequelae of coxitis, Paget's disease, metastasis, etc)	4.08	2.25	7.4	S (0.0001)
Sequelae congenital diseases	1.33	0.90	1.97	NS (0.14)
Femoral head necrosis	1.12	061	2.09	NS (0.71)
Femoral neck fracture and sequelae	1.48	1.02	2.14	S (0.039)
Rheumatic arthritis	2.58	1.20	5.55	S (0.015)

12.2 Survival curves

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, in relationship to the main factors concerning the patient (sex, age, build, disease), the implants (fixation, joint coupling).

The following table shows the number of primary joint arthroplasty operations performed in the period from January 2000 to December 2003 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.

As already stated in the introduction of this report, the recovery of data of operations not reported to RIPO is in progress. The uncertainty that comes from the failure to report about 10% of operations performed in the region give an unquantifiable underestimation at present.

	Number of operations	N. of revisions performed in the same hospital	N. of revisions performed in a different hospital
Primary THA	18.435	199	38
Hemiarthroplasty	7.679	62	14
Total revision	1.278	49	10
Total	27.392	310	62

In 16.0% 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 18.4%. and to total revision the percentage is 16.9%

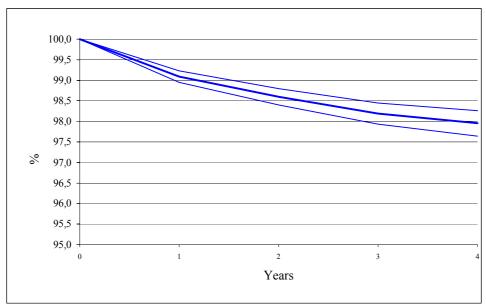
The following table shows the *rate of revision* according to type of surgery:

Type of operation	Revision rate	Percentage
Primary THA	237 /18.435	1.3%
Total revision	59 /1.278	4.6%
Hemiarthroplasty	76 /7.679	1.0%

12.2.1 Analysis of survival in primary total hip arthroplasty

Number of arthroprostheses	Removals	% revision
18.435	237	1.3%

Survival curve



Years	% in site	c.i. at	95%
0	100.0	100.0	100.0
1	99.09	98.95	99.23
2	98.60	98.40	98.80
3	98.19	97.94	98.44
4	97.95	97.64	98.26

The following table shows the rate of revision in total joint arthroplasty according to cause of revision: the % distribution of the causes of failure is shown

Cause of revision	Rate	Percentage	% distribution of cause of failure
Recurrent prosthesis luxation	89 /18.435	0.48%	37.6%
within 60 days	60		
over 60 days	29		
Aseptic loosening of the stem	40 /18.435	0.22%	16.9%
within 60 days	2		
over 60 days	38		
Aseptic loosening of the cup	39 /18.435	0.20%	16.4%
within 60 days	10		
over 60 days	29		
Global aseptic loosening	17 /18.435	0.09%	7.2%
within 60 days	6		
over 60 days	11		
Periprosthetic bone fracture	19 /18.435	0.10%	8.0%
Septic loosening	16 /18.435	0.09%	6.7%
Breakage of prosthesis	4 /18.435	0.02%	1.7%
Pain without loosening	3 /18.435	0.02%	1.3%
Other	2 /18.435	0.01%	0.8%
Unknown	8 /18.435	0.04%	3.4%
Total	237/18.435	1.3%	100.0%

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	587	6	6 /587	1.0%
40-49	1.143	19	19 /1.143	1.7%
50-59	2.629	30	30 /2.629	1.1%
60-69	5.832	85	85 /5.832	1.5%
70-79	6.686	77	77/6.686	1.1%
> 80	1.545	20	20 /1.545	1.3%

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

patient's sex:

Sex	Number of operations	Removal	Rate	Percentage
Males	6.834	93	93 /6.834	1.4%
Females	11.601	144	144 /11.601	1.2%

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

Diagnosis in total joint arthroplasty	Number of operations	Removal		Percentage
Primary arthritis	12.089	135	135 /12089	1.1%
Sequelae of LCA and DCA	2.390	36	36 /2390	1.5%
Femoral neck fracture	1.608	24	24 /1608	1.5%
Necrosis femoral head	985	12	12 /985	1.2%
Rheumatic arthritis	259	7	7/259	2.7%
Post traumatic arthrosis	459	6	6 /459	1.3%
Post traumatic necrosis	270	6	6/270	2.2%
Sequelae femoral neck fracture	69	3	3 /69	4.3%
Tumor	36	2	2 /36	5.6%
Sequelae septic coxitis	26	2	2 /26	7.7%
Sequelae epifisiolysis	45		-	-
Sequelae Perthes disease	40	-	-	-
Sequelae coxitis TBC	15	-	-	-
Sequelae Paget disease	16	-	-	-
Other	62	2	2 /62	3.2%

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

Articular coupling	Number of operations	Removal	Rate	Percentage
Metal-polyethylene	7.578	106	106/7.578	1.4%
Ceramic-polyethylene	5.346	57	57 /5.346	1.1%
Ceramic-ceramic	3.811	49	49 /3.811	1.3%
Metal-metal	1.420	19	19 /1.420	1.3%
Cerid-polyethylene	170	6	6 /170	3.5%

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	40 /7.578	0.53%	
Aseptic loosening of the stem	21/7.578	0.28%	
Aseptic loosening of the cup	19/7.578	0.25%	
Septic loosening	5 /7.578	0.07%	
Periprosthesic bone fracture	4/7.578	0.05%	
Global aseptic loosening	10/7.578	0.05%	
Pain without loosening	2 /7.578	0.03%	
Breakage of prosthesis	1/7.578	0.01%	
Unknown	4/7.578	0.05%	
CERAMIC-PO	OLYETHYLENE		
Cause	Rate	Percentage	
Prosthesis luxation	26 /5.346	0.49%	
Aseptic loosening of the cup	7/5.346	0.13%	
Global aseptic loosening	6/5.346	0.11%	
Septic loosening	5 /5.346	0.09%	
Aseptic loosening of the stem	5 /5.346	0.09%	
Periprosthesic bone fracture	5 /5.346	0.07%	
Periprosthetic ossifications	1/5.346	0.02%	
Poly wear	1/5.346	0.02%	
Breakage of prosthesis	1/5.346	0.02%	

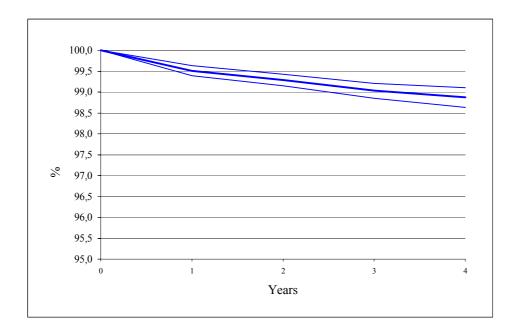
CERAMIC-CERAMIC					
Cause Rate Percentage					
Prosthesis luxation	18 /3.811	0.47%			
Aseptic loosening of the cup	7/3.811	0.18%			
Aseptic loosening of the stem	6 /3.811	0.16%			
Periprothetic bone fracture	8 /3.811	0.21%			
Septic loosening	5 /3.811	0.13%			
Global aseptic loosening	3 /3.811	0.08%			
Breakage of prosthesis	1/3.811	0.03%			
Pain without loosening	1 /3.811	0.03%			
METAL	-METAL				
Cause	Rate	Percentage			
Prosthesis luxation	5/1.420	0.35%			
Aseptic loosening of the cup	4 /1.420	0.28%			
Aseptic loosening of the stem	2 /1.420	0.14%			
Periprothetic bone fracture	2 /1.420	0.14%			
Global aseptic loosening	1/1.420	0.07%			
Septic loosening	1/1.420	0.07%			
Breakage of prosthesis	1/1.420	0.07%			
Unknown	3 /1.420	0.21%			
CERID-PO	LIETILENE				
Cause	Rate	Percentage			
Aseptic loosening of the stem	5 /170	2.9%			
Unknown	1/170	0.6%			

12.2.2 Analysis of cup survival

Summary table: all cup models used in primary THA

Number of arthroprosthesis	Removals of cup and/or liner	% revision
18.435	126	0.68%

Survival curve



Years	% in site	c.i. at 95%	
0	100.0	100.0	100.0
1	99.51	99.39	99.63
2	99.29	99.15	99.43
3	99.03	98.85	99.21
4	98.87	98.63	99.11

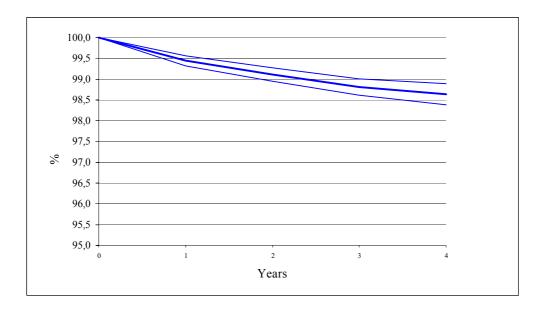
12.2.3 Analysis of stem survival

Summary table: all stem models used in primary THA

Number of arthroprosthesis	Removals of stem and/or modular neck	% revision
18.435	153*	0.83%

^{*52} of them being removal of proximal portion of modular stems

Survival curve



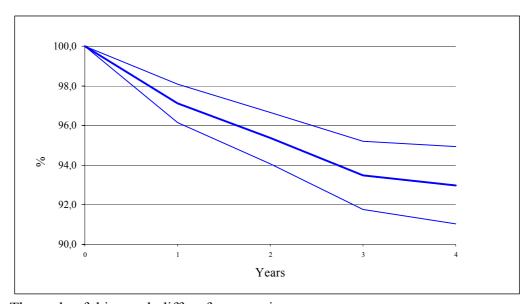
Years	% in site	c.i. at 95%	
0	100.0	100.0	100.0
1	99.44	99.32	99.56
2	99.11	98.95	99.27
3	98.81	98.61	99.01
4	98.64	98.39	98.89

12.2.4 Analysis of total revision survival

Summary table: second revision of total revisions

Number of total revisions	Removals	% revision
1.284	59	4.6%

Survival curves



The scale of this graph differs from previous ones

Years	% in site	c.i. at 95%	
0	100.0	100.0	100.0
1	97.12	96.16	98.08
2	95.37	94.08	96.66
3	93.49	91.77	95.21
4	92.99	91.03	94.95

 ${\it The following table shows the rate of second revision in total first revision according to}$

cause of revision

Cause of the second revision	Rate	Percentage	% distribution of cause of failure
Aseptic loosening of the cup	11/1.284	0.86%	18.6%
Aseptic loosening of the stem	10 /1.284	0.78%	16.9%
Recurrent prosthesis luxation (within 60 days)	9/1.284	0.70%	15.3%
Septic loosening	8 /1.284	0.62%	13.5%
Recurrent prosthesis luxation (over 60 days)	7/1.284	0.54%	11.9%
Global aseptic loosening	6 /1.284	0.39%	10.2%
Periprosthetic bone fracture	5 /1.284	0.31%	8.5%
Unknown	2 /1.284	0.16%	3.4%
Pain without loosening	1/1.284	0.08%	1.7%
Total	59/1.284	4.6%	100.0%

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

Age range	Number of operations	Removal	Rate	Percentage
<40	14	1	1 /14	7.1%
40-49	29	-	-	-
50-59	94	4	4 /94	4.3%
60-69	375	19	19/375	5.1%
70-79	585	25	25 /585	4.3%
> 80	187	10	10 /187	0.5%

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

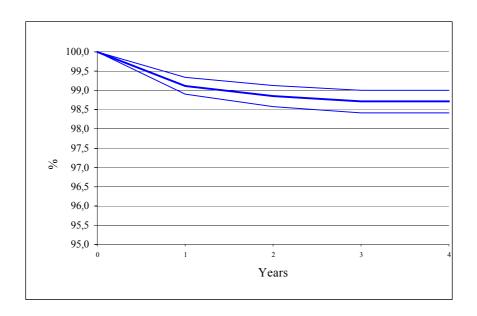
Sex	Number of operations	Removal	Rate	Percentage
Male	383	21	21 /383	5.5%
Female	901	38	38 /901	4.2%

12.2.5 Survival analysis of hemiarthroplasty

Summary table: hemiarthroplasty operations

Number of hemiarthroplasties	Removals	% revision
7.679	76	1.0%

Survival curves



Yaers	% in site	c.i. at 95%		
0	100	100.00	100.00	
1	99.12	98.90	99.34	
2	98.85	98.58	99.12	
3	98.71	98.42	99.00	
4	98.71	98.42	99.00	

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

Cause of revision	Rate	%	% distribution of failure causes
Prosthesis luxation (within 60 days)	35 /7679	0.45%	46.1%
Prosthesis luxation (over 60 days)	11/7679	0.14%	14.6%
Aseptic loosening of the stem	9 /7679	0.12%	11.8%
Acetabular erosion	7 /7679	0.09%	9.2%
Pain without loosening	6 /7679	0.08%	7.9%
Septic loosening	3 /7679	0.04%	3.9%
Bone fracture	2 /7679	0.03%	2.6%
Breakage of cement plug	1/7679	0.01%	1.3%
Protrusio acetabuli	1/7679	0.01%	1.3%
Recurrence of tumor	1/7679	0.01%	1.3%
Total	76/7679	1.0%	100.0%

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

Age range	Number of the hemiarthroplasty	Removals	Rate	Percentage
<40	10	1	1/10	0.1%
40-49	12	-	-	-
50-59	48	-	-	-
60-69	312	7	7/312	2.2%
70-79	2150	30	30 /2150	1.4%
> 80	5128	38	38 /5128	0.74%

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

Sex	Number of the hemiarthroplasty	Removals	Rate	Percentage
Male	1797	16	16 /1797	0.89%
Female	5882	60	60 /5882	1.02%

PART TWO: KNEE PROSTHESES

July 2000 – December 2003

13. RIPO support

13.1 Support for RIPO per hospital in years 2000-2003.

Percentage of R.I.P.O. capture calculated versus Schede di Dimissione Ospedaliera

(S.D.O.), according to Agency.

	Year 2000	Year 2001	Year 2002	Year 2003
BOLOGNA PROVINCE	%	%	%	%
DOLOGIATIKO VIIVEL	support	support	support	support
	R.I.P.O.	R.I.P.O.	R.I.P.O.	R.I.P.O.
Azienda BOLOGNA CITY	77.9%	91.7%	96.6%	98.2%
Azienda Osp. S. Orsola-Malpighi	43.8%	89.5%	83.3%	89.3%
Istituti Ortopedici Rizzoli	86.3%	100.0%	100.0%	98.7%
AZIENDA BOLOGNA NORTH	-	-	50.0%	106.2%
AZIENDA BOLOGNA SOUTH	200.0%	87.0%	98.4%	90.4%
AZIENDA IMOLA	61.9%	85.4%	92.3%	82.0%
FERRARA PROVINCE				
AZIENDA FERRARA	80.2%	67.0%	56.3%	53.6%
Azienda Ospedaliera di Ferrara	70.0%	89.5%	83.3%	38.1%
FORLÌ-CESENA PROVINCE				
AZIENDA FORLI'	109.1%	91.7%	97.7%	104.8%
AZIENDA CESENA	85.1%	97.6%	98.4%	97.4%
MODENA PROVINCE				
AZIENDA MODENA	67.1%	87.0%	91.4%	93.1%
Azienda Ospedal. Policlinico di	84.6%	100.0%	82.0%	92.9%
Modena				
PARMA PROVINCE				
AZIENDA PARMA	44.7%	97.0%	93.5%	93.5%
Azienda Ospedaliera di Parma	60.0%	75.0%	87.9%	86.0%
PIACENZA PROVINCE				
AZIENDA PIACENZA	28.6%	83.3%	101.6%	97.3%
RAVENNA PROVINCE				
AZIENDA RAVENNA	70.7%	98.8%	96.8%	92.1%
REGGIO EMILIA PROVINCE				
AZIENDA REGGIO EMILIA	23.1%	33.1%	52.1%	79.1%
Arcispedale Santa Maria Nuova	150.0%	93.8%	93.8%	69.6%
RIMINI PROVINCE				
AZIENDA RIMINI	100.0%	101.5%	96.2%	95.6%
TOTAL	71.0%	88.3%	90.4%	86.4%

* Percentage higher than 100 is possibly due to a mistake in SDO code.

13.2 Percentage of RIPO support year 2003

Percentage of R.I.P.O. capture calculated versus Schede di Dimissione Ospedaliera (S.D.O.), according to Orthopaedic department

(S.D.O.), according to Orthopaedic depart		2003		
DOLOGNA BROWNIEE	N° of operations	N° operations	%	
BOLOGNA PROVINCE	communicated	communicated	support to	
	to RIPO	via S.D.O.	R.I.P.O.	
Azienda BOLOGNA CITY				
Hospital Maggiore, Bellaria	6	8		
Private hospital "Villa Erbosa"	130	139		
Private hospital "Villa Nigrisoli"	113	115	98.2%	
Private hospital "Villa Torri"	111	107	90.270	
Private hospital "Villa Laura"	192	193		
Private hospital "Villa Regina" (not cred.)	6	6		
Total	558	568		
Azienda Ospedaliera S. Orsola-Malpighi	25	28	89.3%	
Istituti Ortopedici Rizzoli	520	527	98.7%	
AZIENDA BOLOGNA NORTH				
Hospital Bentivoglio, Budrio, San Giovanni in Pers	17	16	106.2%	
Total	17	16		
AZIENDA BOLOGNA SOUTH				
Civil hospital Vergato	11	14		
Private hospital "Prof. Nobili"	13	14	90.4%	
Private hospital "Villa Chiara"	23	24		
Total	47	52		
AZIENDA IMOLA				
Civil hospital Imola Castel San Pietro Terme	41	50	82.0%	
Total	41	50		
FERRARA PROVINCE		1		
Stabilimento Ospedaliero di Cento Ospedale di	51	52		
Bondeno	6.1	6.2	=2 -2.	
Civil hospital Argenta	81	80	53.6%	
Civil hospital Comacchio/ Delta	-	114		
Total	132	246		
A : 1 O 11: 1:E	0	21	20.40/	
Azienda Ospedaliera di Ferrara	8	21	38.1%	

		2003	
FORLÌ-CESENA PROVINCE	N° of operations	N° operations	%
FORLI-CESENA PROVINCE	communicated to		support to
	RIPO	via S.D.O.	R.I.P.O.
AZIENDA FORLI'			
Hospital "Morgagni-Pierantoni" Forlì,	48	45	
Forlimpopoli, Santa Sofia			104.8%
Private hospital "Villa Igea"	7	7	104.0 /0
Private hospital "Villa Serena" Forlì	11	11	
Tot	al 66	63	
AGIEND A GEGENIA			
AZIENDA CESENA	7	1.4	
Hospital "M. Bufalini" Cesena, Bagno di Romagna Hospital Cesenatico	n, 7	14	
Private hospital "Malatesta Novello" Cesena	271	271	97.4%
Private hospital "S. Lorenzino" Cesena	22	23	
Tot		308	
100	ai 300	300	
MODENA PROVINCE			
AZIENDA MODENA			
Hospital S. Agostino-Estense	85	84	
Civil hospital degli Infermi, Carpi	25	25	
Hospital di Finale Emilia	-	1	
Hospital S. Maria Bianca, Mirandola	25	25	
Civil hospital Castelfranco Emilia	6	21	93.1%
Civil hospital, Sassuolo	7	11	
Civil hospital, Vignola	44	44	
Hospital, Pavullo	16	15	
Hesperia Hospital	15	15	
Private hospital Prof. Fogliani	99	105	
Tot	al 322	346	
Azienda Ospedaliera Policlinico di Modena	66	71	92.9%
PARMA PROVINCE			
Civil hospital, Fidenza Hospital San Secondo	45	58	
Parmense			
Hospital Santa Maria, Borgo Val di Taro	72	76	93.5%
Private hospital "Città di Parma"	112	111	20.070
Tot	al 229	245	
Azienda Ospedaliera di Parma	80	93	86.0%
DIA CENZA DE OVENCE			
PIACENZA PROVINCE	27	27	
Civil hospital, Piacenza	27	27	
Presidio Val Tidone, Castel San Giovanni	73	76	97.3%
Presidio Val D'Arda, Fiorenzuola D'Arda, Cortemaggiore	46	47) 1.J /U
Tot	al 146	150	

		2003	
RAVENNA PROVINCE	N° of operations	N° operations	%
MIVERIMINOVINCE	communicated to	communicated	support to
	RIPO	via S.D.O.	R.I.P.O.
AZIENDA RAVENNA			
Hospital S. Maria delle Croci, Ravenna	10	9	
Presidio Ospedaliero, Lugo	58	60	
Hospital Infermi, Faenza	15	19	
Private hospital "Domus Nova"	60	78	92.1%
Private hospital "S. Francesco"	170	176	
Private hospital "Villa Maria Cecilia"	33	34	
Private hospital "S. Pier Damiano"	97	105	
Total	443	481	
REGGIO EMILIA PROVINCE			
AZIENDA REGGIO EMILIA			
Hospital, Guastalla	21	20	
Hospital S. Sebastiano, Correggio	-	3	
Hospital Montecchio Emilia	9	8	
Hospital di Scandiano	14	13	79.1%
Hospital S. Anna, Castelnovo Monti	7	7	
Private hospital "Villa Salus"	157	158	
Private hospital "Villa Verde"(not cred.)	-	54	
Total	208	263	
Arcispedale Santa Maria Nuova, Reggio Emilia	16	23	69.6%
RIMINI PROVINCE			
AZIENDA RIMINI			
Hospital Infermi, Rimini, sant'Arcangelo	13	17	
Hospital G. Ceccarini, Riccione, Cattolica,	31	33	
Cesenatico	51		95.6%
Private hospital "Sol et Salus"	69	70	
Private hospital "Villa Maria"	38	38	
Total		158	
1000			
TOTAL	3282	3799	86.4%
TOTAL	0202	0177	001T/U

²¹ operations performed at Villa Fiorita, 1 a Villa Toniolo, 7 a Villalba e 2 a Villa Prof Montanari are not recorderd

13.3 Ratio public/private activity

Percentage of primary total knee arthroplasty and revisions of the knee performed in

public hospitals.

	% of operations performed in public hospitals (AUSL, AOSP, IRCCS)			
Year of surgery	Revision			
2000	57%	75%		
2001	59%	71%		
2002	53%	70%		
2003	49%	70%		

More than 1/2 of TKA (total knee arthroplasties) are performed in public hospitals; nearly 2/3 of revision are performed in public hospitals.

14. Type of operation

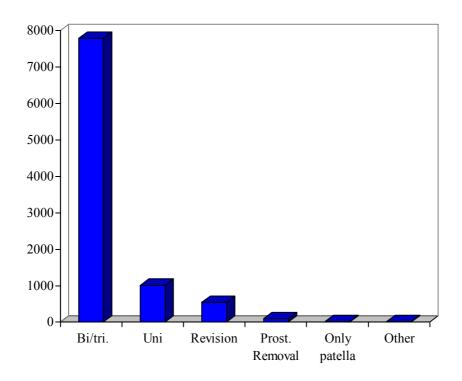
Number of knee operations carried out on patients with admission date between 1st July

2000 and 31st December 2003, according to **type**.

Type of operation	Number of operations	Percentage
Primary bi/tricompartmental knee arthroplasty	7.782	82.2%
Primary unicompartmental	1.011	10.7%
Revision*	546	5.8%
Prosthesis removal	93	1.0%
Implant of artificial patella only (2nd time prosth)	21	0.2%
Other	16	0.1%
Total*	9.469	100.0%

^{*} In 11 cases (0.1%) the information was not reported to RIPO, therefore these operations were excluded from subsequent calculations.

Implant of artificial patella only means the transformation of a bicompartmental into a tricompartmental prosthesis



In the group bi-tri compartmental there are 92% bicompartmental and 8% tri compartmental (with patella) knee prostheses

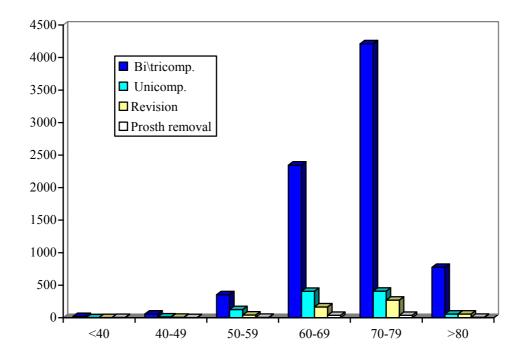
15. Descriptive statistics of patients

15.1. Age

Number of <u>knee operations</u> carried out on patients with admission date between 1^{st} July 2000 and 31^{st} December 2003, according to **type of operation** and **age group** of patients at the time of surgery.

Type of	<4	40	40-	-49	50-	-59	60-	69	70-	·79	2	80	Total
operation	N.	%	N.	%	N.	%	N.	%	N.		N.	%	Total
Prim. bi-tricomp	19	0.2	57	0.7	355	4.6	2346	30.3	4211	54.2	775	10.0	7763
Prim. unicomp	ı	1	13	1.3	125	12.4	405	40.2	408		56	5.6	1007
Revision	2	0.4	8	1.5	41	7.5	166	30.5	271	49.7	57	10.4	545
Prosthesis	5	5.4	3	3.2	6	6.4	36	38.7	36	38.7	7	7.6	93
removal													
Only patella	ı	1	ı	1	1	5.0	4	20.0	14	70.0	1	5.0	20
Other	•	-	-	-	4	25.0	5	31.2	6	37.5	1	6.3	16
Total*	2	6	8	1	53	32	29	62	49	46	89	97	9444

^{*} In 25 cases (0.26%) the data were not supplied to RIPO



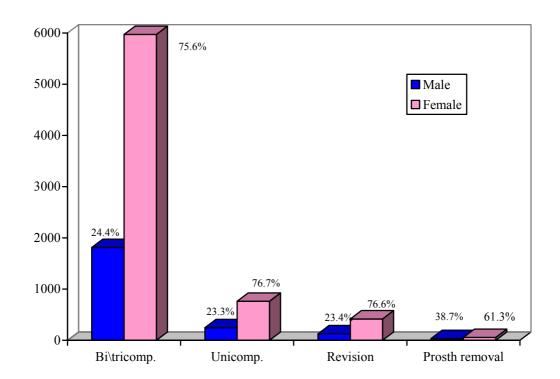
Type of operation	Mean age	Range
Prim. bi-tricomp		20-103
Prim. unicomp	68.7	43-88
Revision	71.0	32-90
Prosthesis removal	67.3	15-85
Only patella	72.3	54-88
Global	71.4	15-103

Unicompartmental knee prosthesis are implanted to younger patients Mean age for knee implant is nearly 3 years higher than for hip implant.

15.2. Sex

SexNumber of <u>knee operations</u> carried out on patients with admission date between 1st July 2000 and 31st December 2003, according to *type of operation* and *sex* of patient.

Type of operation	Male	Female	Total
Bi/tricompartmental	1.812	5.970	7.782
Unicompartmental	247	764	1.011
Revision	128	418	546
Prosthesis removal	36	57	93
Only patella	4	17	21
Other		8	16
Total	2.235	7.234	9.469

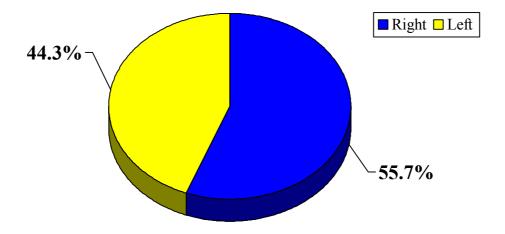


As for hip prosthesis, female sex is more affected by diseases that require operations of the knee. In the case of knee the difference between sexes is more evident (63.3% of females for the hip, 76% for the knee).

15.3 Side of surgery

Right knee is more often implanted than left knee (55.7% vs 44.3%). The percentage has been calculated on patients wearing only one implant.

Percentage distribution of primary TKA according to side



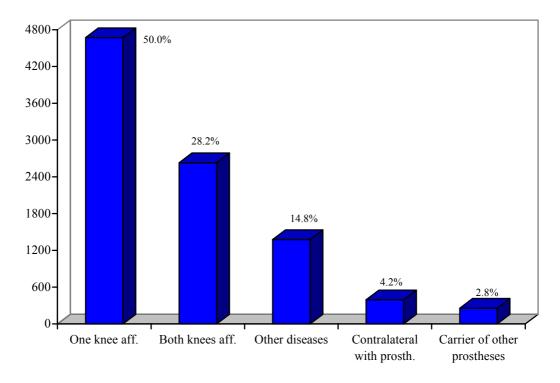
In hip prosthesis the value for the right side is 58%.

15.4 Clinical condition

Number of <u>arthroplasty knee operations</u> carried out on patients with admission date between 1st July 2000 and 31st December 2003, according to **clinical condition** of patients at the time of surgery

Clinical condition	Number	Percentage
One knee affected	4.672	50.0%
Two knees affected	2.631	28.2%
Other diseases that restrict motor		
ability	1.378	14.8%
Contralateral knee with prosthesis	395	4.2%
Carrier of joint prostheses other than		
that of the knee	257	2.8%
Total*	9.333	100.0%

^{*} In 136 cases (1.4 %) the information was not given to RIPO



During the 42 months of registration, 612 patients were treated for both knees. In 4.7% of these, the patient chose to undergo the second operation at a different hospital.

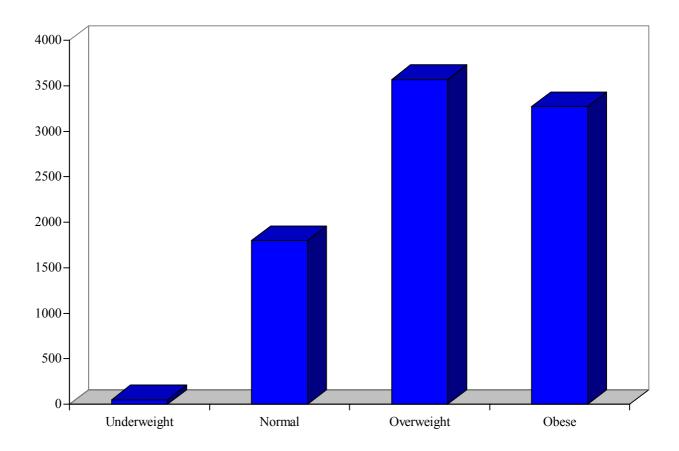
In these cases the first knee was the right one in 55% of cases. 3.1% of the patients registered also had hip prostheses.

15.5 Body mass index (BMI)

Number of <u>total knee arthroplasty</u> operations performed on patients admitted to hospital between 1st July 2000 and 31st December 2003, according to **body mass index** at the time of surgery.

Body mass index	Number	Percentage
Underweight (≤19)	50	0.6%
Normal (20-25)	1.798	
Overweight (26-29)	3.570	41.1%
Obese (≥ 30)	3.273	37.6%
Total*	8.691	100.0%

^{*} In 778 cases (8.2%) the information was not give to RIPO



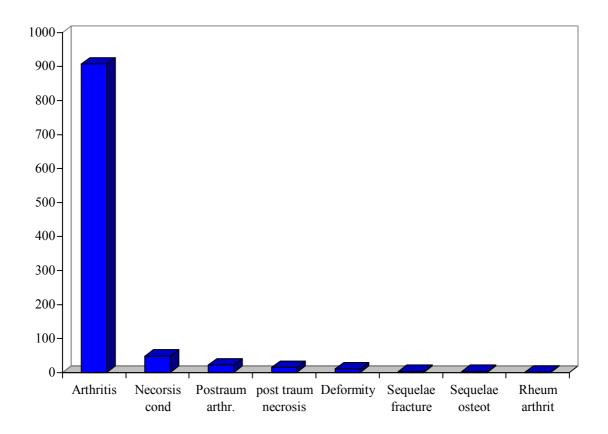
Over 77% of the patients that underwent arthroplasty were either overweight or obese, according to BMI [weight in kg/(height in meters)²]. In hip prosthesis the percentage is 52.4%.

15.6 Pathology in unicompartmental knee prosthesis

Number of <u>primary unicompartmental knee arthroplasty</u> carried out on patients with admission date between I^{st} July 2000 and $3I^{st}$ December 2003, according to **diagnosis**.

Diagnosis in unicompartmental knee prosthesis	Number	Percentage
Primary arthritis	907	89.8%
Necrosis of the condyle	48	4.7%
Post traumatic arthritis	22	2.2%
Post traumatic necrosis	15	1.5%
Deformity		1.1%
Sequelae of fracture	3	0.3%
Sequelae of osteotomy		0.3%
Rheumatic arthritis		0.1%
Total*	1010	100.0%

^{* 1} datum missing, equal to 0.1% of the series



15.7 Pathology in bi-tri compartmental knee prosthesis

Number of <u>primary bi-tri compartmental knee arthroplasty</u> carried out on patients with admission date between I^{st} July 2000 and $3I^{st}$ December 2003, according to **diagnosis**.

Diagnosis in bi-tri compartmental knee prosthesis	Number	Percentage
Primary arthritis	7.019	90.6%
Deformity	209	2.7%
Post traumatic arthritis	171	2.2%
Rheumatic arthritis	167	2.2%
Sequelae of fracture	86	1.1%
Necrosis of the condyle	38	0.5%
Septic arthritis	15	0.2%
Post traumatic necrosis	10	0.1%
Tumor	6	0.1%
TBC arthritis	2	0.0%
Other	21	0.3%
Total*		100.0%

^{* 38} data missing, equal to 0.5% of the series

Primary arthritis is the first cause for knee arthroplasty, both uni and bi-tri compartmental. The necrosis of the condyle is the second cause of implant of unicompartmental.

15.8 Causes for revision

Number of <u>revision operations</u> carried out on patients admitted between 1st July 2000 and 31 December 2003, according to **diagnosis**.

In the Table all revisions performed in the Region, without taking care of site and date of primary implant are reported. No indication of follow-up time is in theses data

Diagnosis in revision surgery	Number	Percentage
Total aseptic loosening	260	48.7%
Septic loosening	88	16.5%
Poly wear	42	7.9%
Pain without loosening	34	6.4%
Aseptic loosening of tibial component	28	5.3%
Aseptic loosening of femoral component	24	4.5%
Esito espianto	13	2.4%
Prosthesis luxation	11	2.1%
Bone fracture	5	0.9%
Prosthesis breakage	4	0.8%
Stiffness of the joint	3	0.6%
Other	21	3.9%
Total*	533	100.0%

^{* 13} data missing, equal to 2.4% of the series of revision operations

The rate of septic loosening is very high compared to that of hip arthroplasty. This result was already outlined in previous report..

Number of **knee prosthesis removal** performed on patients admitted to hospital between 1st July 2000 and 31st December 2003, according to **diagnosis**.

Diagnosis in prosthesis removal	Number	Percentage
Septic loosening	86	95.6%
Aseptic total loosening	4	4.4%
Total*	90	

^{* 3} results missing, equal to 3.3% of the series

16. Type of knee prosthesis

16.1 Unicompartmental prosthesis

The following table shows the types of unicompartmental knee prostheses used for primary knee arthroplasty in patients admitted to hospital between 1st July 2000 and 31st December 2003.

Type of Prosthesis	N.	%
OXFORD Unicompartmental – Biomet Merck	299	29.5%
EFDIOS – CITIEFFE	222	22.0%
ALLEGRETTO UNI – Protek Sulzer	163	16.1%
GENESIS UNI – Smith & Nephew	92	9.1%
P.F.C. – UNI – DePuy	50	4.9%
MILLER GALANTE UNI – Zimmer	48	4.7%
MITUS – ENDO-MODEL UNICONDYLAR SLED – Link	30	3.0%
PRESERVATION – UNI – DePuy	28	2.8%
UNICIA – Vecteur Orthopedic, Stratec	27	2.7%
HLS UNI Evolution – Tornier	26	2.6%
ADVANCE Unicompartmental – WRIGHT	5	0.5%
DURACON UNI - Stryker Howmedica	3	0.3%
EIUS UNI – Stryker Howmedica	2	0.2%
UC – PLUS SOLUTION – Endoplus	16	1.6%
TOTAL	1011	100.0%

16.2 Bi – tri compartmental prostheses

The following table shows the types of bi-tri compartmental knee prostheses used for primary knee arthroplasty in patients admitted to hospital between 1st July 2000 and 31st December 2003.

Type of Prosthesis	N.	%
NEXGEN – Zimmer	2048	26.3%
PROFIX – Smith & Nephew	1243	16.0%
P.F.C –DePuy	592	7.6%
T.A.C.K. – Link	557	7.1%
INTERAX – Stryker Howmedica	535	6.9%
LCS – DePuy	308	4.0%
913 – Cremascoli	286	3.7%
OPTETRACK – Exactech	256	3.3%
SCORPIO – Stryker Howmedica	226	2.9%
ROTAGLIDE – Corin Medical	226	2.9%
GENIUS TRICCC – Dedienne Santé	222	2.8%
ADVANCE – Wright	191	2.5%
PERFORMANCE – Kirschner Biomet Merck	191	2.5%
GENESIS II – Smith & Nephew	138	1.8%
NUOVA DURACON II – Stryker Howmedica	121	1.5%
ENDO-MODEL – Link	105	1.3%
C. K. S. – Stratec Medical	75	1.0%
G. K. S. – Permedica	72	0.9%
CONSENSUS – Hayes Medical.	42	0.5%
CEDIOR – Sulzer	33	0.4%
AGC – Kirschner Biomet Merck	23	0.3%
GENUFITT – Lafitt (comp. fem and insert) +	21	0.3%
EFDIOS – Citieffe (comp tib)	<i>Z</i> 1	0.570
Other	211	2.7%
Unknown	60	0.8%
TOTAL*	7782	100.0%

16.3 Type of prostheses used in total revision

The following table shows the types of knee prostheses used for revision arthroplasty in patients admitted to hospital between 1^{st} July 2000 and 31^{st} December 2003.

Type of Prosthesis	N.	%
NEXGEN – Zimmer	89	24.6%
ENDO-MODEL – Link	77	21.3%
PROFIX – Smith & Nephew	45	12.4%
AGC – Kirschner Biomet Merck	28	7.7%
P.F.C. – DePuy	25	6.9%
INTERAX – Stryker Howmedica	17	4.7%
GENIUS TRICCC – Dedienne Santé	8	2.2%
GENUFITT – Lafitt (comp. femorale e inserto) + EFDIOS – Citieffe (componente tibiale)	8	2.2%
UNKNOWN	8	2.2%
TOTAL STABILIZER – Stryker Howmedica	7	1.9%
C. K. S. – Stratec Medical	6	1.7%
G. K. S. – Permedica	6	1.7%
S-ROM NRH - DePuy	5	1.4%
T.A.C.K. – Link	4	1.1%
ADVANCE – WRIGHT	4	1.1%
OPTETRACK – Exactech	3	0.8%
913 – Cremascoli	3	0.8%
NUOVA DURACON II – Stryker Howmedica	3	0.8%
SCORPIO – Stryker Howmedica	2	0.6%
CEDIOR – Sulzer	2	0.6%
ROTAGLIDE – Corin Medical	1	0.3%
UNKNOWN	11	3.0%
TOTAL	362	100.0%

16.4 Relationship between joint components

Number of <u>knee prosthesis arthroplasty</u> performed on patients admitted to hospital between 1st July 2000 and 31^{st} December 2003, according to femoral-tibial component relationship

Femoral-tibial component	Primary unicomp.			nary comp.	Total r	Total revision		Total	
relationship	N.	%	N.	%	N.	%	N.	%	
Non stabilized	1011	100	3916	50.5	65	18.0	4992	54.7	
Posterior	-	-	3484	44.9		32.7	3602	39.4	
stabilization									
Other	-	ı	6	0.1	28	7.7	34	0.4	
Pivot	-	ı	317	4.1		34.1	440	4.8	
Hinge	_	-	34	0.4	27	7.5	61	0.7	
Total*	1011		7757		361		9129		

^{* 26} results missing, equal to 0.3% of the series

16.5 Tibial insert

Number of <u>knee prosthesis arthroplasty</u> performed on patients admitted to hospital between 1st July 2000 and 31^{st} December 2003, according to **articular coupling**

Articular coupling	Primary unicomp.		Primary		Total revision		Total	
	N.	%	N.	%	N.	%	N.	
Metal-polyethylene	1010	99.9	7758	99.7	358	98.9	9126	99.7
Ceramic- polyethylene	1	0.1	24	0.3	4	1.1	29	0.3
Total	10	11	77	82	30	62	91	55

Number of <u>knee prosthesis arthroplasty</u> performed on patients admitted to hospital between 1st July 2000 and 31st December 2003, according to **type of insert**

Primary Primary Total revision Total Type of insert unicomp. bi/tricomp. % **%** N. % N. N. % **Fixed** 705 5576 317 87.5 6598 72.1 69.7 71.7 306 2206 12.5 2557 27.9 **Rotating** 30.3 28.3 45 Total 1011 7782 362 9155

16.6 Fixation of prosthesis

Number of <u>knee prosthesis arthroplasty</u> performed on patients admitted to hospital between 1st July 2000 and 31^{st} December 2003, according to **prosthesis fixation**

Type of fixation	Primary unicomp.		Primary bi/tricomp.		Total revision		Total	
	N.	%	N.	%	N.	%	N.	%
Cemented	789	78.0	6801	87.7	343	96.3	7933	86.9
Uncemented	218	21.6	539	6.9	9	2.5	766	8.4
Fem uncem +. tib cem	4	0.4	409	5.3	2	0.6	415	4.5
Fem cem +. tib uncem	-	-	10	0.1	2	0.6	12	0.2
Total*	10	11	77	59	3.	56	91	26

^{* 29} results missing, equal to 0.3% of the series

Fixation of femoral component

Number of <u>knee prosthesis arthroplasty</u> performed on patients admitted to hospital between 1st July 2000 and 31st December 2003, according to **femoral component fixation**

Fixation of femoral	Primary unicomp.		Primary bi/tricomp.		Total revision		Total	
component	N.	%	N.	%	N.	%	N.	%
Cemented	788	77.9	6215	80.2		21.6	7081	77.6
Cemented with	1	0.1	518	6.8	270	74.8	789	8.7
endomedullary stem								
Uncem. without screws	222	22.0	934	12.0	11	3.0	1167	12.8
Uncemented with endomed	-	-	73	0.9	-	-	73	0.8
stem								
Cemented with screws	-	-	10	0.1	2	0.6	12	0.1
Uncemented with screws	-	-	3	0.0	-	-	3	0.0
Total*	1	011	77	53	30	61	91	25

^{* 30} results missing, equal to 0.3% of the series

Fixation of tibial component

Number of <u>knee prosthesis arthroplasty</u> performed on patients admitted to hospital between 1st July 2000 and 31st December 2003, according to **tibial component fixation**

Fixation of tibial	Primary unicomp.		Primary bi/tricomp.		Total revision		Total	
component	N.	%		%	N.	%	N.	%
Cemented	723	71.5	5682	73.4	49	13.7	6454	70.8
Cemented with endomed	1	0.1	1439	18.6	296	82.5	1736	19.0
stem								
Uncem. without screws	-		506	6.5	3	0.8	509	5.6
Uncemented with	-		78	1.0	3	0.8	81	0.9
endomed stem								
Cemented with screws	69	6.8	-		-		69	0.8
Uncemented with screws	218	21.6	35	0.5	8	2.2	261	2.9
Total*	10	11	77	40	3.	59	91	10

^{* 45} results missing, equal to 0.5% of the series

16.7 Bone cement

Bone cement used for fixation of knee prosthesis is Surgical Simplex P in 52.0% of cases

Bone cement loaded with antibiotic is used in 11.0% of cases.

16.8 Surgical technique

The most commonly used *surgical approach is the antero-medial* (95.4%) regardless of type of operation

Use of bone grafts

Number of <u>knee prosthesis arthroplasty</u> performed on patients admitted to hospital between 1st July 2000 and 31^{st} December 2003, according to **type of operation and use**

of bone grafts

Bone grafts		nary omp.	Primary bi/tricomp.		Total r	evision	Total	
	N.	%	N.	%	N.	%	N.	%
Not used	1010	99.9	7742	99.5		96.4	9101	99.4
Femoral	-		28	0.4	2	0.6	30	0.3
Tibial and femoral	1	0.1	1	0.0	3	0.8	5	0.1
Femoral	-		11	0.1	8	2.2		0.2
Total	10	11	7782		362		9155	

Use of augmentation blocks

Number of <u>knee prosthesis arthroplasty</u> performed on patients admitted to hospital between 1st July 2000 and 31st December 2003, according to **use of augmentation blocks**

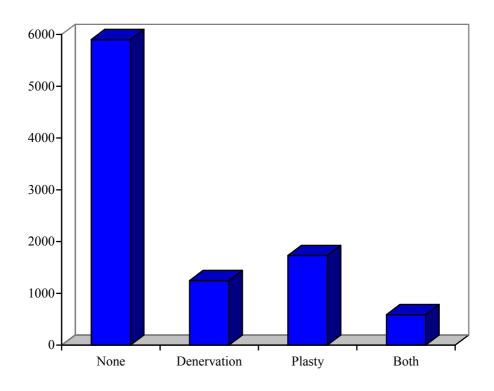
Augmentation blocks	Primary unicomp.		bi/tri	bi/tricomp.		Total revision		Total	
DIUCKS		%	N.	%	N. %		N.	%	
Non used	991	100	7712	99.1	221	61.0	8924	97.7	
Tibial	-	-	50	0.7	43	11.9	93	1.0	
Tibial and femoral	-	-	10	0.1	61	16.9	71	0.8	
Femoral	1	1	8	0.1	37	10.2	45	0.5	
Total*	99	991		7780		362		9133	

^{*22} results missing, equal to 0.24% of the series

Surgery of patella (non- prosthetic)

Number of <u>surgery on patella</u> performed on patients admitted to hospital between 1st July 2000 and 31st December 2003, during prosthetization of the knee

Type of surgery of patella	Number	Percentage
None	5902	62.3%
Patella-plasty	1731	18.3%
Denervation of patella	1248	13.2%
Both	588	6.2%
Total	9469	100.0%



17. Antibiotic prophylaxis

List of active principles used in preoperative antibiotic prophylaxis in cases of **knee** arthroplasty.(data registered since 30/09/01)

Active principle	Percentage
AMPICILLIN	9.2%
AMPICILLIN + GENTAMICIN	4.0%
CEFAMANDOL	0.5%
CEFAMANDOL + GENTAMICIN	0.3%
CEFAZOLINE	18.0%
CEFAZOLINE + GENTAMICIN	2.1%
CEFAZOLINE + TOBRAMICIN	4.3%
CEFEPIME	6.1%
CEFOTAXIME	6.3%
CEFOTAXIME + LEVOFLOXACINA	3.3%
CEFTIZOXIMA	0.8%
CEFTRIAXONE	5.6%
CEFTRIAXONE + GENTAMICIN	1.4%
CEFUROXIM	9.7%
CIPROFLOXACINE	1.4%
GENTAMICIN	0.4%
TEICOPLANIN	3.3%
TEICOPLANIN + NETILMICIN	1.7%
VANCOMICIN	2.3%
VANCOMICIN + GENTAMICIN	10.5%
Other	8.8%
TOTAL	100.0%

Active principles used for the prophylaxis are the same as for hip, even if in different percentage.

Way of administration

Administration	N.	%
Single administrations	1.496	15.8%
Multiple administrations	7.973	84.2%
Total	9.469	100.0%

18. Blood transfusion

RIPO started to collect this data only in 30/09/2002; therefore they cannot be analyzed

19. Complications and deaths occurred during hospitalization.

Rate of complications in knee prosthetic surgery carried out on patients hospitalized between July 1st 2000 and December 31st 2003.

Types of complication	N.	% complications/ operations
Post-operative general	76	0.8%
(anemia, fever, respiratory)	, 0	
Post-operative local	33	0.3%
(hematoma, TVP, prosthesis luxation)	33	0.5 /0
Intra-operative		
(fem fracture, tibial fracture, lesion of tendon or	11	0.1%
ligament)		
Total	120	1.3%

Only 3 deaths occurred during hospitalization, following bicompartmental prosthesis (0.04%).

20. Hospitalization time

	Mean hospitalization	Range	Mean pre-op hospitalization	Range pre-op hospitalization	Mean post-op hospitalization	Range post- op hospit.
Primary	12.6	1-99	1.8	0-40	10.9	0-96
Bi/tricom.						
Prosth	15.7	0-73	4	0-15	11.6	0-67
removal						
Primary	10.1	2-50	2.2	0-35	8.3	0-47
unicomp.						
Revision	15.6	3-84	3.1	0-63	12.4	1-68
Global	12.6	0-99	1.9	0-63	10.7	0-96

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.

Hospitalization time is similar to the one observed for the hip.

21. Analysis of survival of knee prosyhesis

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 uni and bicompartmental prosthesis in relationship to the main factors concerning the patient (sex, age), and the implants (type of insert).

The following table shows the number of primary joint arthroplasty operations performed in the period from July 2000 to December 2003 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.

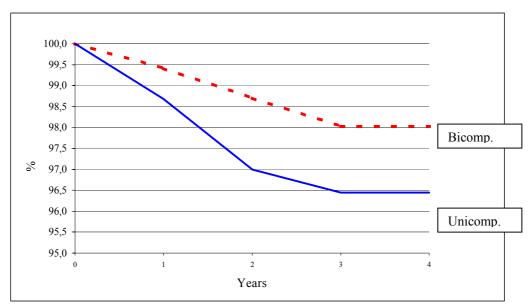
	Number of operations	Number of revisions in the same hospital	Number of revisions in a different hospital	% revision
Primary bi\tricomp	7782	63	15	1.0%
Primary unicomp.	1011	16	4	2.0%
Total revision	362	11	1	3.3%
Total	9155	90	20	1.2%

In 19.4% 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

21.1 Survival analysis of bi-tri and unicompartmental prostheses

	Number of operations	N. of revisions	% revision
Primary bi\tricomp	7782	78	1.0%
Primary unicomp.	1011	20	2.0%

Survival curve



The two curves are statistically different (Log Rank test)

Results in detail

	Primary bi\tricompartmental				
Years	% in site				
0	100.00	100.00	100.00		
1	99.41	99.21	99.61		
2	98.7	98.39	99.01		
3	98.03	97.54	98.52		
4	98.03	97.54	98.52		
	Pri	mary unicompartn	nental		
Years	% in site	c.i. at	t 95%		
0	100.00	100.00	100.00		
1	98.68	97.92	99.44		
2	96.99	95.60	98.38		
3	96.45	94.71	98.19		
4	96.45	94.71	98.19		

The following tables show the rate of revision in <u>bi-tri compartmental</u> arthroplasty according to **type of prosthesis and cause of revision**:

Pimary bi – tri compartmental operations

Cause of revision	Rate	Percentage	% distribution of failure causes
Septic loosening	18 /7782	0.2%	23.1%
Global aseptic loosening	14/7782	0.2%	17.9%
Tibial component aseptic loosening	9/7782	0.1%	11.5%
Insert wear	8 /7782	0.1%	10.2%
Femoral component aseptic loosening	7 /7782	0.1%	9.0%
Pain without loosening	6/7782	0.07%	7.7%
Prosthesis luxation	5 /7782		6.4%
Stiffness	3 /7782	0.04%	3.9%
Unknown	3 /7782	0.04%	3.9%
Bone fracture	1/7782	0.01%	
Other	4/7782	0.05%	5.1%
Total	78 /7782	1.0%	100.0%

Pimary uni - compartmental operations

Cause of revision	Rate	Percentage	failure causes
Pain without loosening	6 /1011	0.6%	30.0%
Septic loosening		0.4%	20.0%
Global aseptic loosening	6 /1011	0.6%	30.0%
Femoral component aseptic loosening	2 /1011	0.2%	
Tibial component aseptic loosening	1 /1011	0.1%	5.0%
Bone fracture	1 /1011	0.1%	5.0%
Total	20/1011	2.0%	100.0%

The following table shows the rate of revision in <u>bi-tri compartmental</u> arthroplasty according to **patient's age**:

Age range	Number of operations	Removal	Rate	Percentage
<40	19	-	-	-
40-49	57	1	1/57	1.8%
50-59	355		10/355	2.8%
60-69	2346	30	30/2346	1.3%
70-79	4211	34	34/4211	0.8%
> 80	775	3	3/775	0.4%

The following table shows the rate of revision in <u>uni-compartmental</u> arthroplasty according to **patient's age**:

Age range	Number of operations	Removal	Rate	Percentage
<40	-	-	-	-
40-49	13	1	1/13	7.7%
50-59	125	4	4/125	3.2%
60-69	405	5	5/405	1.2%
70-79	408	9		2.2%
> 80	56	1	1/56	1.8%

The following table shows the rate of revision in <u>bi-tri compartmental</u> arthroplasty according to **patient's sex**:

Sex	Number of operations	Removal		Percentage
Male		24	24/1812	1.3%
Female	5970	54		0.9%

The following table shows the rate of revision in <u>uni-compartmental</u> arthroplasty according to **patient's sex**:

Sex	Number of operations	Removal	Rate	Percentage
Male	247	8	8/247	3.2%
Female	764	12	12/764	1.6%

The following table shows the rate of revision in <u>bi-tri compartmental</u> arthroplasty according to **type of insert**:

Polyethylene insert	Number of operations	Removal	Rate	Percentage
Fixed	5576	53	53/5576	0.95%
Rotating	2203	25	25/2203	1.1%

The following table shows the rate of revision in <u>bi-tri compartmental</u> arthroplasty according to femoral-tibial component relationship:

Femoral-tibial component relationship	Number of operations	Removal	Rate	Percentage
Non stabilized	3916	38	38 /3916	0.97%
Posterior stabilized	3484	35	35 /3484	1.0%

21.2 Second time surgery for patella prothesization

In 9 patients out of 7162 with bicompartmental knee prosthesis, a re-operation was necessary to substitute natural patella with an artificial one. Here are the details:

Primary bi-compartmental prosthesis	Reason for patellar prosthetisation	Time before re- operation
Rotaglide - Corin medical	Patellar pain	90 days
Genius Triccc – Dedienne Sante	Patellar pain	97 days
Genius Triccc – Dedienne Sante	?	238 days
Genius Triccc – Dedienne Sante	?	277 days
Profix - Conforming - Smith & Nephew	Patellar pain	1.0 years
Multigen PS – Lima	Patellar pain	1.2 years
Rotaglide - Corin Medical	Patellar pain	1.2 years
Profix - Conforming - Smith & Nephew	Patellar pain	1.8 years
Nexgen - CR - Zimmer	Patellar pain	2.0 years

These operations are not to be considered as implant failure; they are registered to quantify the two-stage surgery.