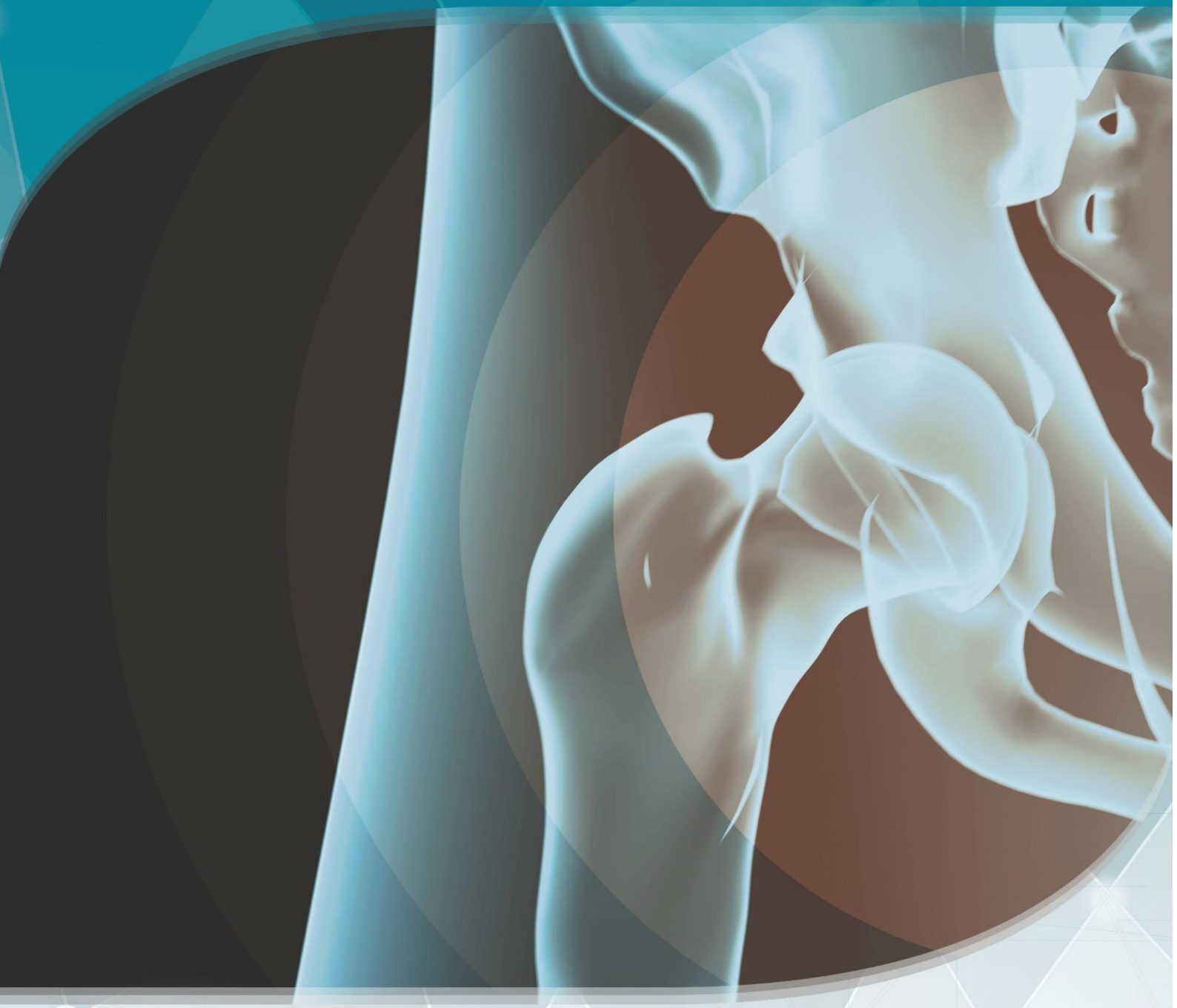
HIP BIENNIAL REPORT 2015



ROMANIAN
ARTHROPLASTY
REGISTER

WWW.RNE.RO

Romanian Hip Arthroplasty Register

2015 Hip Arthroplasty Report

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Introduction

Reaching 19.86 million inhabitants, Romania is the 7th largest country by population in the European Union, and has a 15 year old nation-wide joint register.

1. Background

The 2015 Hip Arthroplasty Report is the third biennial report of the Romanian Arthroplasty Register. The Report is based on the analysis of 123,298 interventions, primary (116,069) and revision (7,229) procedures, between September 2001 and December 2015.

Compared to the first biennial Report (2011) the cohort increased, between 2012-2015 being reported an additional 41,942 interventions (primary and revision procedures).

The biennial report contains descriptive statistics that highlight the evolution of hip arthroplasty, statistical survival analysis (Kaplan Meier 10-year Survival Curves and Cox's proportional hazards model), and future projections of hip arthroplasty in Romania.

From the total orthopaedic surgeries that add up to a yearly average of 57,000 surgeries performed in the orthopaedic clinics each year, around 14.000 are hip and knee joint replacements reported to the Romanian Arthroplasty Register (RAR).

Around 526 surgeons in over 110 clinics perform hip replacements in Romania. In comparison to the 2011 Hip Arthroplasty Report, the number of reporting private hospitals has increased from 4 to 13* hospitals.

The Romanian Arthroplasty Register web-based application was launched in October 2001 at The National Congress of Orthopaedics and Trauma in Craiova. At the time, reporting the hip arthroplasties to RAR was not mandatory. The application was designed from the very beginning to be fully compatible with the EFORT minimal data set. Later, as the minimal data set was extended, the application was updated accordingly.

2. Aims

- Surveillance tool that compares the quality of different types of endoprosthesis
- Detection of low-quality implants and procedures
- Analysis of cementing and surgical techniques
- Analysis of the endoprosthesis by their survival rates
- Analysis of the results of different medical devices and techniques used
- Information source for orthopaedic surgeons and patients

3. Benefits

The Romanian Arthroplasty Register is mainly used to help patients or potential patients and surgeons by providing information about endoprosthesis and surgeries. The information is released by published reports and statistics that are also available on the official website www.rne.ro.

4. Data Collection

The data is collected directly from public and private hospitals through Registry Forms that were introduced in 2001 and updated in 2005, 2006, 2008. Another update is expected in 2018. These forms are filled-in by the end of each surgery and submitted monthly to the Romanian Arthroplasty Register.

* *Two of the private hospitals are registered in RAR database since 2015*

5. Data Validation

Data validation is a two-tier process:

1. Internal validation – the forms undergo a validation process which requires a minimum data set to be complete;
2. Cross-validation of the Romanian Arthroplasty database by comparing its data to other institutions data:
   - The National Health Insurance House
   - The National Institute of Population Registry

6. Executive Summary

The 2015 biennial Report follows the main structure of the first biennial Report (2011), however, being visibly improved with specific results and outcomes of the hip arthroplasties during the studied period. Over the last 15 years, an increasing trend in the number of Hip Replacement procedures can be observed in Romania, based on the reported data collected from the hospitals with orthopaedic departments.

The first sections of the Report include Romania's demographical and social context adapted to population characteristics, national medical system, Romanian Arthroplasty Register objective and represents an overview of the Romanian Arthroplasty activity.

The following sections of the report are structured to present outcomes of the Primary and Revision Hip Arthroplasty activity. There are outcomes for each type of implant: Total Hip Replacement, Resurfacing, Bipolar/Unipolar and Moore type. The section on re-operations is divided by type of revision: total, partial and conversion type. Also, within this section, a subsection has been dedicated to the analysis of the risk of revision of main implant types, respectively to the survival analysis of different implant types by age groups and diagnoses.

The 2015 biennial Report offers a complex radiography of the arthroplasty activity in Romania by studying the quantitative characteristics of the analyzed data set.

1 Demographical and Social Context

1.1 Population of Romania

Table 1 – Population by gender

Population	'07	'08	'09	'10	'11	'12	'13	14	15
Male	10,169,596	10,000,515	9,916,107	9,856,669	9,805,108	9,770,353	9,754,851	9,728,663	9,712,029
Female	10,713,384	10,537,333	10,451,330	10,390,129	10,342,549	10,289,829	10,230,963	10,184,530	10,148,971
Total	**20,882,980**	**20,537,848**	**20,367,437**	**20,246,798**	**20,147,657**	**20,060,182**	**19,985,814**	**19,913,193**	**19,861,000**

**Data source: National Institute of Statistics (NIS), Tempo Online, "Resident population at July 1st."*
Analyzed Period: 2007-2015

1.2 Population by gender and geographical area

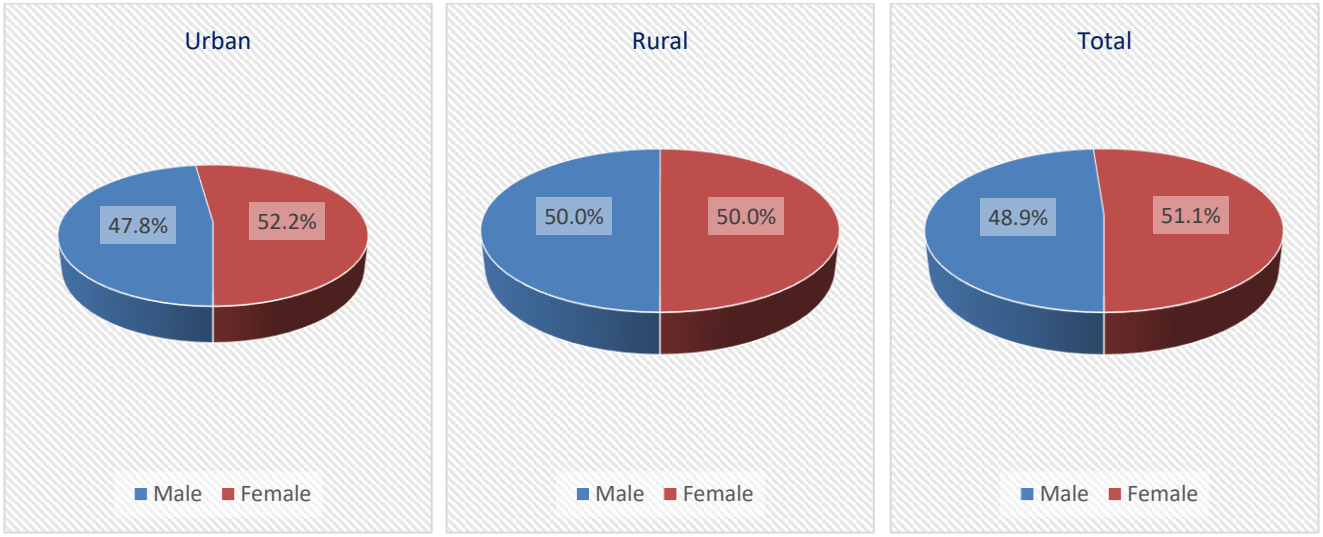


Figure 1.1, 1.2, 1.3 - Distribution of population by geographical area

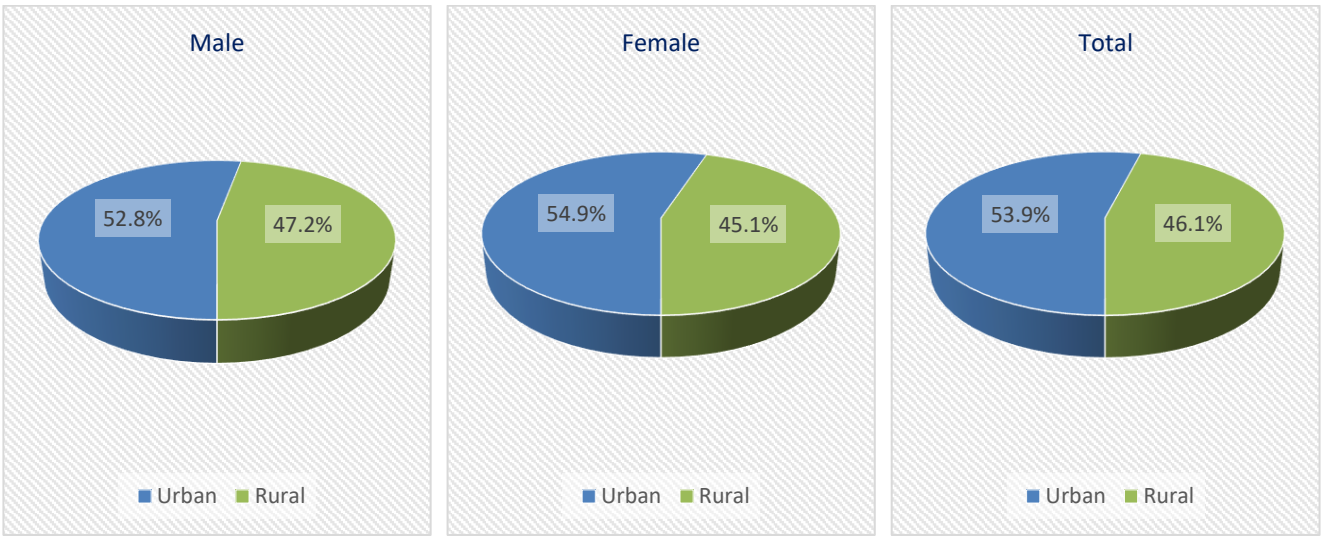


Figure 2.1, 2.2, 2.3 - Distribution of population by gender

**Source: National Institute of Statistics (NIS) 2015, Tempo Online*

1.3 Population by age and gender

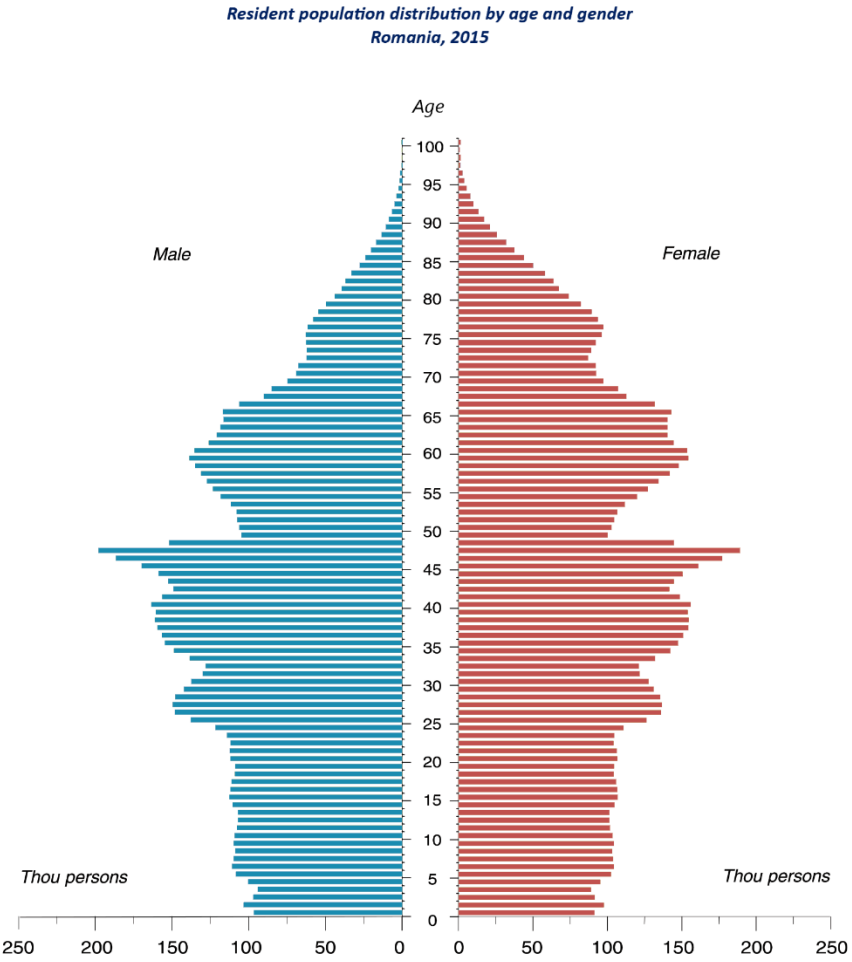


Figure 3 – Resident population, Romania 2015 – distribution by age and gender. Data source: Romanian Statistical Yearbook, 2016

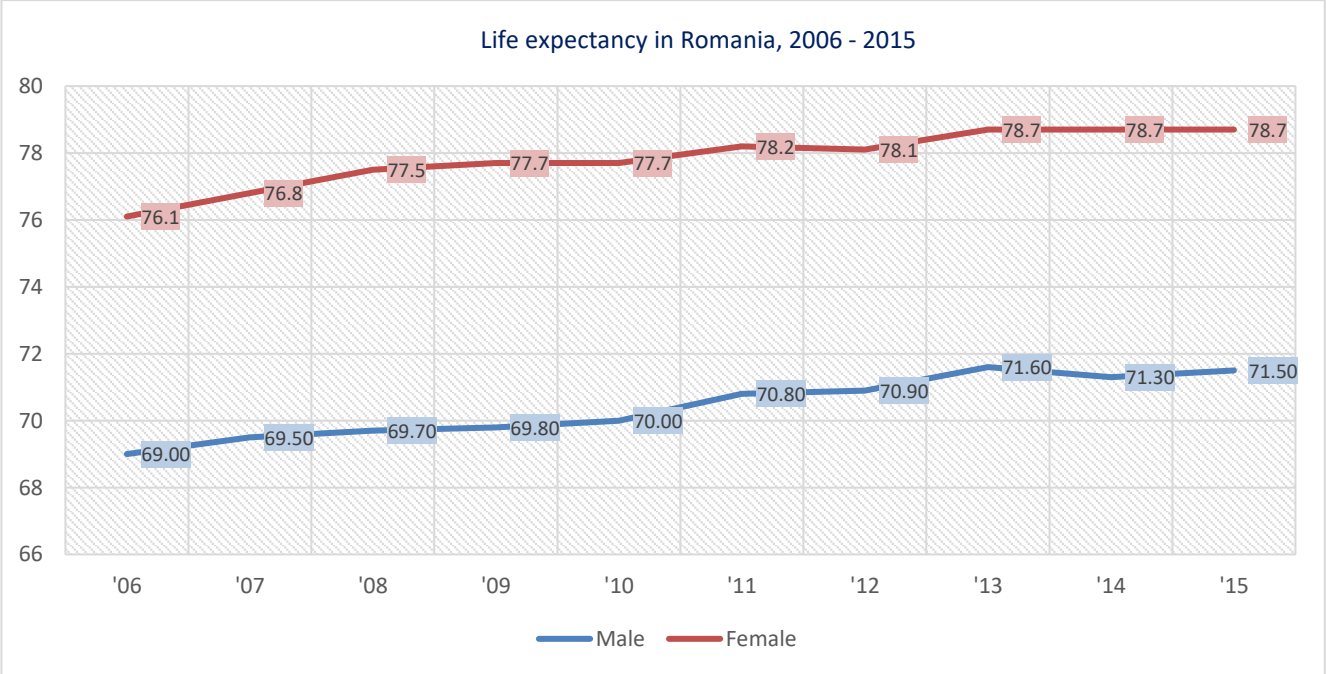


Figure 4 – Life expectancy by gender and years

**Data Source: Eurostat Online Database, http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=demo_mlexpec&lang=en*

1.4 Evolution of orthopedic medical physicians

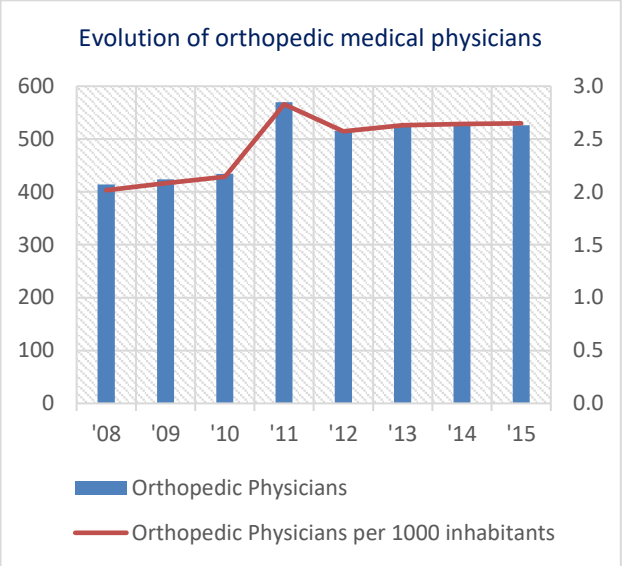


Figure 5 – Evolution of orthopaedic physicians, Data Source: RAR

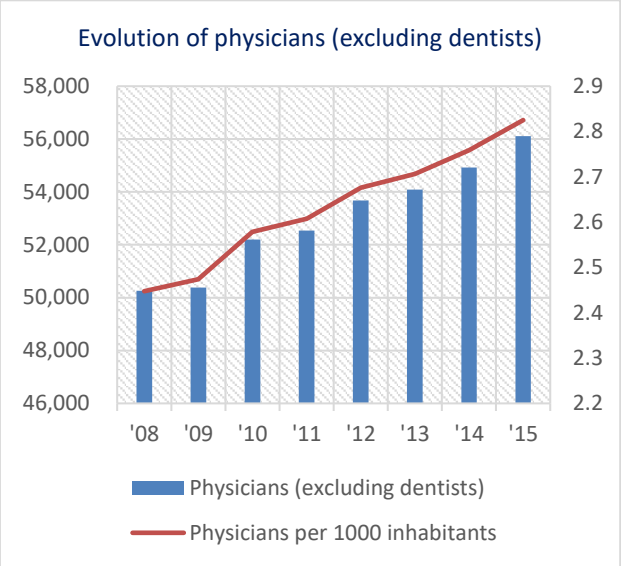


Figure 6 – Evolution of physicians (excluding dentists).
Data source: National Institute of Statistics (NIS), 2008-2015

Considering the number of orthopaedic physicians included in RAR Database for 2015, Romania registered 2.65 orthopaedic physicians per 100.000 inhabitants. This evidence places Romania in the last quartile of Eurostat available data* (ordered descending) regarding the number of orthopaedic physicians in Europe, with significantly lower figures than Germany, Italy, UK (20, 16 respectively 11 orthopaedic physicians per 100.000 inhabitants).

1.5 Evolution of orthopedic patient beds in health units

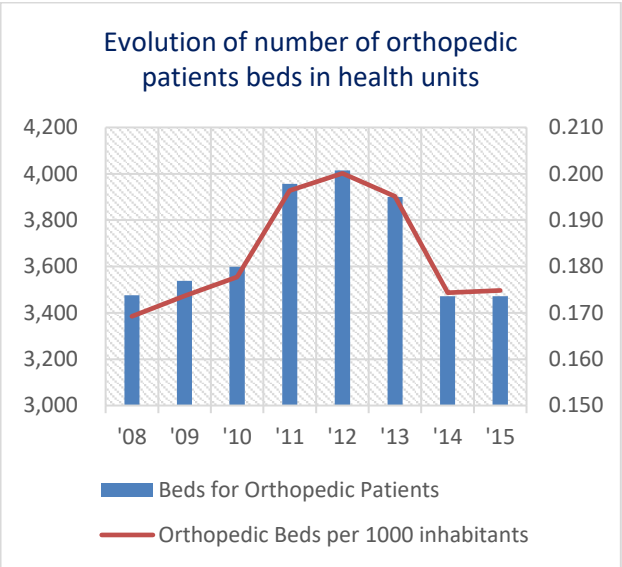


Figure 7 – Evolution of number of orthopedic patient beds.
Data source: RAR, 2008-2015

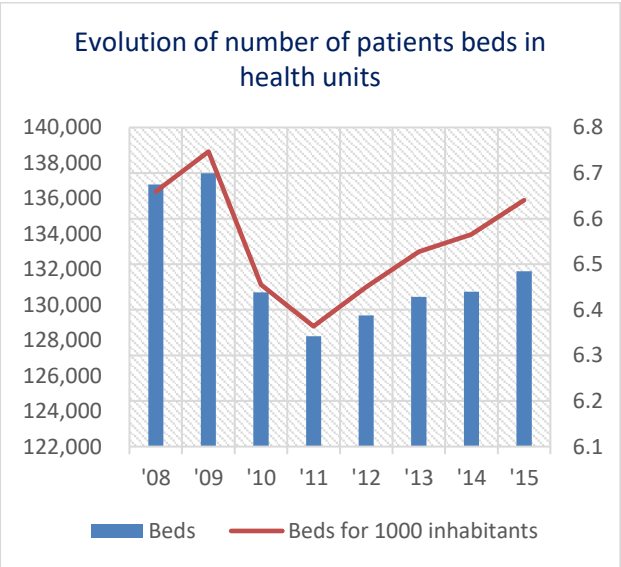


Figure 8 – Evolution of number of hospital beds.
Data source: National Institute of Statistics (NIS), 2008-2015

** Data Source: Eurostat Online Database, http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=hlth_rs_spec&lang=en*

2 Register Data

2.1 Introduction to the Romanian Arthroplasty Register

The Romanian Arthroplasty Register represents an integrated reporting framework for the Romanian Orthopaedic Community, initiated by the Ministry of Health in 2001.

The Register is functioning on non-competitive principles, meaning that the data for each hospital is private, and that the patients' data is classified.

The main objective of RAR is to function as a surveillance tool that compares the quality of different types of endoprosthesis, cement and surgical techniques and to detect low quality implants and procedures as soon as possible by comparing the results of different medical devices and techniques used.

The Romanian Arthroplasty Register, also the main database for the Romanian Orthopaedics and Trauma Specialty, is in a unique situation among international registers. It collects a sum of complementary data to the implant and patient specific information: financial information, detailed database of orthopaedic clinics and their equipment level, detailed database of surgeons and their qualifications.

Aside of the complementary information and general patient details, the arthroplasty database is structured as 5 independent registries: Romanian Hip Arthroplasty Register, Romanian Knee Arthroplasty Register, Romanian Spinal Surgery Register and Romanian Cruciate Ligament Reconstruction Register.

Arthroplasty Registries

Romanian *Hip* Arthroplasty Register:

- Primary hip arthroplasties;
- Revision hip arthroplasties;
- Soft tissue re-intervention.

Hospital/department database:

- Administrative information;
- Surgeons and residents;
- Auxiliary theater personnel;
- Technological and professional level – surgery technique.

General activity by department:

- Type of implants per month;
- Average cost per implant type;
- Number of surgeries and admissions (incl. Fractures, tumors);
- Quality indicators.

Statistical module – real-time:

- Hip statistics;
- Knee statistics;
- Survival statistics (KM);
- Hospital statistics (administrative /personnel).

Patient database:

- Uniquely coded personal identifier;
- INEP and CNAS validation.

Barcode implant database:

- Barcode tracking system;
- Implant details (technical specifications, LOT and REF).

X-Ray Database:

- Available for hip, knee and spinal surgery registry.

Romanian *Knee* Arthroplasty Register:

- Primary knee arthroplasties;
- Revision knee arthroplasties;
- Soft tissue re-intervention.

Romanian *Spinal* Surgery Register:

- Segmentary spinal arthroplasties;
- Postoperative evaluation.

Romanian *Cruciate Ligament Reconstruction Register:*

- Primary cruciate ligament;
- Revision cruciate ligament.

The RAR website (www.rne.ro) is the main portal for both patients and professionals. The website has been constantly enhanced to be more transparent for the public and to include a larger set of online statistics.

For updated statistics on each clinic please visit the www.rne.ro website.

2.2 Register description and timeline

Back in 2001, when RAR started, the authorities were interested to collect financial information for the Health Program Budgets. At the same time the orthopaedic community was interested in a medical register and, since there were no other registries in Romania to share the know-how, RAR was a pilot project with a lot of flexibility to define the outcomes and the internal procedures.

The Romanian Arthroscopy Register's activity started in 2001 with the development of the data collection forms and the Register web-based platform, leading to the present focus towards the analysis of the collected data.

RAR Evolution Overview

Start-up **2001**	•Hip register start-up •EFORT minimal dataset support •Low cost software infrastructure, mainly open-source products
Expansion **2003**	•Hip forms improvement (v2) •Knee register start-up •General activity by department Spine register Soft Tissue Data Collection Implant barcode tracking
Redesign **2005**	•Software architecture redesign and implementation for a better data exchange with EAR •Logical division into 3 separate registers: Hip, Knee, Spine •Validation procedure
Data Analysis **2007**	•Electronic file archiving •Internationalization support •First medical study on partial primary implants using RAR data, 2006 •Online statistics module implemented for surgeons access
Transparency **2009**	•Software infrastructure extension •Public website increased transparency •Department activity published on the public website
Publications **2011**	•2010 Annual Hip Statistics •2010 Annual Knee Statistics
Publications **2013**	•2011 Annual Hip Report (first biennial report)
Publications & Expansion **2015**	•2013 Biennial Hip Report (second biennial report) •Statistical analysis- Hemiarthroplasty in Romania 2001-2013 •Romanian Cruciate Ligament Register
Publications **2016**	•Statistical study: "A survival comparison based on cemented and cementless endoprostheses reported to the R.A.R." - presented at the ISAR Conference 2016

The first biennial report published in English by Romanian Arthroplasty Register was in 2013 and included analysis based on 2001-2011 data. The report is published on the official website www.rne.ro.
The second biennial RAR report published was in 2016 and includes statistical analysis based on data between 2001-2013.

2.3 Follow-up activity (PROMs)

The introduction of hip and knee Patient Reported Outcome Measures during the initial RAR development stages was not an option due to political and economic context.

The first attempt to start a pilot PROM project was with the start of the Spinal Registry, due to the much lower volume of data. Unfortunately, the attempt was not seen as a real benefit by the surgeons, it lacked medical support and was not fully adopted in the end.

Given the wide international recognition of PROMs benefits, Romanian Arthroplasty Register permanently tries to find feasible ways to start implementing PROM forms for both the hip and knee registries.

3 Coverage and completeness of the data

3.1 Hospital Coverage by County

Table 2 – List of participating hospitals in Romanian Arthroplasty Register between 2001-2015

Hospital/County	Total number of Primary Hip	% Primary Hip 2001-2015	% Primary Hip 2014	% Primary Hip 2015	Total number of Revision Hip	% Hip Revision 2001-2015	% Hip Revision 2014	% Hip Revision 2015
Alba	**2206**	**1.90%**	**2.67%**	**2.40%**	**115**	**1.59%**	**2.66%**	**4.15%**
Sp. Jud. Urg. Alba Iulia	2184	1.88%			114	1.58%		
Sp. Mun. Aiud	7	0.01%			1	0.01%		
Sp. Mun. Blaj	15	0.01%			0	0.00%		
Arad	**2694**	**2.32%**	**2.62%**	**2.42%**	**23**	**0.32%**	**0.00%**	**0.00%**
Sp. Cl. Jud. Urg. Arad	2694	2.32%			23	0.32%		
Arges	**1224**	**1.05%**	**1.29%**	**1.56%**	**18**	**0.25%**	**0.30%**	**0.75%**
Sp. Jud. Urg. Arges	1224	1.05%			18	0.25%		
Bacau	**1191**	**1.03%**	**1.82%**	**2.20%**	**32**	**0.44%**	**1.92%**	**1.70%**
Sp. Jud. Urg. Bacau	808	0.70%			22	0.30%		
Sp. Mun. Onesti	98	0.08%			0	0.00%		
Sp. Mun. Urg. Moinesti	285	0.25%			10	0.14%		
Bihor	**2856**	**2.46%**	**3.33%**	**3.25%**	**86**	**1.19%**	**1.18%**	**2.26%**
Sp. Cl. Jud. Urg. Oradea	2334	2.01%			47	0.65%		
Sp. Pelican Oradea	522	0.45%			39	0.54%		
Bistrita Nasaud	**263**	**0.23%**	**0.15%**	**0.31%**	**0**	**0.00%**	**0.00%**	**0.00%**
Sp. Jud. Urg. Bistrita Nasaud	263	0.23%			0	0.00%		
Botosani	**747**	**0.64%**	**0.87%**	**0.76%**	**22**	**0.30%**	**0.59%**	**0.19%**
Sp. Jud. Urg. "Mavromati" Botosani	747	0.64%			22	0.30%		
Braila	**1526**	**1.31%**	**1.39%**	**1.37%**	**51**	**0.71%**	**0.59%**	**1.51%**
Sp. Jud. Urg. Braila	1526	1.31%			51	0.71%		
Brasov	**5093**	**4.39%**	**5.39%**	**5.80%**	**425**	**5.88%**	**6.66%**	**11.32%**
Sp. Cl. Jud. Urg. Brasov	2915	2.51%			208	2.88%		
Clinicile ICCO Ortopedie Brasov	1026	0.88%			172	2.38%		
Sp. Medlife Brasov	152	0.13%			8	0.11%		
Sp. Mil. Urg. Brasov	127	0.11%			13	0.18%		
Sp. Mun. Fagaras	114	0.10%			2	0.03%		
Sp. Sf. Constantin Brasov	39	0.03%			3	0.04%		
Sp. Copii Brasov	2	0.00%			0	0.00%		
Bucuresti	**34046**	**29.33%**	**24.73%**	**23.23%**	**2809**	**38.86%**	**37.87%**	**37.92%**
Sp. Cl. C.F. Nr.2 Bucuresti	338	0.29%			25	0.35%		
Sp. Cl. Colentina Bucuresti	3043	2.62%			334	4.62%		
Sp. Cl. Ort-Traum "Foisor" Bucuresti	8036	6.92%			985	13.63%		
Sp. Cl. Urg. "Bagdasar Arseni" Bucuresti	2554	2.20%			99	1.37%		
Sp. Cl. Urg. "Sf. Pantelimon" Bucuresti	3569	3.07%			231	3.20%		

Hospital/County	Total number of Primary Hip	% Primary Hip 2001-2015	% Primary Hip 2014	% Primary Hip 2015	Total number of Revision Hip	% Hip Revision 2001-2015	% Hip Revision 2014	% Hip Revision 2015
Sp. Cl. Urg. "Sf.Ioan" Bucuresti	1223	1.05%			72	1.00%		
Sp. Cl. Urg. Bucuresti	3965	3.42%			183	2.53%		
Sp. Mil. Urg. "Agrippa Ionescu"	34	0.03%			3	0.04%		
Sp. Penitenciar Rahova Bucuresti	1	0.00%			1	0.01%		
Sp. Univ. Urg. Bucuresti	7373	6.35%			496	6.86%		
Sp. Univ. Urg. Elias Bucuresti	2093	1.80%			251	3.47%		
Sp. Univ. Urg. Mil. Central Bucuresti	1339	1.15%			87	1.20%		
Sp. Urg. "Dim. Gerota" Bucuresti	211	0.18%			20	0.28%		
Sp. Ort. Traum. Medlife Bucuresti	110	0.09%			10	0.14%		
Sp. Sanador	99	0.09%			7	0.10%		
Sp. Monza	4	0.00%			1	0.01%		
Sp. Euroclinic "Regina Maria"	54	0.05%			4	0.06%		
Buzau	**154**	**0.13%**	**0.24%**	**0.22%**	**0**	**0.00%**	**0.00%**	**0.00%**
Sp. Jud. Urg. Buzau	77	0.07%			0	0.00%		
Sp. Mun. Ramnicu Sarat	77	0.07%			0	0.00%		
Calarasi	**228**	**0.20%**	**0.10%**	**0.07%**	**5**	**0.07%**	**0.00%**	**0.00%**
Sp. Jud. Urg. Calarasi	228	0.20%			5	0.07%		
Caras Severin	**475**	**0.41%**	**0.35%**	**0.34%**	**6**	**0.8%**	**0.15%**	**0.00%**
Sp. Jud. Urg. Resita	183	0.16%			0	0.00%		
Sp. Mun. Urg.Caransebes	291	0.25%			6	0.08%		
Sp. Oras. Oravita	1	0.00%			0	0.00%		
Cluj	**9006**	**7.76%**	**6.00%**	**6.42%**	**545**	**7.54%**	**8.14%**	**3.58%**
Sp. Cl. Jud. Urg. Cluj-Napoca	2189	1.89%			153	2.12%		
Sp. Cl. Rec. Cluj-Napoca	2453	2.11%			141	1.95%		
Sp. Cl. Urg. "Prof. dr. Octavian Fodor" Cluj-Napoca	4160	3.58%			251	3.47%		
Sp. Mil. Urg. "Dr. Ct. Papilian" Cluj Napoca	204	0.18%			0	0.00%		
Constanta	**2684**	**2.31%**	**2.07%**	**2.29%**	**88**	**1.22%**	**1.18%**	**1.51%**
Sp. Cl. Jud. Urg. Constanta	1502	1.29%			50	0.69%		
Sp. Ort. Traum. Rec. Med. Eforie Sud[1]	1130	0.97%			32	0.44%		
Sp. Cl. CF Constanta	8	0.01%			3	0.04%		
Ovidius Clinical Hospital	44	0.04%			3	0.04%		
Covasna	**1470**	**1.27%**	**1.02%**	**1.07%**	**78**	**1.08%**	**0.74%**	**0.19%**
Sp. Jud. Urg. "Dr. Fogolyan Kristof" Sf. Gheorghe	1470	1.27%			78	1.08%		
Dambovita	**464**	**0.40%**	**0.46%**	**0.60%**	**4**	**0.06%**	**0.00%**	**0.00%**
Sp. Jud. Urg. Targoviste	464	0.40%			4	0.06%		
Dolj	**3444**	**2.97%**	**2.62%**	**2.56%**	**146**	**2.02%**	**2.96%**	**1.89%**
Sp. Cl. Jud. Urg. Craiova	3444	2.97%			146	2.02%		
Galati	**1924**	**1.66%**	**2.03%**	**1.36%**	**33**	**0.46%**	**1.18%**	**0.57%**
Sp. Cl. Jud. Urg. "Sf. Ap. Andrei" Galati	1792	1.54%			23	0.32%		

[1] Activity terminated in August 2013

Hospital/County	Total number of Primary Hip	% Primary Hip 2001-2015	% Primary Hip 2014	% Primary Hip 2015	Total number of Revision Hip	% Hip Revision 2001-2015	% Hip Revision 2014	% Hip Revision 2015
Sp. Mun. "Anton Cincu" Tecuci	132	0.11%			10	0.14%		
Giurgiu	**110**	**0.09%**	**0.18%**	**0.32%**	**0**	**0.00%**	**0.00%**	**0.00%**
Sp. Jud. Urg. Giurgiu	110	0.09%			0	0.00%		
Gorj	**324**	**0.28%**	**0.95%**	**1.18%**	**5**	**0.07%**	**0.30%**	**0.57%**
Sp. Or. Tg. Carbunesti	146	0.13%			0	0.00%		
Sp. Jud. Urg. Targu Jiu	175	0.15%			5	0.07%		
Sp. Or. Rovinari	3	0.00%			0	0.00%		
Harghita	**762**	**0.66%**	**1.30%**	**1.44%**	**13**	**0.18%**	**0.59%**	**0.38%**
Sp. Jud. Urg. Miercurea Ciuc	749	0.65%			13	0.18%		
Sp.Mun.Odorheiul Secuiesc	13	0.01%			0	0.00%		
Hunedoara	**2037**	**1.75%**	**2.05%**	**2.53%**	**42**	**0.58%**	**0.89%**	**0.75%**
Sp. Jud. Deva	1460	1.26%			39	0.54%		
Sp. Mun. "Dr. A. Simionescu" Hunedoara	397	0.34%			3	0.04%		
Sp. Urg. Petrosani	180	0.16%			0	0.00%		
Ialomita	**178**	**0.15%**	**0.14%**	**0.14%**	**0**	**0.00%**	**0.00%**	**0.00%**
Sp. Jud. Urg. Slobozia	144	0.12%			0	0.00%		
Sp. Mun. Urziceni	34	0.03%			0	0.00%		
Iasi	**5507**	**4.74%**	**3.10%**	**1.83%**	**273**	**3.78%**	**1.78%**	**0.94%**
Sp. Cl. de Urg. Iasi	2300	1.98%			96	1.33%		
Sp. Cl. Mil. Urg. Iasi	53	0.05%			0	0.00%		
Sp. Cl. Rec. Iasi	3040	2.62%			171	2.37%		
Sp. Mun. Pascani	83	0.07%			5	0.07%		
Arcadia Hospital Iasi	30	0.03%			1	0.01%		
Sp. Cl. Urg. Copii "Sf Maria" Iasi	1	0.00%			0	0.00%		
Maramures	**1263**	**1.09%**	**1.20%**	**1.37%**	**17**	**0.24%**	**0.30%**	**0.38%**
Sp. Jud. Urg. "Dr. Constantin Opris" Baia Mare	1263	1.09%			17	0.24%		
Mehedinti	**216**	**0.19%**	**0.38%**	**0.55%**	**0**	**0.00%**	**0.00%**	**0.00%**
Sp. Jud. Urg. Dr. Turnu Severin	216	0.19%			0	0.00%		
Mures	**13914**	**11.99%**	**10.25%**	**10.18%**	**1587**	**21.95%**	**17.01%**	**16.42%**
Centru Medical Galenus	3	0.00%			0	0.00%		
Sp. Cl. Jud. Targu-Mures	8589	7.40%			1051	14.54%		
Sp. Cl. Jud. Urg. Targu Mures	5321	4.58%			536	7.41%		
Centrul Medical Topmed	1	0.00%			0	0.00%		
Neamt	**2022**	**1.74%**	**2.37%**	**2.56%**	**85**	**1.18%**	**0.44%**	**1.70%**
Sp. Jud. Urg. Piatra Neamt	1904	1.64%			85	1.18%		
Sp. Mun. Urg. Roman	118	0.10%			0	0.00%		
Olt	**650**	**0.56%**	**0.92%**	**0.87%**	**5**	**0.07%**	**0.15%**	**0.19%**
Sp. Jud. Urg. Slatina	198	0.17%			0	0.00%		
Sp. Mun. Caracal	452	0.39%			5	0.07%		
Prahova	**3085**	**2.66%**	**3.40%**	**3.51%**	**42**	**0.58%**	**1.04%**	**0.75%**
Sp. Jud. Urg. Ploiesti	2344	2.02%			30	0.41%		

Hospital/County	Total number of Primary Hip	% Primary Hip 2001-2015	% Primary Hip 2014	% Primary Hip 2015	Total number of Revision Hip	% Hip Revision 2001-2015	% Hip Revision 2014	% Hip Revision 2015
Sp. Or. Ort-Traum. "Principele Nicolae" Azuga	708	0.61%			12	0.17%		
Sp. Mun. Campina	33	0.03%			0	0.00%		
Salaj	**456**	**0.39%**	**0.66%**	**0.66%**	**2**	**0.03%**	**0.00%**	**0.00%**
Sp. Jud. Urg. Zalau	456	0.39%			2	0.03%		
Satu Mare	**1732**	**1.49%**	**1.94%**	**2.14%**	**100**	**1.38%**	**1.33%**	**0.75%**
Sp. Jud. Urg. Satu Mare	1592	1.37%			94	1.30%		
Sp. Mun. Carei	128	0.11%			5	0.07%		
Sp. Oras. Negresti-Oas	12	0.01%			1	0.01%		
Sibiu	**2385**	**2.05%**	**2.01%**	**1.89%**	**161**	**2.23%**	**3.25%**	**1.89%**
Sp. Cl. Jud. Urg. Sibiu	2315	1.99%			159	2.20%		
Sp. Mun. Medias	63	0.05%			2	0.03%		
Sp. Cl. Pediatrie Sibiu	2	0.00%			0	0.00%		
Clinica Polisano Sibiu	5	0.00%			0	0.00%		
Suceava	**875**	**0.75%**	**1.49%**	**2.02%**	**12**	**0.17%**	**0.59%**	**0.75%**
Sp. Jud. Urg."Sf. Ioan cel Nou" Suceava	849	0.73%			12	0.17%		
Sp. Mun. Falticeni	26	0.02%			0	0.00%		
Teleorman	**89**	**0.08%**	**0.00%**	**0.00%**	**0**	**0.00%**	**0.00%**	**0.00%**
Sp. Jud. Urg. Alexandria	89	0.08%			0	0.00%		
Timis	**5658**	**4.87%**	**5.37%**	**5.39%**	**319**	**4.41%**	**4.88%**	**5.85%**
Sp. Cl. Jud. Urg. Timisoara Nr.2	2799	2.41%			166	2.30%		
Sp. Cl. Jud. Urg. Timisoara Nr.1	2428	2.09%			130	1.80%		
Sp. Mil. Urg. "Victor Popescu" Timisoara	310	0.27%			23	0.32%		
Sp. Mun. Lugoj	121	0.10%			0	0.00%		
Tulcea	**2**	**0.00%**	**0.00%**	**0.00%**	**0**	**0.00%**	**0.00%**	**0.00%**
Sp. Jud. Urg. Tulcea	2	0.00%			0	0.00%		
Valcea	**1888**	**1.63%**	**1.72%**	**1.73%**	**59**	**0.82%**	**1.18%**	**0.75%**
Sp. Jud. Urg. Valcea	1874	1.62%			59	0.82%		
Sp. Mun. Dragasani	14	0.01%			0	0.00%		
Vaslui	**286**	**0.25%**	**0.39%**	**0.45%**	**1**	**0.01%**	**0.00%**	**0.00%**
Sp. Jud. Urg. Vaslui	203	0.17%			1	0.01%		
Sp. Mun. Urg."Elena Beldiman" Barlad	83	0.07%			0	0.00%		
Vrancea	**908**	**0.78%**	**1.05%**	**1.04%**	**20**	**0.28%**	**0.15%**	**0.38%**
Sp. Jud. Urg. "Sf. Pantelimon" Focsani	373	0.32%			0	0.00%		
Sp. Mil. Urg. Focsani	277	0.24%			12	0.17%		
Sp. Mun. Adjud	258	0.22%			8	0.11%		
Unknown	27	0.02%	0.00%	0.00%	0	0.00%	0.00%	0.00%
Grand Total	**116069**	**100.0%**	**100%**	**100%**	**7229**	**100.0%**	**100%**	**100%**

The total volume of arthroplasty activity has increased with 52% within the period 2012-2015, the coverage of the reporting data reaching 98% from all territorial hospitals with orthopaedic activity in Romania.

3.2 Completeness of data

Table 3 – Percentage of missing data of primary hip procedures, RAR vs. CNAS

Number of primary arthroplasties	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
RAR Data	5928	5921	6343	7135	7251	8876	8880	8866	8830	8969	9806	10370
CNAS Data	5221	5784	5743	6896	6975	8078	8108	7370	6706	7234	7944	9036
*Possible missing reported forms RAR vs. CNAS**	-103	-115	-95	-298	-605	-198	-378	-88	-38	-223	-106	-81
Minimal degree of completeness	98.2%	98.0%	98.5%	95.6%	90.9%	97.7%	95.6%	99.00%	99.6%	97.5%	98.9%	99.2%

* Difference between total no. of primary endoprosthesis identified in CNAS database and those found in RAR database

To assure the quality of the data and accuracy in the main statistical analysis performed, the degree of completeness represents a very important indicator. As presented in Table 3, the data reported to the RAR has been compared to the data provided by the National Health Insurance House (CNAS) - summarized data by county was available.

The degree of completeness is defined as the difference between the 100% absolute completeness, and the indicator computed by the ratio between the number of implants found in the CNAS database but not found in the RAR versus the total number of primary hip implants registered in the RAR.

Our analysis reveals a missing data indicator from 0.43% to 9.1%, this can partially be explained by the supra-unitary ratio of data reported to the RAR versus CNAS, since RAR is collecting all surgeries, not only the ones covered by the National Insurance House (also patient and private insurance covered cost). Also, the indicator cannot compensate the difference in classification of primary and revision arthoplasties between RAR and CNAS. CNAS classification is based on implant type and not on procedure type (eg.: revision type procedures using a primary type implant are classified by CNAS as primary interventions and as reoperations by RAR; so they appear as possibly missing from RAR primary hip arthroplasties reported forms). This aspect was approximated when calculating the degree of completeness.

3.3 Participating hospitals by type and activity

120 hospitals are registered in the RAR database as having orthopaedic departments, but only 88 of them were active in 2015.

From a total of 120 hospitals registered, around 17 hospitals do not perform arthroplasty procedures, just general orthopaedic and trauma cases. They are not included for the moment in the National Health Program – Prevention in Orthopaedics and Trauma. The total number of active hospitals, that are reporting to RAR is 104.

Table 4 – Participating hospitals by type and activity – 2015

Hospital type	Number of active hospitals	% of total active hospitals	Number of beds	% of total no. of beds	% of total primary implants	% of total revision implants
Active hospitals:	104		3,472			
• **Public**	**90**	**86.54%**	**3,271**	**94.21%**	**95.88%**	**89.81%**
Clinical university hospitals	31	29.81%	1,762	50.75%	60.32%	70.94%
Clinical general hospitals	60	57.69%	1,509	43.46%	35.55%	18.87%
• **Private**	**13**	**12.50%**	**201**	**5.79%**	4.12%	10.19%

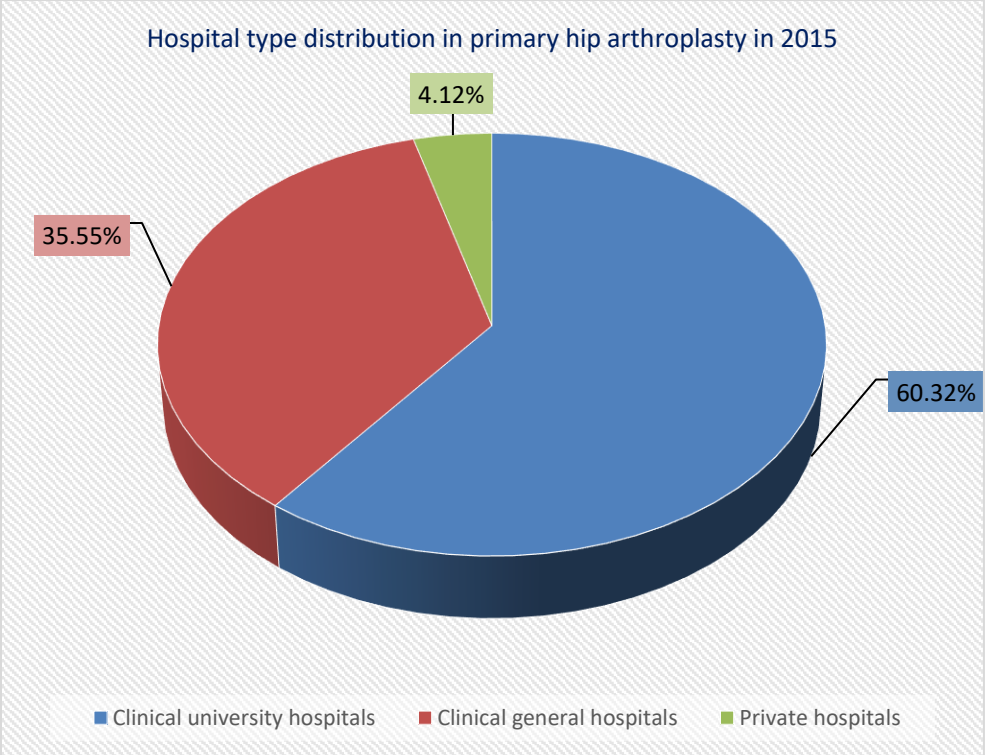


Figure 9 – Hospital type distribution of primary hip arthroplasty (2015)

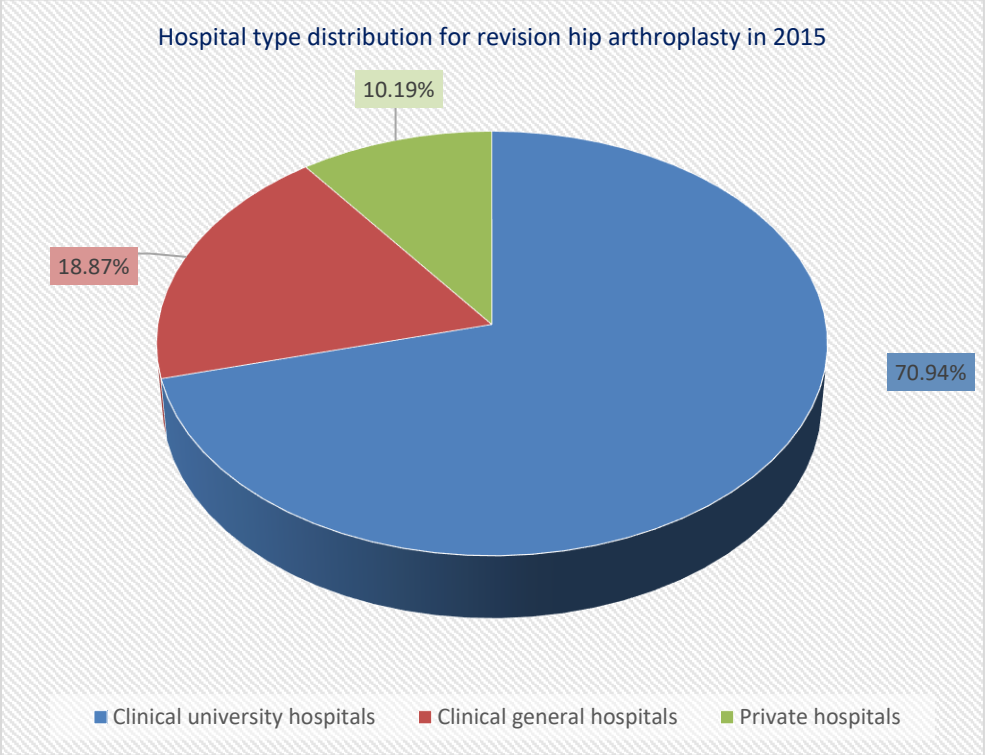


Figure 10 – Hospital type distribution of revision hip arthroplasty (2015)

In comparison to the 2001-2013 period, from the total number of primary hip arthroplasties, in 2015 the number of all primary hip arthroplasty procedures performed in private hospitals has increased to 4.12%. Also, hip revision procedures performed by private hospitals doubled since 2013 reaching 10.19% of the total nationwide procedures in 2015.

Primary hip arthroplasties performed by clinical university hospitals decreased from 77.21% in 2011 to 60.32% in 2015. The decrease is also observed in revision hip arthroplasties, from 88.20% in 2011 to 70.94% in 2015.

3.3.1 Private health sector (2008-2015)

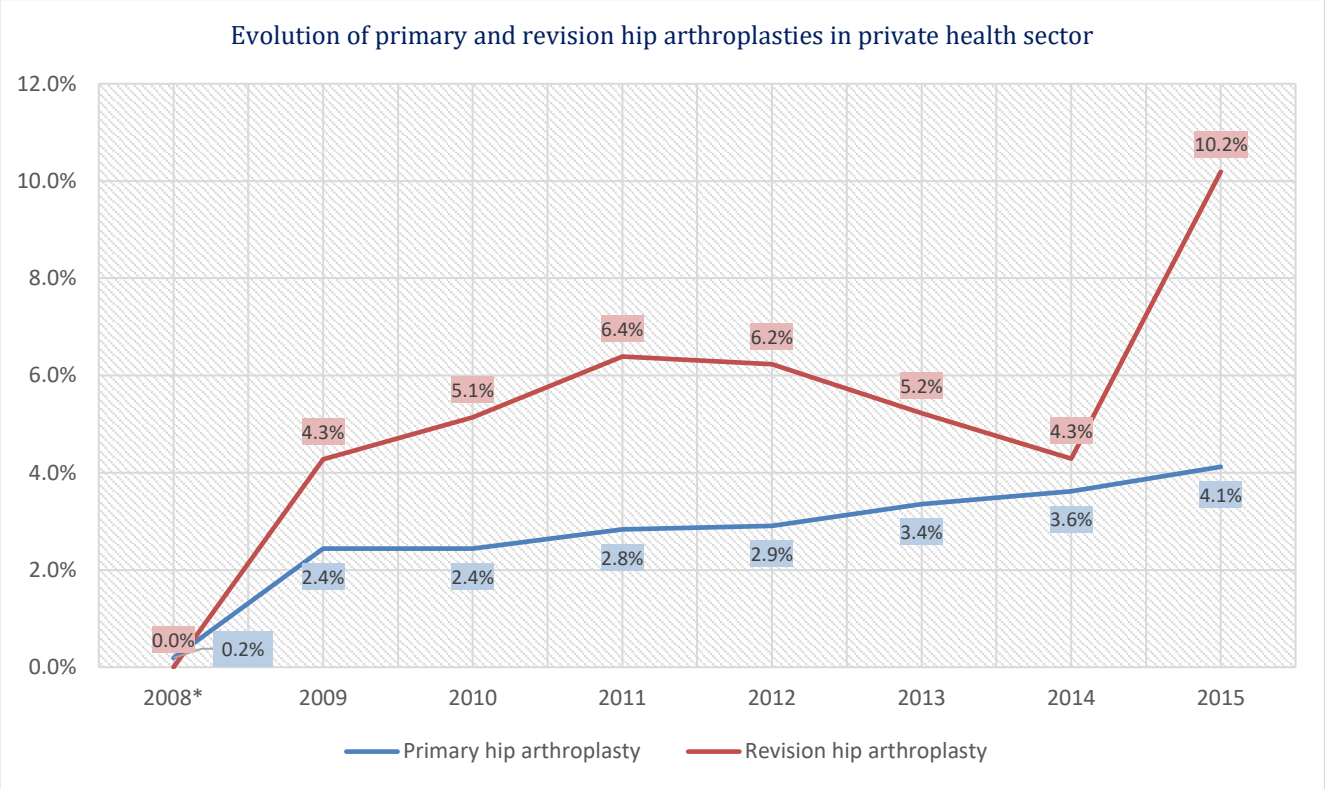


Figure 11 – Evolution of primary and revision hip arthroplasties in private health sector

**data on private health sector has been collected in RAR starting with 2008*

The private healthcare sector in Romania is in its early development stages. Between 2009 and 2015 both primary and revision hip arthroplasties have increased up to 4.1% and 10.2%, respectively.

Considering the private healthcare sector, the county that performs the highest number of primary hip arthroplasty surgery is Brasov with 3 private hospitals and with approximately 58% of all primary operations. Also, Brasov is the main county that performs revision arthroplasties with almost 74% of all private sector revision procedures.

The evolution of top counties with the highest number of hip arthroplasty procedures from 2008 to 2015 is presented in the table below:

Table 5 – Private health sector, primary and revision procedures performed, 2008 - 2015

County	'08	'09	'10	'11	'12	'13	'14	'15	Total	%
Primary arthroplasties										
Bihor	17	81	74	87	71	86	54	52	522	24.99%
Brasov	0	135	139	154	154	183	214	238	1217	58.26%
Bucuresti	0	0	0	0	35	57	71	104	267	12.78%
Constanta	0	0	0	0	0	0	24	20	44	2.11%
Iasi	0	0	3	9	0	3	5	10	30	1.44%
Mures	0	1	0	0	1	0	2	0	4	0.19%
Sibiu	0	0	0	0	0	0	5	0	5	0.24%
Revision arthroplasties										
Bihor	0	7	6	6	4	7	3	6	39	15.73%
Brasov	0	18	23	31	30	25	19	37	183	73.79%
Bucuresti	0	0	0	0	3	5	3	11	22	8.87%
Constanta	0	0	0	0	0	0	3	0	3	1.21%
Iasi	0	0	0	0	0	0	1	0	1	0.40%

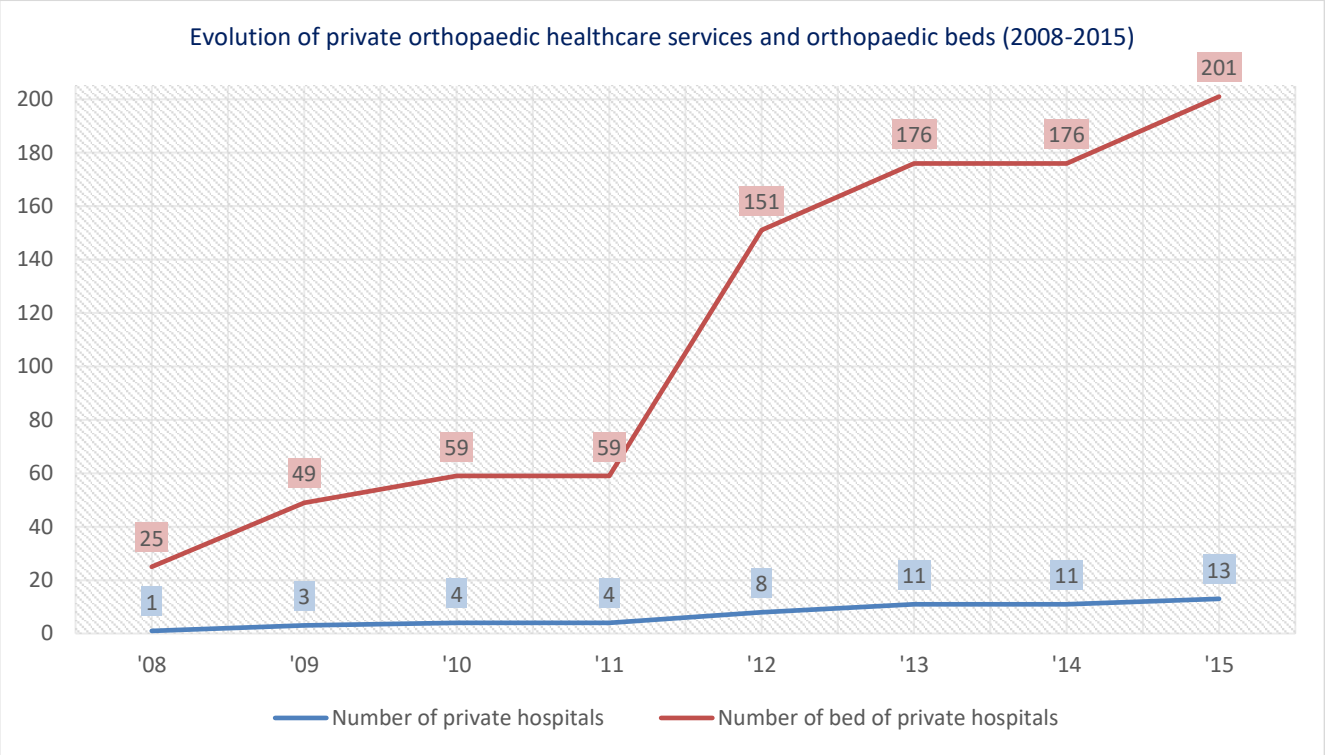


Figure 12 – Evolution of private orthopaedic healthcare services and orthopaedic beds (2008-2015, reporting to R.A.R.)

4 Romanian Arthroplasty Overview

Romania benefits of a universal healthcare system. The state finances primary, secondary and tertiary healthcare and the public health campaigns are independently financed by the Government of Romania. Universal healthcare is not a one-size-fits-all concept; nor does it imply coverage of medical costs for all Romanians. In the case of orthopedic implants, it should cover completely the cost of both surgery and implant related cost. Since the amount covered by the National Insurance House for patient care is insufficient, hardly covering the cost of surgery (in basic trauma intervention), a National Healthcare Prevention Program in Orthopedics was founded to cover for the cost of endoprosthesis and related materials.

Patient waiting lists are created depending on hospital budgets allocated through the program, as the budget of this program is also limited. Patients that need to have the surgery ahead of the waiting list are required to pay for their implants (counting for 18% of implantations). The total budget of the National Program and the public acquisition legislation in Romania dictates both the number of endoprosthesis and their quality.

4.1 Romanian arthroplasty activity map

The Romanian arthroplasty activity map indicates the percentage of arthroplasty activity performed by each county. In time, the percentage has been influenced by the amount of funds allocated through the National Program especially towards University Clinic Hospitals. High activity levels are maintained in the counties by the university centers - Bucharest (B – 29.90%), Mures (MS – 12.57%), Cluj (CJ – 7.75%), %), Timis (TM – 4.85), Iasi (IS – 4.69%). Nearly 60% of the total hip arthroplasty procedures performed in Romania are totalized by the top 5 indicated counties.

The lowest arthroplasty activity is mainly identified in the southern part of Romania (Gorj, Mehedinti, Teleorman, Giurgiu, Calarasi, Tulcea).

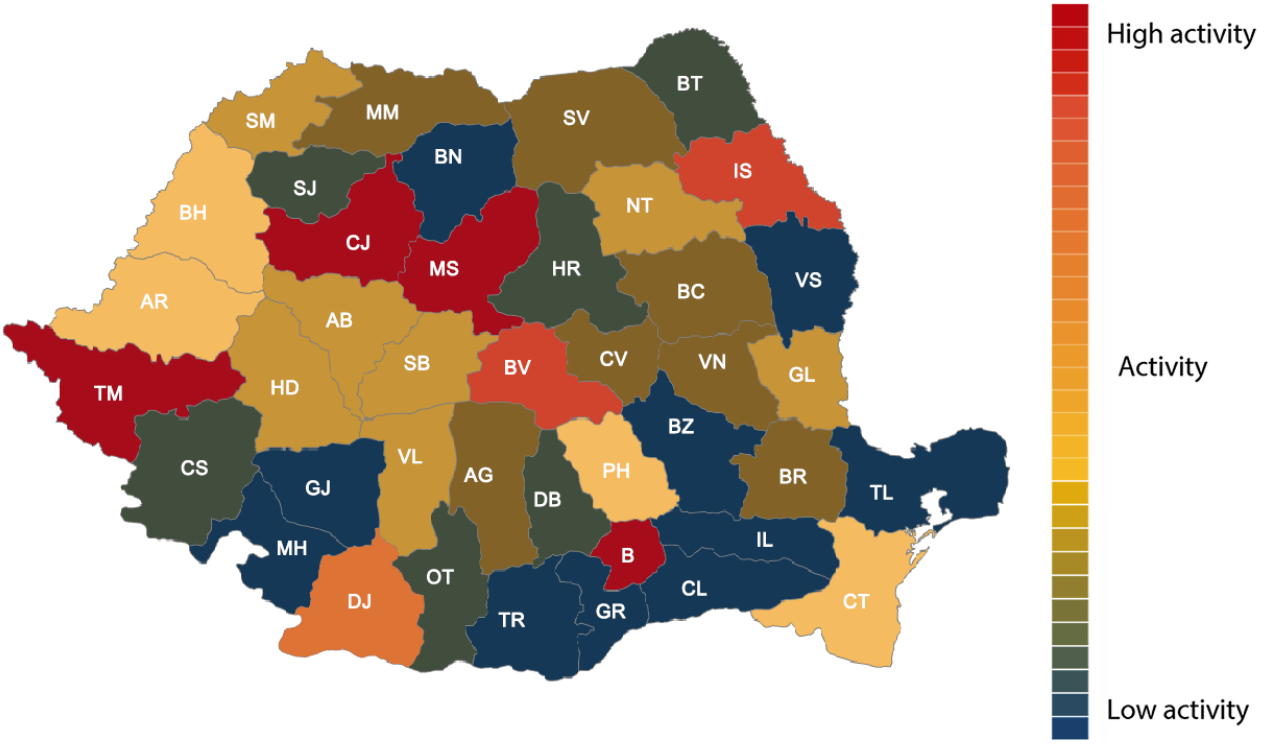


Figure 13 – Romanian arthroplasty activity map, 2001 - 2015

Table 6 – Romanian arthroplasty activity map, 2001 - 2015

Counties	% of total	Counties	% of total	Counties	% of total
(AB) Alba County	1.88%	(CT) Constanta County	2.25%	(NT) Neamt County	1.71%
(AR) Arad County	2.20%	(CV) Covasna County	1.26%	(OT) Olt County	0.53%
(AG) Arges County	1.01%	(DB) Dambovita County	0.38%	(PH) Prahova County	2.54%
(BC) Bacau County	0.99%	(DJ) Dolj County	2.91%	(SJ) Salaj County	0.37%
(BH) Bihor County	2.39%	(GL) Galati County	1.59%	(SM) Satu Mare County	1.49%
(BN) Bistrita Nasaud County	0.21%	(GR) Giurgiu County	0.09%	(SB) Sibiu County	2.07%
(BT) Botosani County	0.62%	(GJ) Gorj County	0.27%	(SV) Suceava County	0.72%
(BR) Braila County	1.28%	(HR) Harghita County	0.63%	(TR) Teleorman County	0.07%
(BV) Brasov County	4.48%	(HD) Hunedoara County	1.69%	(TM) Timis County	4.85%
(B) Bucuresti	29.90%	(IL) Ialomita County	0.14%	(TL) Tulcea County	0.002%
(BZ) Buzau County	0.12%	(IS) Iasi County	4.69%	(VL) Valcea County	1.58%
(CL) Calarasi County	0.19%	(MM) Maramures County	1.04%	(VS) Vaslui County	0.23%
(CS) Caras Severin County	0.39%	(MH) Mehedinti County	0.18%	(VN) Vrancea County	0.75%
(CJ) Cluj County	7.75%	(MS) Mures County	12.57%		

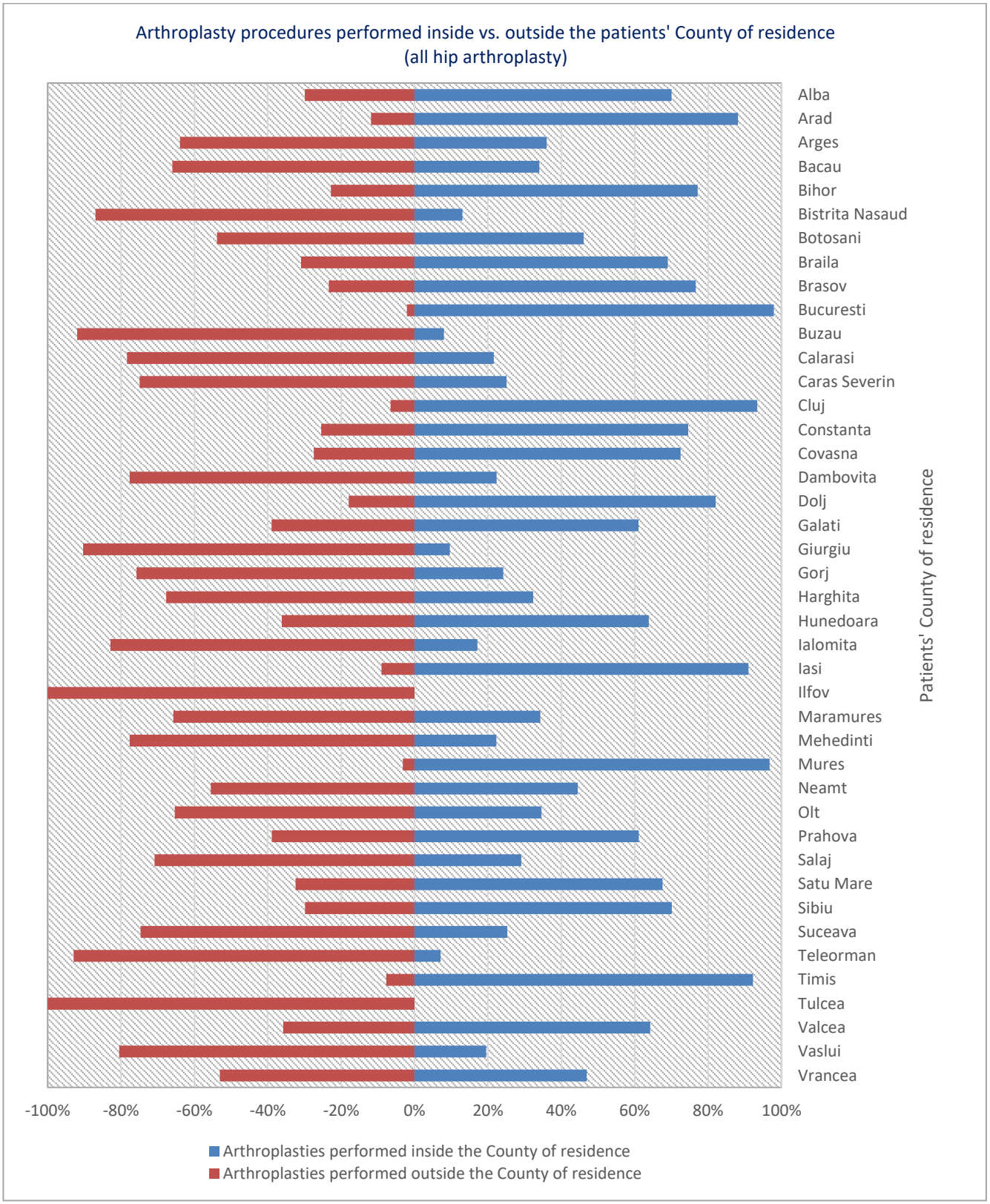


Figure 14 – Proportion of arthroplasties performed inside vs. outside the patients' County of residence, 2001- 2015

To better understand the patients' migration phenomenon, a breakdown by the percentage of arthroplasty procedures performed inside and outside the patients' County of residence was needed.

While only between 2% to 9% of the patients from Bucharest, Mures, Cluj, Timis and Iasi opted for procedures outside their own County of residence, between 90% an 100% of the patients from Giurgiu, Buzau, Teleorman, Tulcea and Ilfov opted for procedures outside their County of residence.

Further analysis on social and demographic disparities is needed to understand why more than 50% of the patients from 23 counties opted for arthroplasty procedures outside their County of residence.

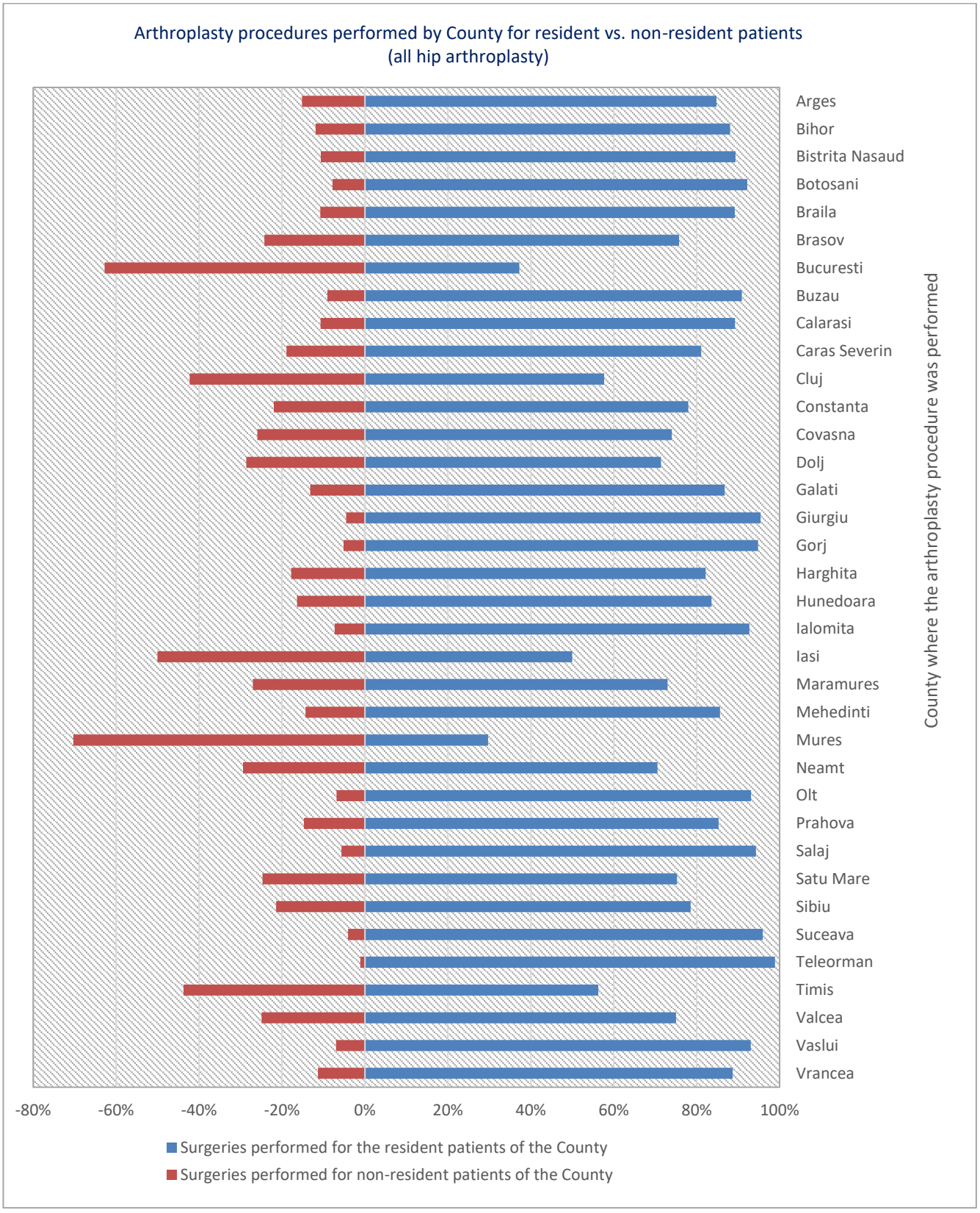


Figure 15 – County of performed arthroplasty procedure – proportion of resident vs. non-resident patients, 2001- 2015

The patients' preference for arthroplasty surgeries performed outside the County of residence is observed by analyzing the number of procedures performed by each County, divided by resident and non-resident patients.

Mures and Bucharest performed 70% and 63% respectively of the arthroplasty procedures for non-resident patients. Other Counties with a high percentage of non-resident arthroplasty patients are: Iasi (50%), Timis (44%), Cluj (42%), Neamt (29%), Dolj (29%).

4.2 Surgeries vs. admissions (all surgeries)

Table 7 – Admissions versus surgeries (all surgeries), 2001 - 2015

	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
Admited patients	427,552	84,784	78,034	86,935	79,352	92,661	83,782	77,765	80,171	77,763	67,774	**1,236,573**
Surgeries (All incl.Trauma)	255,309	55,264	53,305	59,596	54,085	62,560	60,216	58,322	60,434	57,568	54,531	**831,190**
Admissions vs. surgeries	59.7%	65.2%	68.3%	68.6%	68.2%	67.5%	71.9%	75.0%	75.4%	74.0%	80.5%	**67.2%**

While the ratio of the total performed orthopaedic procedures from the total number of admitted patients was approximately 59.7% between 2001-2005, Table 7 presents an overall increase with an average annual growth rate of 1.7% between 2006-2015. Therefore, from 65.2% in 2006 the percentage of surgeries performed from the total number of admitted patients reached 80.5% in 2015.

4.3 Fractures treated through surgery

Table 8 – Fractures treated through surgery (including arthroplasty), 2001 - 2015

	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
Upper limb fractures	30,742	7,673	8,692	7,951	7,447	8,683	9,113	8,798	8,245	6,782	6,432	**110,558**
Lower limb fractures	91,339	21,831	20,620	19,110	19,016	21,335	22,364	20,951	18,634	16,555	17,881	**289,636**
Spine	528	181	219	336	237	258	136	136	204	218	185	**2,638**

Between 2001 to 2015, the number of upper and lower limb fractures treated through surgery has decreased by 29% and 20%, respectively.

The number of spinal surgeries treated in orthopaedic departments is relatively low, between 123 and 336 cases per year. The data is collected only from the orthopaedic departments registered with RAR, though this pathology is treated by neuro-surgeons as well.

4.4 Hip Arthroplasties

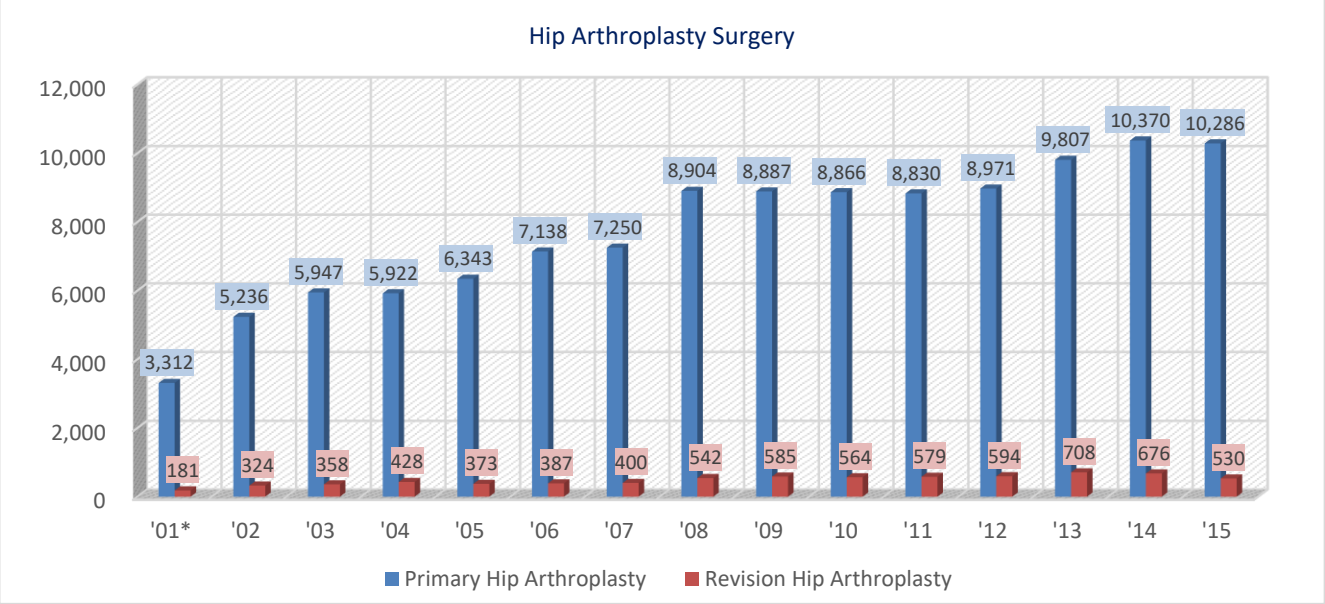


Figure 16 – Hip Arthroplasty Surgery, 2001 - 2015

**Data on hip arthroplasties has been collected in RAR starting with the second semester of 2001.*

Since 2002, the annual evolution presents an increasing trend both in primary and revision hip arthroplasty procedures. The highest annual growth rate for primary procedures was registered in 2008 with almost 23% more surgical procedures than the preceding year. Between 2009-2015 the annual evolution is constant up until 2013 when the number of primary hip arthroplasty registered an increase of almost 10% compared to previous years and again in 2014 with another 4%. Overall, from 2002 to 2015 the number of primary hip arthroplasty has almost doubled.

Consequently, the increase of primary hip arthroplasties has been followed by a similar increase in the number of revision procedures.

4.5 Hip replacement rate per 100.000 inhabitants. Romania, 2001-2015

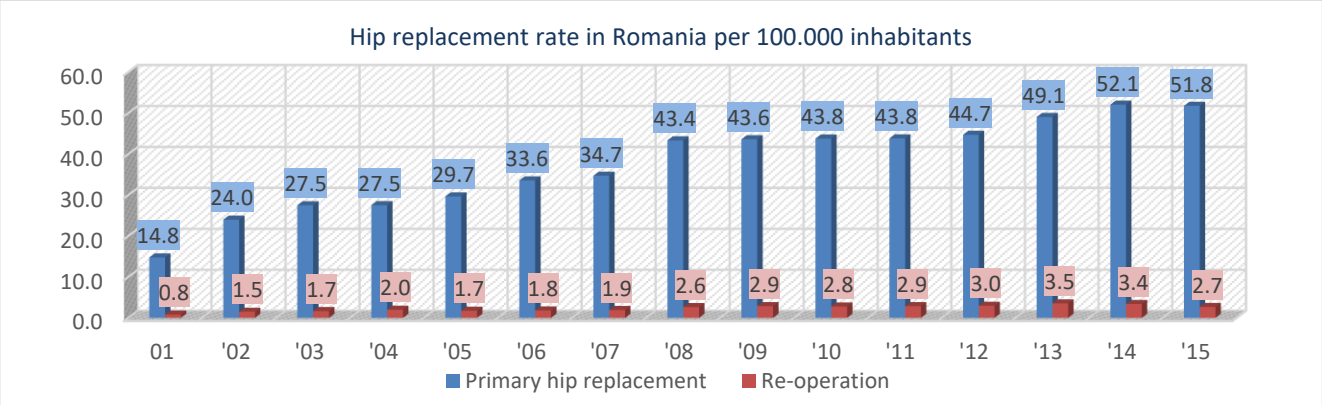


Figure 17 – Hip replacement rate per 100.000 inhabitants. Romania, 2001-2015

The annual rate of primary hip replacement in Romania has significantly increased in the last 15 years. The growing demand of hip replacement is contributing to a visible health expenditure growth that must be sustained mainly by the social insurance system (see Section 4.13). According to the analyzed data, 51.8 Romanian residents out of 100.000 suffered a primary hip replacement procedure, whereas 2.7 patients out of 100.000 suffered a re-operation in 2015.

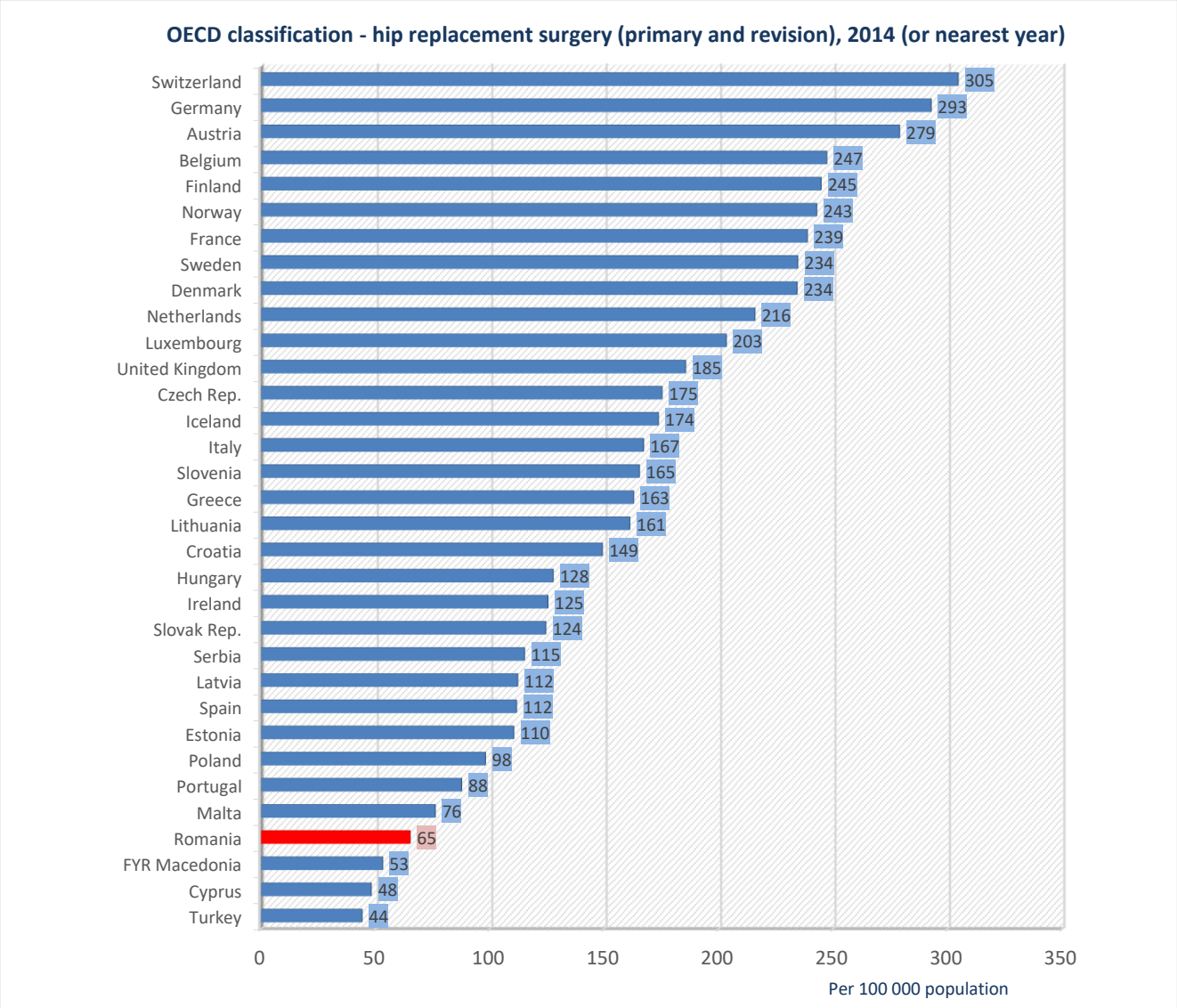


Figure 18 – Hip replacement surgery, 2015. Source:OECD Health Statistics 2016, http://dx.doi.org/10.1787/health-data-en

According to the Report[2] released by the World Organization for Cooperation and Regional Development (OECD) in 2016, as the previous Report in 2015 stated, for the year 2014 Switzerland still holds the top of the list with the highest hip replacement rate in Europe with approximately 305 interventions out of 100,000 resident population. The following positions are occupied by Germany (RE = 293), Austria (RE = 279), Belgium (RE = 247), Finland (RE = 245) and Norway (RE = 243).

Amongst the classification of OECD, Romania has approximately 65 hip replacement interventions out of 100.000 resident population. Even so, from the data reported to the RAR, in 2014 Romania has an overall replacement rate of 54 interventions out of 100.000 resident population, probably due to different demographic data sources (OECD uses EUROSTAT, while RAR uses NIS data and there is a known difference between the total number of inhabitants).

As reported by the same source, an upward trend can also be observed in the other states, the main identified factor that determines the yearly increasing number of hip interventions consists in population structure modifications by progressive aging.

4.6 Age distribution of hip arthroplasty patients by gender

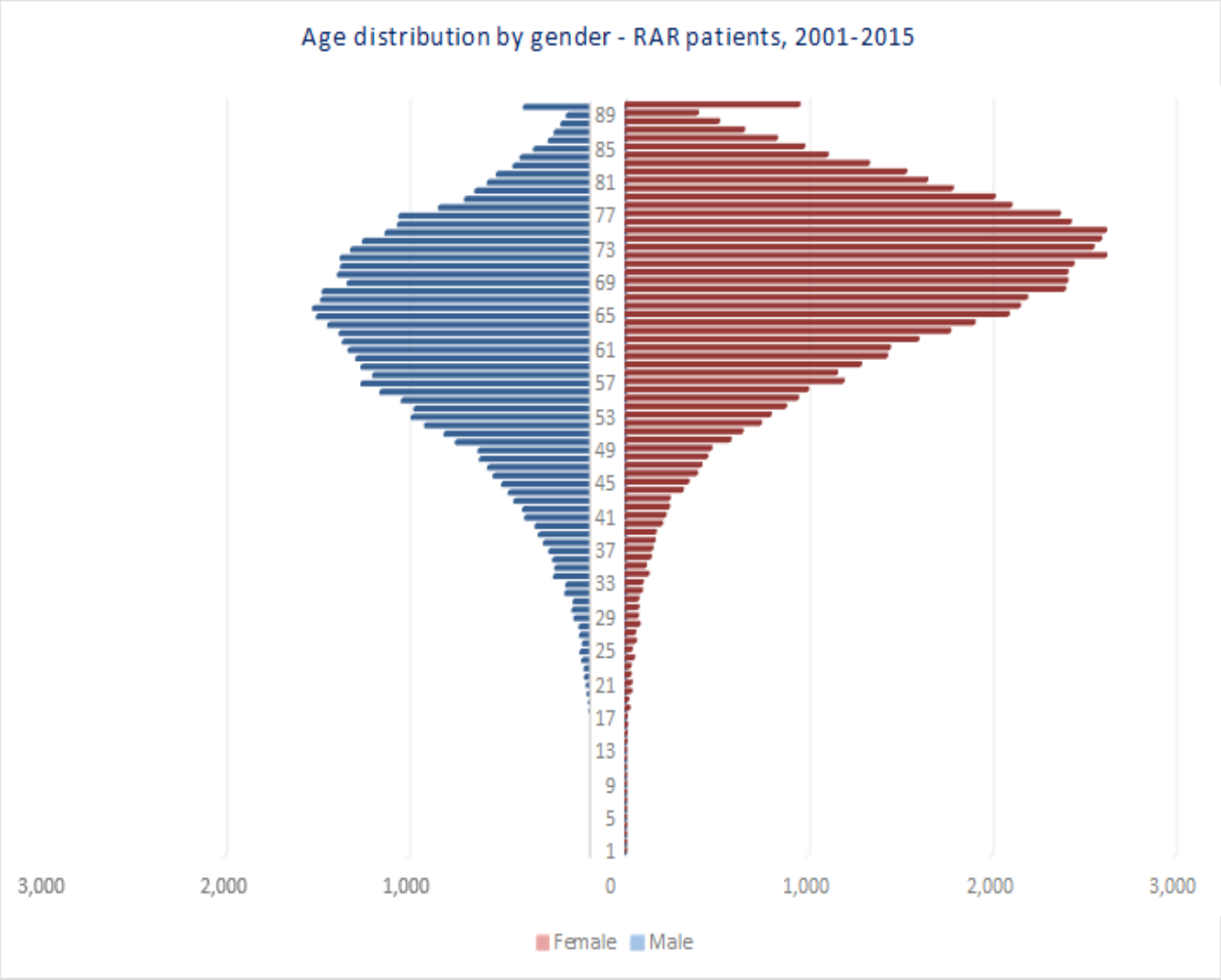


Figure 19 – Age distribution at time of primary hip replacement procedure by gender – R.A.R. patients, 2001-2015

Age distribution pyramid offers a clear preponderance of female patients and a majority of 99.3% of the patients aged 30 and over. The data supports the trend identified the OECD regarding the yearly increasing demand, that comes with a visible economic burden for all the countries with low or negative natality – mortality rate.

[2] OECD (2016), Health at a Glance: Europe 2016
State of Health in the EU Cycle, OECD Publishing, Paris.

4.7 Projections of primary hip arthroplasty in the next decade

Osteoarthritis represents the main diagnosis leading to hip replacement procedures in Romania. Also, taking in consideration the UN studies[3] indicating that the elderly population will exceed the threshold of 40% of the total population in 2050 – an alarming percentage which has increased yearly since the early 2000s – the empirical conclusion is that the annual number of hip replacements in Romania will keep the increasing trend in the following decades, due to the aging population.

To determine the effect of the aging Romanian population over the incidence of primary hip replacements, Poisson regression model was conducted to predict the values of the dependent variable (the dependency between the elderly population proportion and the number of primary hip replacements).

The rate was calculated based on the predictor outcome and projections between 2016 and 2025 regarding the Romanian population aged 30 and over (representing 99.2% from the total R.A.R. database) – with data provided by the EUROSTAT database.

The analysis of the Poisson predictor presented statistical significance, indicating that with every increase of one unit (10^5 population aged 30+), the number of patients with primary hip replacements will increase with 11.2%.

Based on the EUROSTAT annual population projections, and taking into account the Poisson predictor, the estimated annual number of hip replacements presents a continuously increasing trend. Starting with 10.527 patients with primary hip replacement in 2013, it is estimated that in 2025 the number of patients to have a primary hip replacement will be approximately 15.021, with 35% more than 2015.

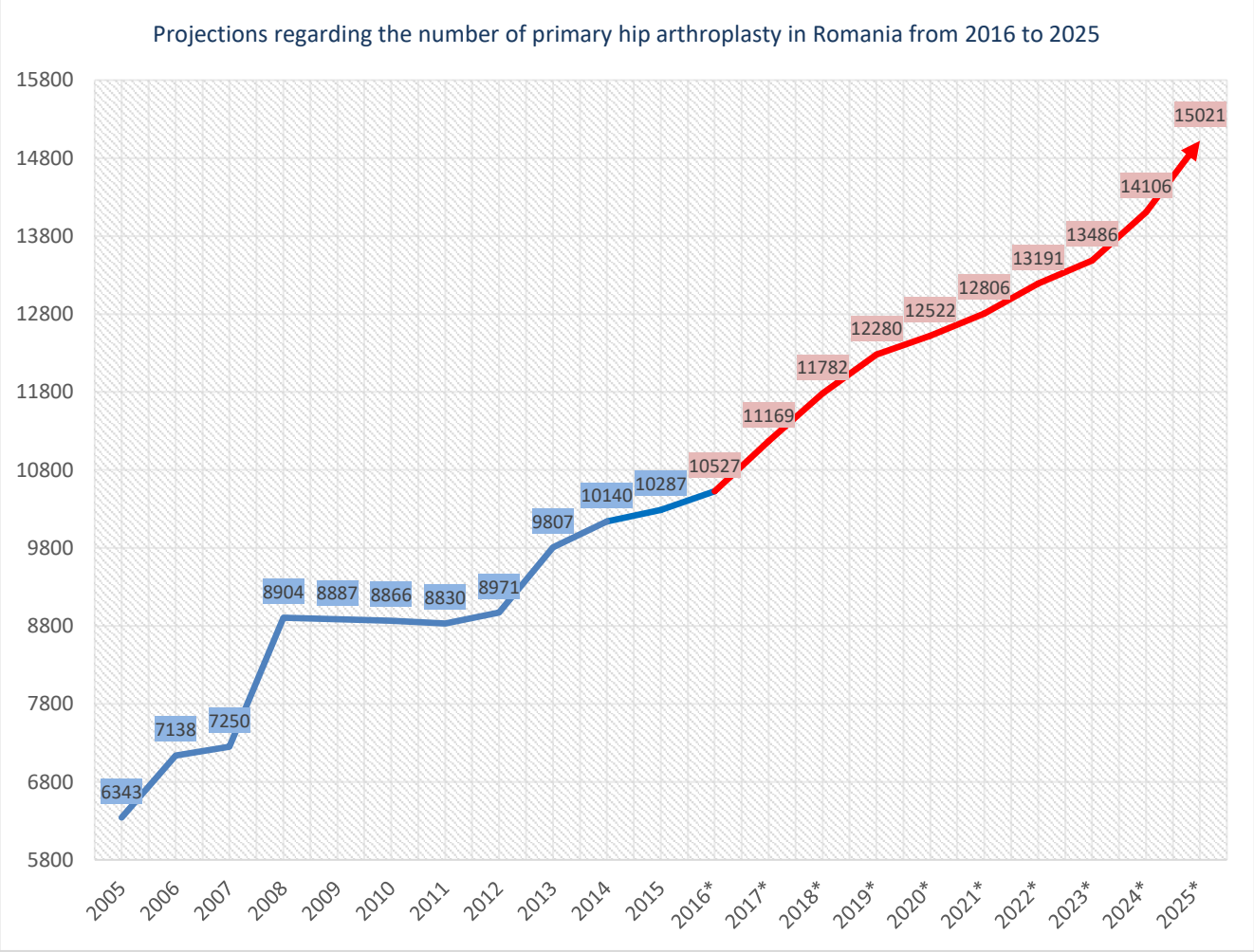


Figure 20 – Projections of primary hip arthroplasty in Romania 2016 – 2025, based on EUROSTAT estimated population aged 30+.
Source: EUROSTAT Database, Population projections, http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=proj_15npms&lang=en

[3] United Nations, Department of Economic and Social Affairs, Population Division (2015). World Population Prospects: The 2015 Revision, Key Findings and Advance

4.8 Evolution of financing sources for primary hip arthroplasties

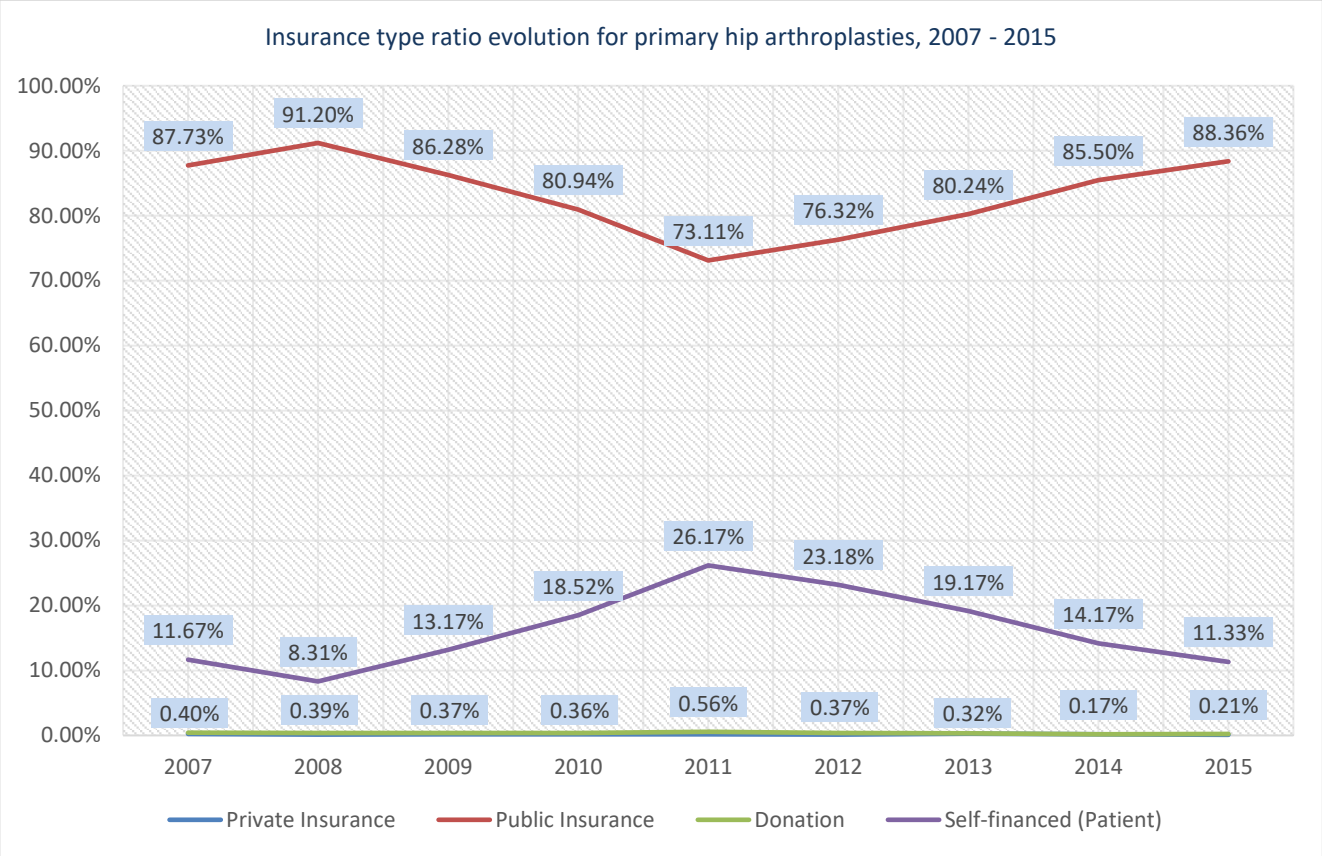


Figure 21 – Evolution of insurance type for primary hip arthroplasties, 2001 - 2015*

**Insurance type documentation in RAR forms was introduced in 2006-2007*

The National Program of Prevention in Orthopedics and Trauma of the National Health Insurance House (CNAS) is the main insurance financing for primary hip arthroplasty interventions, covering from an average of 83.3% of all interventions between 2007 - 2015, while the private insurance health system is extremely low (0.16% on average). This situation can be explained by the lack of legislation in public and private healthcare systems. The policy of CNAS in Romania implies the financing of the private hospital sector from social funds, being allowed as a part of the National Program for Prevention in Orthopaedics.

Table 9 – Evolution of insurance financing sources for primary hip arthroplasties, 2001 - 2015*

	'07*	'08	'09	'10	'11	'12	'13	'14	'15	Grand total
Private insurance	10	8	15	15	13	11	25	16	9	**124**
Public insurance	4382	7201	7082	6742	6010	6378	7380	8389	8483	**62536**
Donation	20	31	30	30	46	31	29	17	20	**256**
Self-paying patient	583	656	1081	1543	2151	1937	1763	1390	1088	**12283**
Other	2255	1008	679	536	610	614	610	558	686	**6972**
Grand total	**7250**	**8904**	**8887**	**8866**	**8830**	**8971**	**9807**	**10370**	**10286**	**82171**

** Insurance type documentation in RAR forms was introduced in 2006-2007*

The evolution of the financing sources for primary hip arthroplasties indicates a peak in 2011 and 2012 in patients' self-financing for the primary hip arthroplasties, because of the budget cuts that started in 2008. Influenced by the Global Recession that also affected the Romanian National Accounts, budget cuts were applied in all public sectors, including the healthcare sector.

4.9 Primary implant type distribution by hospital category

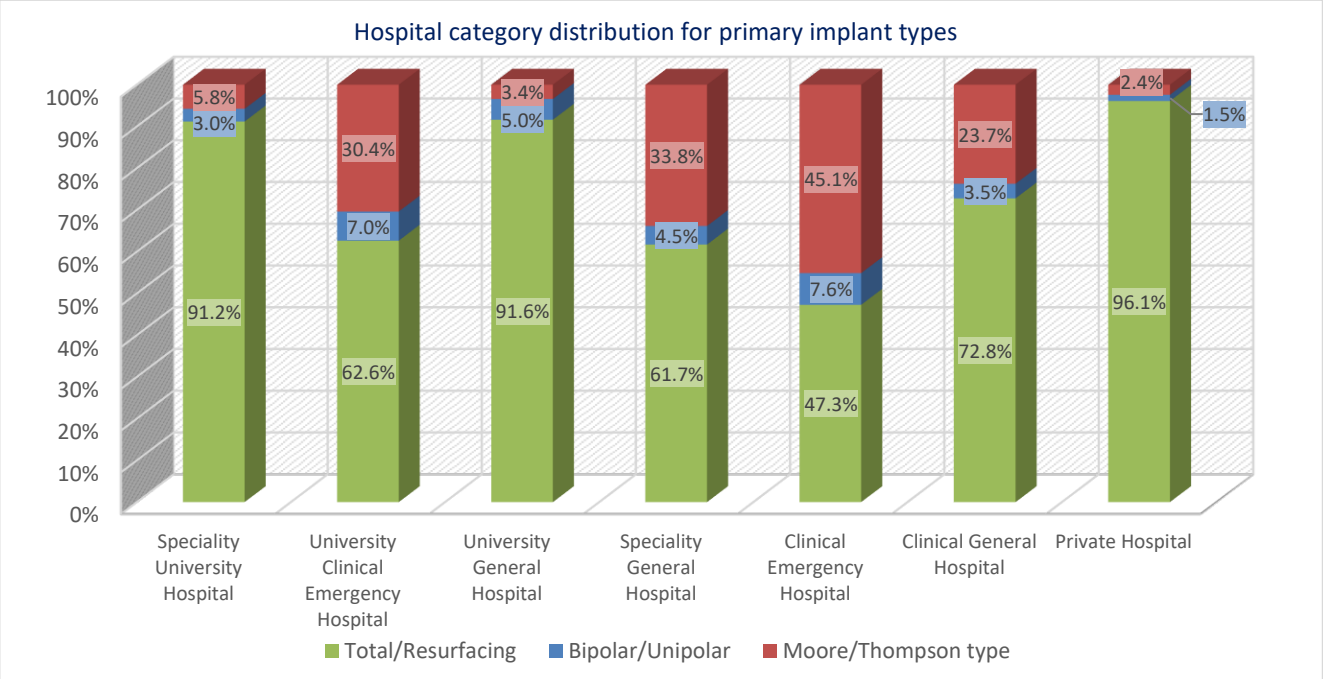


Figure 22 – Hospital category distribution for primary implants types, 2001-2015

Considering the implant type distribution by hospital category from 2001-2015, emergency clinical hospitals have increased usage of partial implants (Moore Type) as an impact of the numerous trauma events and low intervention costs. The usage of Bipolar/Unipolar implants is relatively low, as shown in the graph above.

4.10 Primary THR fixation type by hospital category

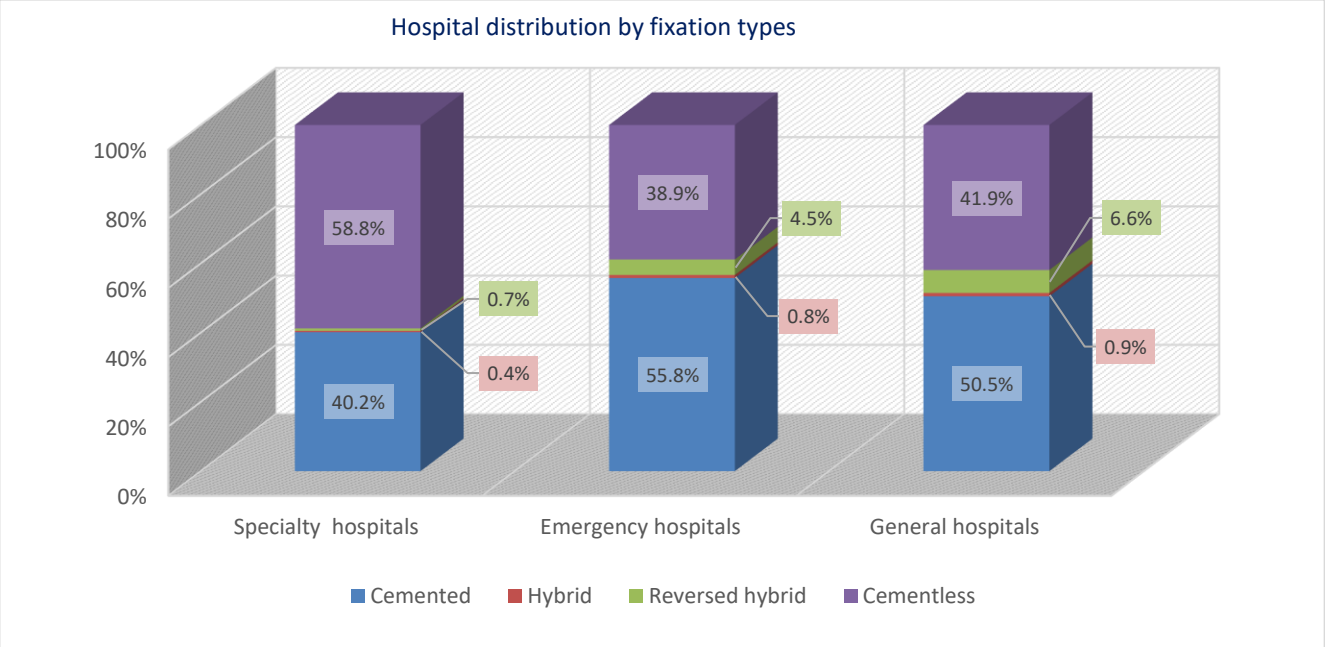


Figure 23 – Hospital distribution for fixation types, 2001-2015

Primary cemented implants have the highest usage (approximately half of the implants) in two of the hospital categories observed (emergency, general hospitals). Cementless implants are used more than cemented implants in specialized orthopaedic hospitals. The number of hybrid implants is relatively low with ratios from 0.4% to 6.6% depending on the hospital type.

4.11 Hospital category distribution by revision type

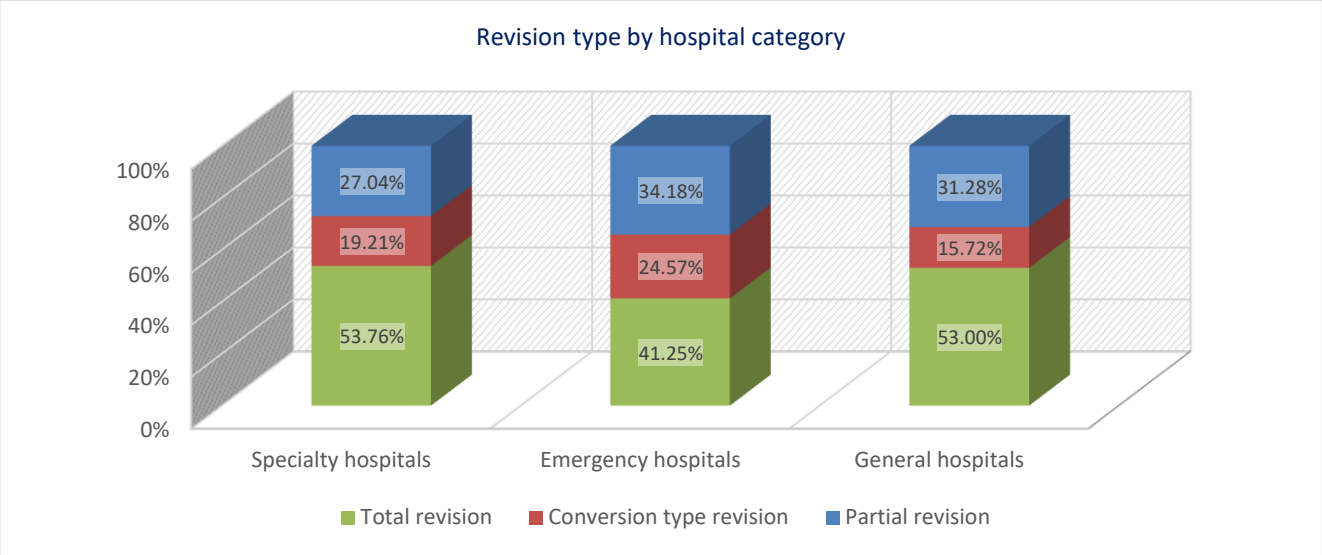


Figure 24 – Revision type by hospital category, 2001-2015

Regarding the revision type, emergency hospitals are shown to have the highest ratio of partial and conversion type revisions, similar to their ratio of hemi-arthroplasties, in between all the other types.

Revision type figures in 2015 indicate that the first choice in re-interventions are total revisions mainly used in specialty and general hospitals and the partial revision is mainly used in emergency (34.18%) and general (31.28%) hospitals. Please see chapter 6 Arthoplasty re-operations for revision type definitions.

4.12 PN 2.9 Budget Evolution

Table 10 – National Program PN 2.9 – Budget Evolution, 2005 - 2015

Year	'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15
Budget for the National Orthopedic Program (EUR)	5,047,510	5,903,507	9,216,409	10,842,067	8,330,824	7,284,424	7,698,721	7,698,253	10,139,139	10,655,719	13,094,038
Budget for the National Orthopedic Program (RON)	19,846,306	23,212,000	36,238,000	39,000,000	33,200,000	30,800,000	32,872,000	32,870,000	45,471,000	47,760,000	58,203,000
Budget evolution in % vs. previous year	15.53%	16.96%	56.12%	17.64%	-23.16%	-12.56%	5.69%	-0.01%	31.71%	5.09%	22.88%

**n/a – data on previous year budget not available*

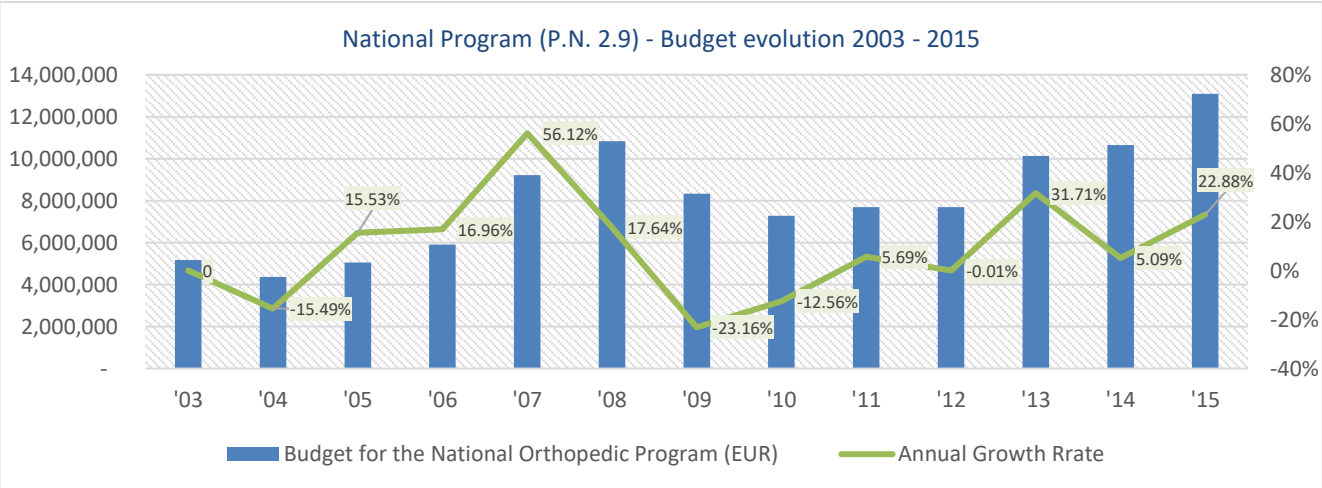
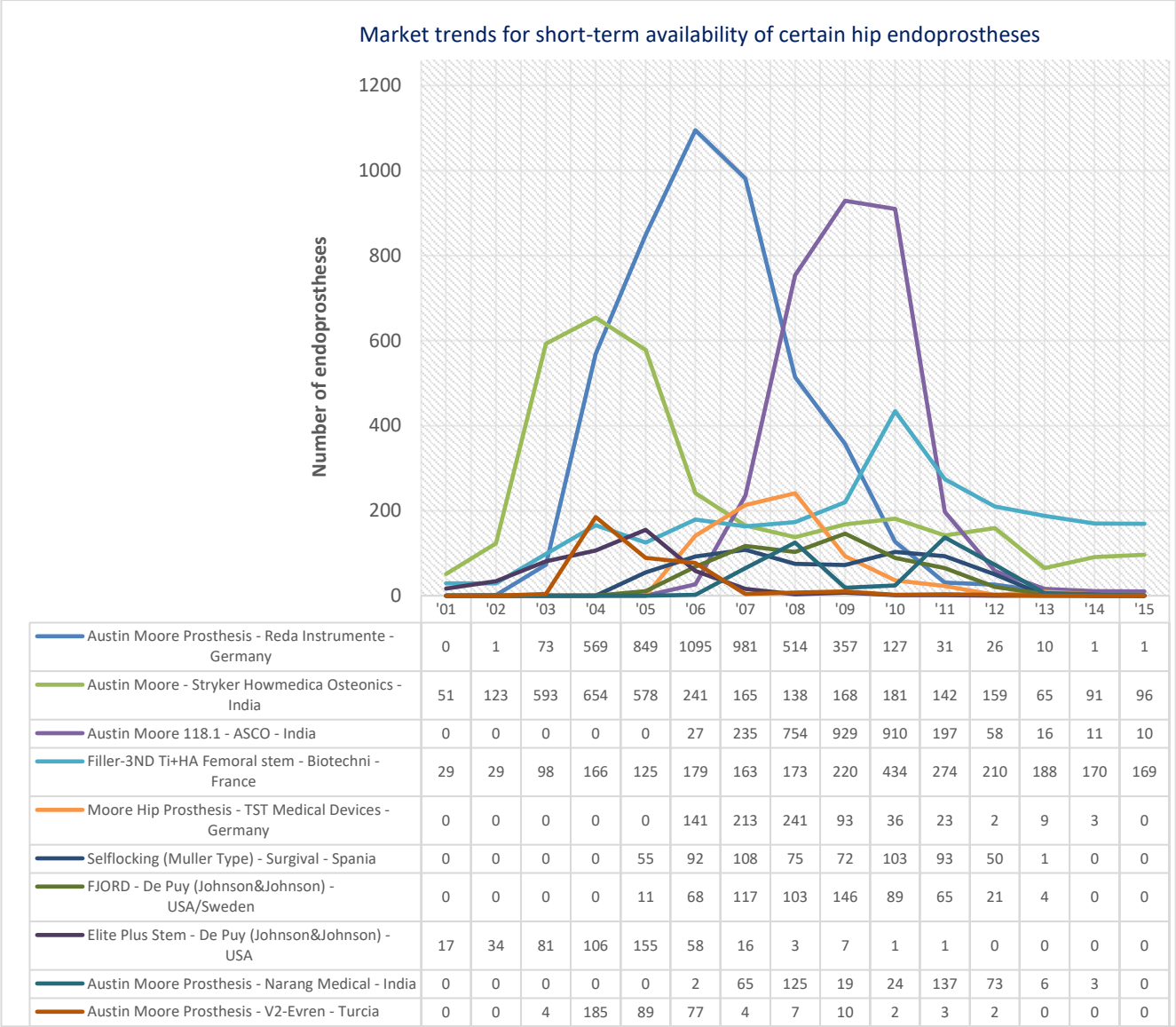


Figure 25 – National Program (P.N. 2.9) – Budget evolution between 2003 – 2015

4.13 Market trends for short-term availability of certain hip endoprostheses



	'01	'02	'03	'04	'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15
Austin Moore Prosthesis - Reda Instrumente - Germany	0	1	73	569	849	1095	981	514	357	127	31	26	10	1	1
Austin Moore - Stryker Howmedica Osteonics - India	51	123	593	654	578	241	165	138	168	181	142	159	65	91	96
Austin Moore 118.1 - ASCO - India	0	0	0	0	0	27	235	754	929	910	197	58	16	11	10
Filler-3ND Ti+HA Femoral stem - Biotechni - France	29	29	98	166	125	179	163	173	220	434	274	210	188	170	169
Moore Hip Prosthesis - TST Medical Devices - Germany	0	0	0	0	0	141	213	241	93	36	23	2	9	3	0
Selflocking (Muller Type) - Surgival - Spania	0	0	0	0	55	92	108	75	72	103	93	50	1	0	0
FJORD - De Puy (Johnson&Johnson) - USA/Sweden	0	0	0	0	11	68	117	103	146	89	65	21	4	0	0
Elite Plus Stem - De Puy (Johnson&Johnson) - USA	17	34	81	106	155	58	16	3	7	1	1	0	0	0	0
Austin Moore Prosthesis - Narang Medical - India	0	0	0	0	0	2	65	125	19	24	137	73	6	3	0
Austin Moore Prosthesis - V2-Evren - Turcia	0	0	4	185	89	77	4	7	10	2	3	2	0	0	0

Figure 26 – Market trends for short-term availability of certain implants, 2001 - 2015

When analyzing the above volatile evolution of certain endoprosthesis availability on the market regardless of the manufacturer, certain series with limited market availability of only 2-5 years. One of the concerning factors that lead to this phenomenon is the “smallest price” criteria used in legal acquisition tenders. As a result, the local dealers cannot support the long term product availability in regard to the medical sustainability needs.

5 Primary Hip Arthroplasty

In 2011, the distribution graph for primary hip arthroplasty indicates a very high rate of Moore/Thompson type endoprostheses (29.4%), with a average annual growth of 6.8% from 2002 to 2011. Between 2001 and 2015, the share of total hip replacement from all primary hip arthroplasties had a constant evolution, meanwhile hemi-arthroplasties have a share of more than one third, decreasing from 37% in 2011 to 32.2% in 2015.

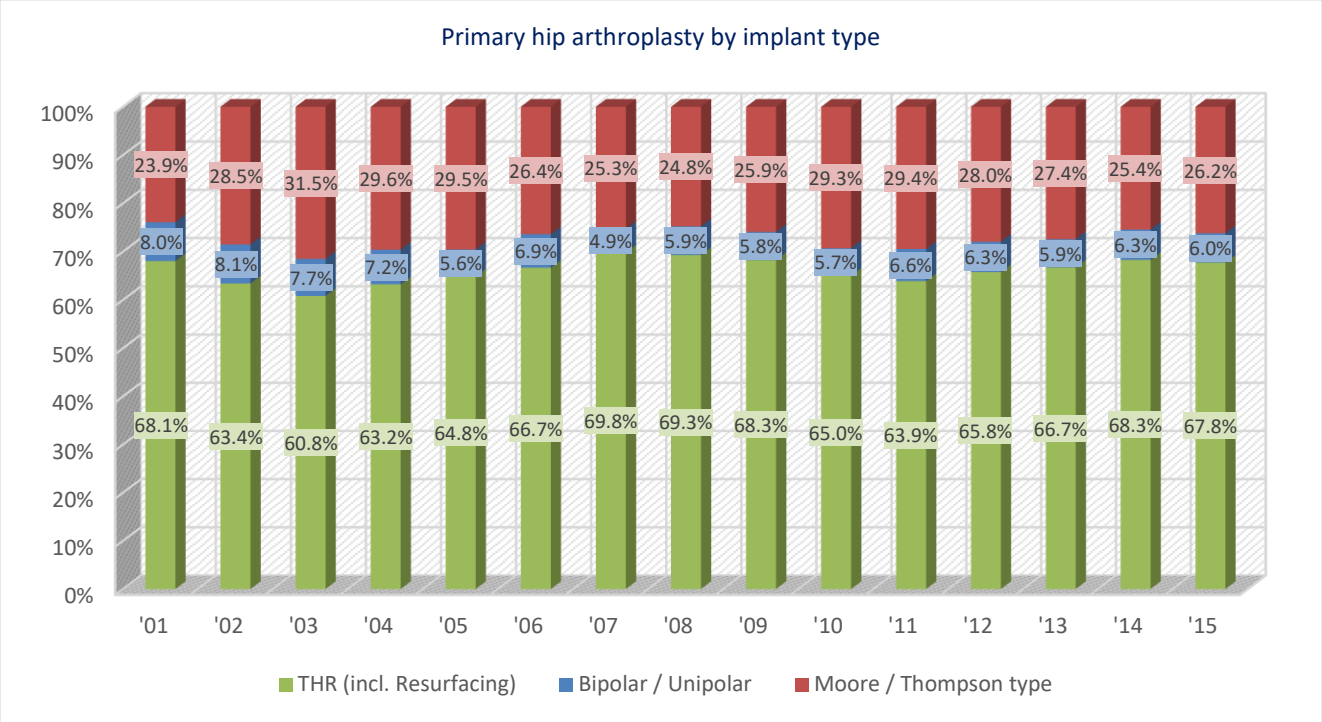


Figure 27 – Primary hip arthroplasty by implant type, 2001-2015

The high percentage of hemiarthoplasty is mainly impacted by the budget instability of the National Program for Prevention in Orthopaedics and Trauma Surgery, pushing down to the acceptable limits and lowering the quality when it comes to hip implant selection. Still, most hemiarthoplasties are implanted in the case of elderly patients (*See section 5.2.1.1 and 5.2.2.4*), patients which are predisposed to femoral neck fractures in osteoporotic bone. From 2011, the number of hemiarthroplasties is in a constant decrease.

Table 11 – Primary Hip Arthroplasty by implant type

	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Grand Total
Total Hip Arthroplasty	**17,047**	**4,759**	**5,061**	**6,171**	**6,067**	**5,763**	**5,643**	**5,900**	**6,544**	**7,082**	**6,969**	**77,006**
THR	16,944	4,736	4,990	6,092	6,020	5,708	5,607	5,885	6,537	7,078	6,968	76,565
Resurfacing	103	23	71	79	47	55	36	15	7	4	1	441
Hip Hemiarthroplasty	**9,713**	**2,379**	**2,189**	**2,733**	**2,820**	**3,103**	**3,187**	**3,071**	**3,263**	**3,288**	**3,317**	**39,063**
Bipolar	1,878	493	353	528	516	506	587	563	574	652	622	7,272
Moore/Thompson type	7,783	1,883	1,836	2,205	2,304	2,597	2,600	2,508	2,689	2,636	2,695	31,736
Unipolar modular	52	3	0	0	0	0	0	0	0	0	0	55
Grand Total	**26,760**	**7,138**	**7,250**	**8,904**	**8,887**	**8,866**	**8,830**	**8,971**	**9,807**	**10,370**	**10,286**	**116,069**

5.1 Primary Total Hip Arthroplasty

5.1.1 Total Hip Replacement (THR) (excluding Resurfacing)

Within the first 15 years of existence (2001-2015), the Romanian Arthroplasty Register recorded a total number of 76,565 total hip replacements (excluding Resurfacing).
The overall annual growth rate of all primary hip arthroplasties was positive and constant, even if the National Program budget was affected by the economic crisis starting with 2008. The evolution was constant because the number of THR decreased, meanwhile the hemiarthroplasties increased between 2008 – 2013. From 2013, THR slowly began to increase reaching 67.8% of all primary hip arthroplasties in 2015.

Table 12 – Distribution of Primary Total Hip Replacement by fixation type and years

THR (excl. Resurfacing)	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
Cemented	11,834	2,914	2,778	3,177	3,089	2,754	2,653	2,809	2,790	2,883	2,579	40,260
Hybrid	267	53	50	49	58	27	23	26	28	20	26	627
Reversed hybrid	112	58	63	60	83	273	517	478	633	612	718	3,607
Cementless	4,731	1,711	2,099	2,806	2,790	2,654	2,414	2,572	3,086	3,563	3,645	32,071
Total	**16,944**	**4,736**	**4,990**	**6,092**	**6,020**	**5,708**	**5,607**	**5,885**	**6,537**	**7,078**	**6,968**	**76,565**

5.1.1.1 THR (excluding Resurfacing) interventions by age and gender

5.1.1.1.1 Mean age at time of primary intervention by gender

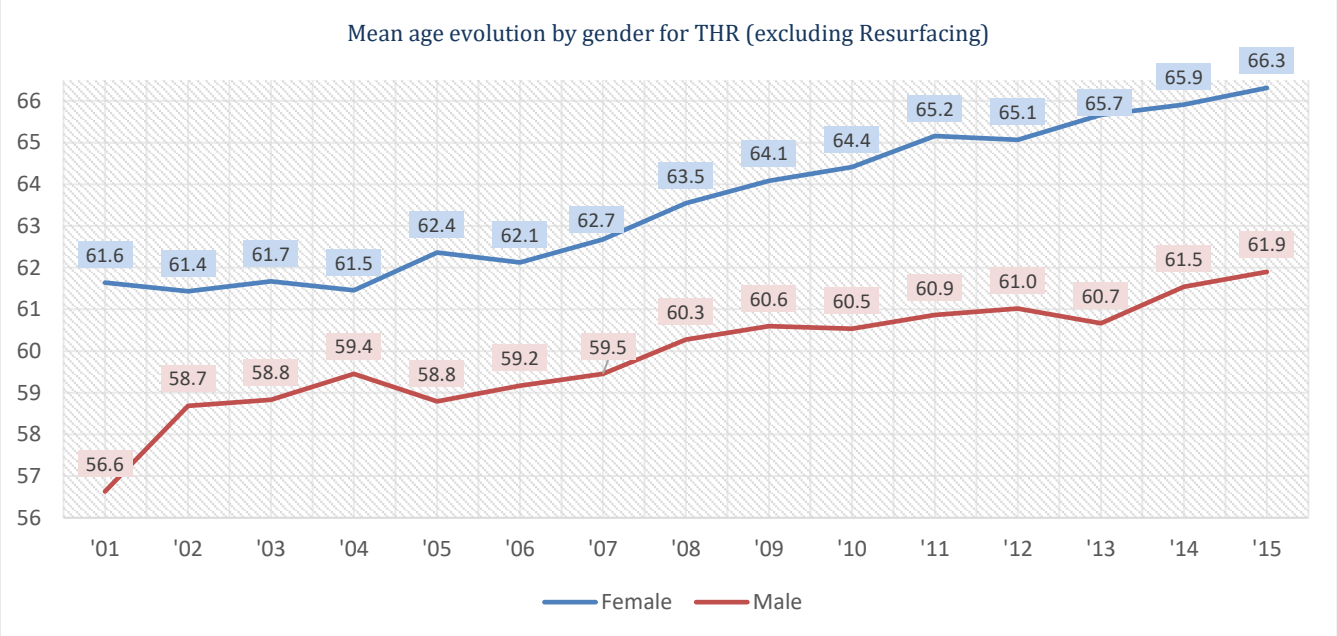


Figure 28 – Mean age at time of primary intervention for THR due to all diagnoses, 2001-2015

The evolution of the patients' mean age at time of primary intervention indicates a general increase in both male and female patients. Starting in 2001 with a mean age of 56.6 years old for male patients and 61.6 for female patients, the increase in the last decade was of approximately 5 years for both genders.

5.1.1.1.2 *Primary THRs (excluding Resurfacing) by age groups and gender*

Table 13 - Distribution of Primary Total Hip Replacement by gender and age groups, 2001 - 2015

Gender / age group	0-39	40-49	50-59	60-69	70-79	>80	n/a*	Grand Total
Male	2,088	4,114	8,895	11,464	7,328	883	22	34,794
Female	1,503	2,958	7,781	15,024	12,653	1,820	31	41,770
Grand Total	3,591	7,072	16,676	26,488	19,981	2,703	53	76,564

**age group not available*

The analysis of primary THRs broken down by age groups and gender indicates that most of the THRs were performed on patients between 60 and 69 years old. For 50-59 and younger age groups THRs are predominantly performed on male patients, meanwhile over 59 years old, female patients are more likely to have THRs. In absolute numbers, female patients are subject to more THR interventions than men aged over 59 years old, the figures indicating 29,497 female patients and 19,675 male patients. (Women also have a higher life expectancy than men, with approximately 7 years – *chapter 1.4 Life expectancy by gender*).

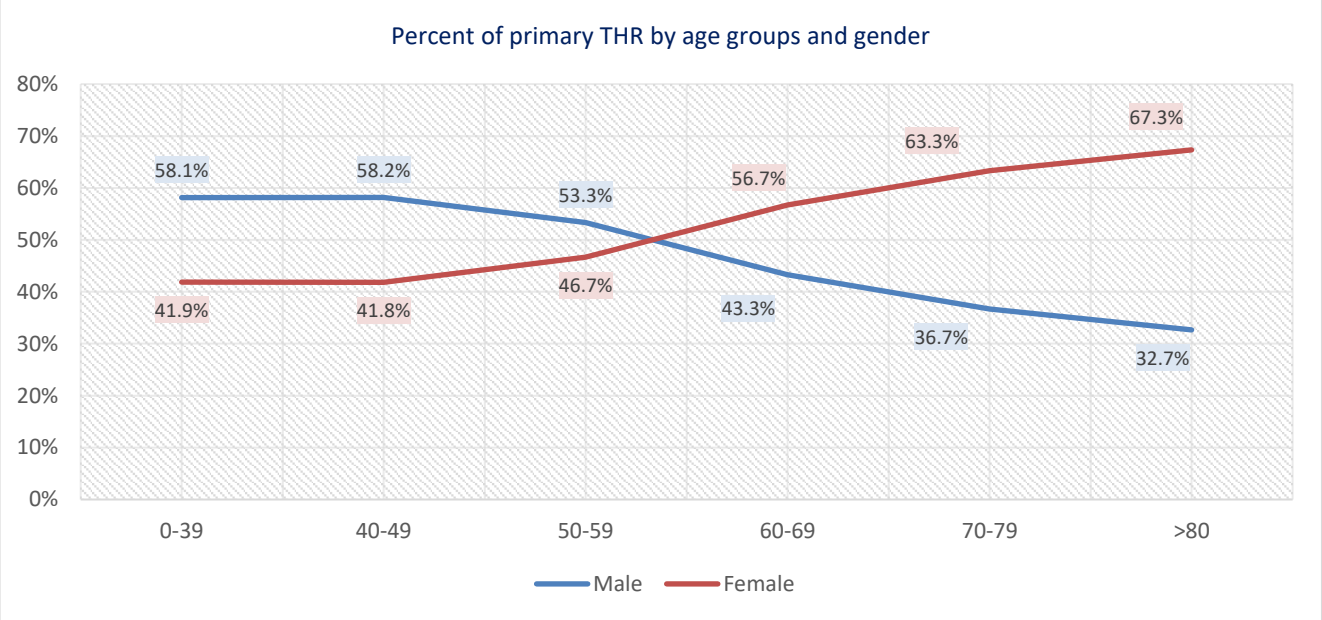


Figure 29 – Percent of primary THR by age groups and gender, 2001-2015

5.1.1.2 Diagnoses in THR (excluding Resurfacing)

5.1.1.2.1 THR diagnosis type incidence by gender

The most common THR pre-operative diagnosis from all reported diagnosis between 2001-2015 was primary osteoarthritis with over 57.8% for male patients, and 61.8% in female patients. Meanwhile, secondary osteoarthritis, which is the second most common reason for THR procedures, has a higher incidence within the male patients with almost 7.3% than in female patients. The remaining percentage is divided by femoral neck fractures and other illnesses.

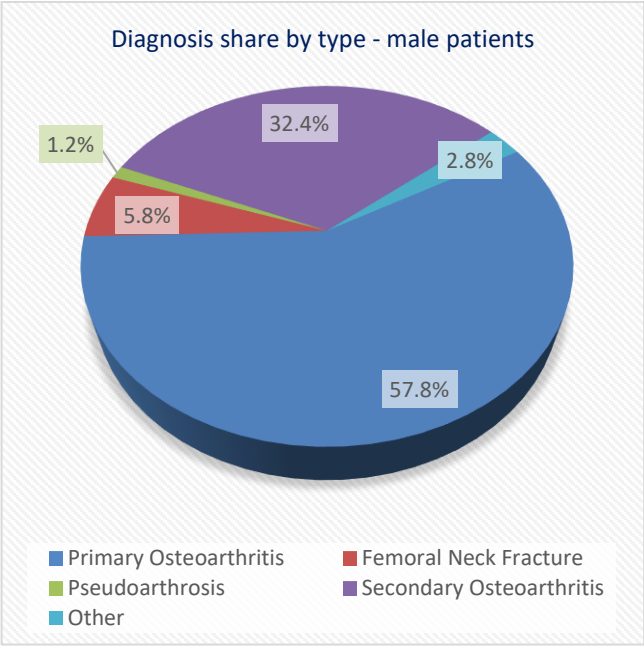


Figure 30 - Diagnosis share by type - male patients, 2001-2015

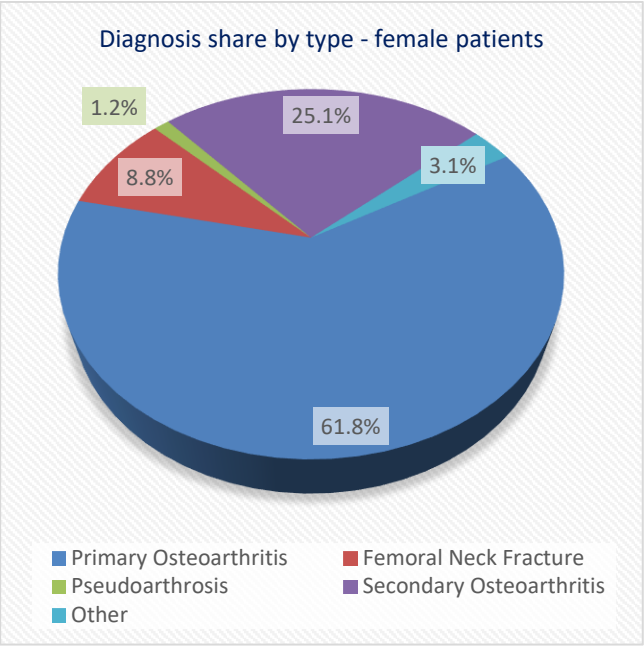


Figure 31 - Diagnosis share by type - female patients, 2001-2015

5.1.1.2.2 Primary, secondary osteoarthritis and femoral neck fracture

The number of total hip replacement procedures performed due to any diagnosis increased with 25% from 2011 to 2015. THR procedures performed due to primary osteoarthritis shows an increasing trend up until 2011 when the lowest plateau within the last 4 years of analysis was reached. The number of endoprostheses implanted due to secondary osteoarthritis increased with 4% from 2011 to 2015.

Table 14 – Diagnosis occurrence frequency in primary THR, 2001 - 2015

Diagnosis	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Grand Total
Primary Osteoarthritis	9,847	2,987	3,026	3,689	3,734	3,717	3,401	3,555	3,882	4,275	4,367	**46,480**
Femoral Neck Fracture	396	255	315	449	493	440	500	592	707	775	861	**5,783**
Pseudoarthrosis	125	6	75	123	96	86	85	65	81	89	82	**913**
Secondary Osteoarthritis	5,925	1,331	1,504	1,738	1,625	1,419	1,545	1,621	1,836	1,875	1,608	**22,027**
Dysplasia	1,893	458	497	502	454	405	378	431	428	422	383	**6,251**
R.P. or A.A.	383	61	58	66	67	42	44	37	47	69	54	**928**
Posttraumatic	1,379	203	149	177	152	104	91	137	126	124	97	**2,739**
Post-Perthes	77	15	20	11	21	12	17	12	13	18	8	**224**
Aseptic necrosis (Fem. Head)	2,190	583	645	797	747	647	683	745	908	837	734	**9,516**
Other	739	231	145	167	159	98	145	123	102	184	182	**2,275**
Grand Total	**17,032**	**4,810**	**5,065**	**6,166**	**6,107**	**5,760**	**5,676**	**5,956**	**6,608**	**7,198**	**7,100**	**77,478**

Femoral neck fractures treated throught THR have increased from 8% in 2002 to 21% in 2015. At the same time, the use of Moore type endoprosthesis in the treatment of femoral neck fractures has varied slightly from 77% in 2002 to 64% in 2015.

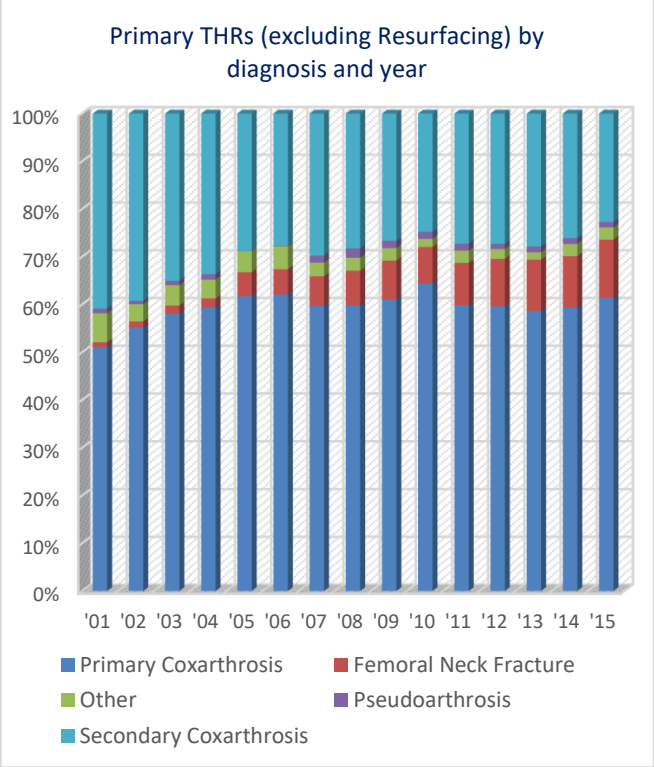


Figure 32 – Primary THRs (excluding Resurfacing) by diagnosis frequency, 2001-2015

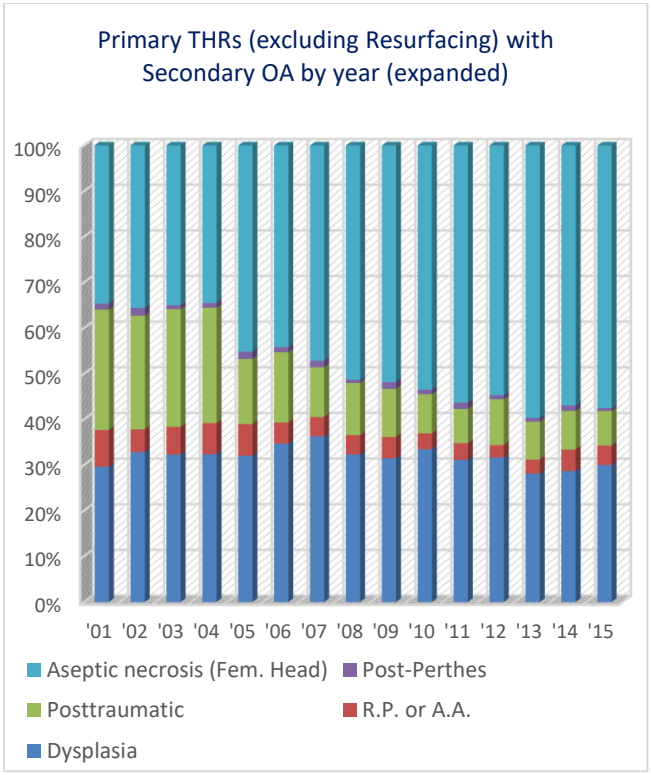


Figure 33 – Primary THRs (excluding Resurfacing) with Secondary OA Diagnosis frequency by type, 2001-2015

The number of THRs performed for post-traumatic consequences registered an average yearly decrease of -1.7% between 2001-2015. Subsequently, total hip arthroplasties due to femoral neck fractures have reduced at least partially the incidence of post-traumatic delayed complications.

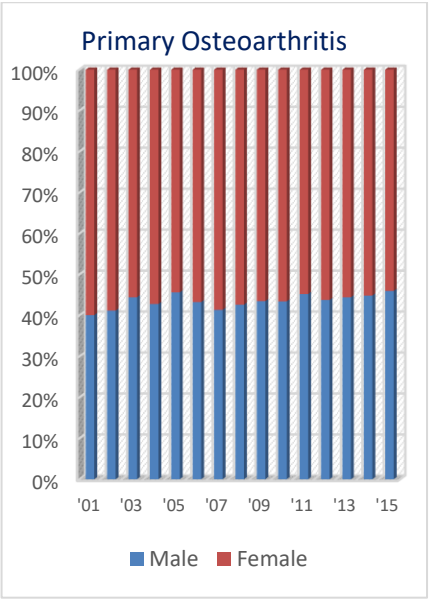


Figure 34 – Distribution of Primary Osteoarthritis by gender, 2001-2013

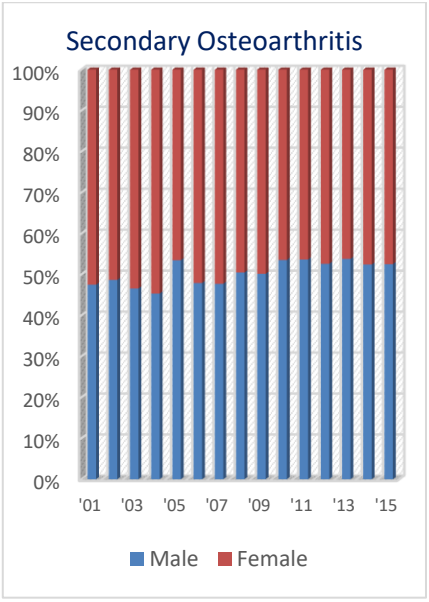


Figure 35 – Distribution of Secondary Osteoarthritis by gender, 2001-2013

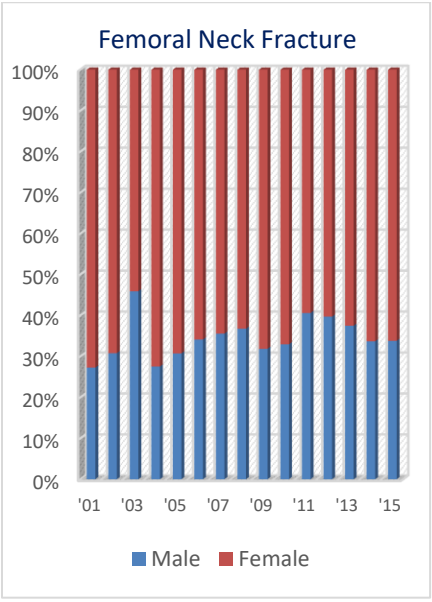


Figure 36 – Distribution of Femoral Neck Fracture by gender, 2001-2013

The observed number of total hip procedures performed due to primary OA and secondary OA had a relatively constant distribution in time between male and female patients, except for Femoral Neck Fracture diagnosis where the distribution indicates a predominant incidence within female patients.

5.1.1.2.3 *Mean age by diagnosis and gender for THRs (excluding Resurfacing)*

The mean age at time of primary intervention is higher for patients with OA (63.6 yrs. men and 65.9 yrs. women), femoral neck fracture (65 yrs. men and 69.7 yrs. women) and pseudarthrosis (60.9 yrs. men and 68.2 yrs. women). The mean age is much lower in all secondary OA diagnoses.

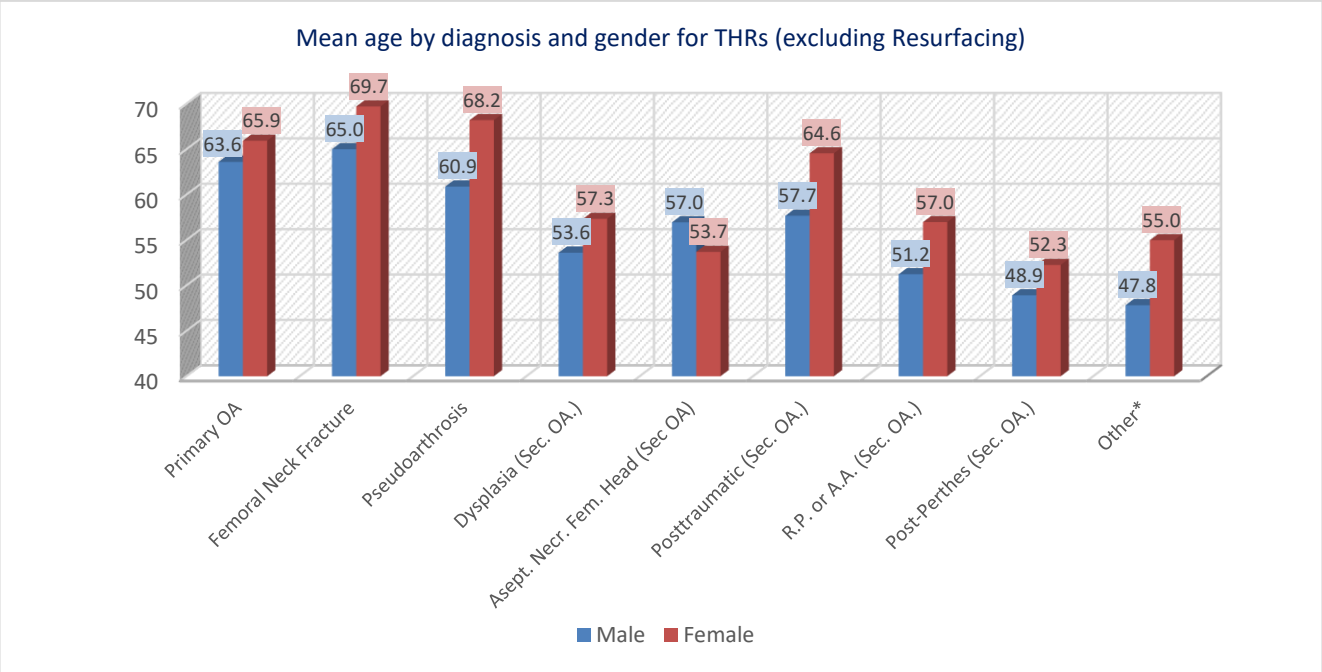


Figure 37 – Mean age by diagnosis and gender for THRs (excluding Resurfacing), 2001-2015

5.1.1.3 *THR (excluding Resurfacing) incidence by type of fixation*

5.1.1.3.1 *Number of primary THRs (excluding Resurfacing) by type of fixation and age groups*

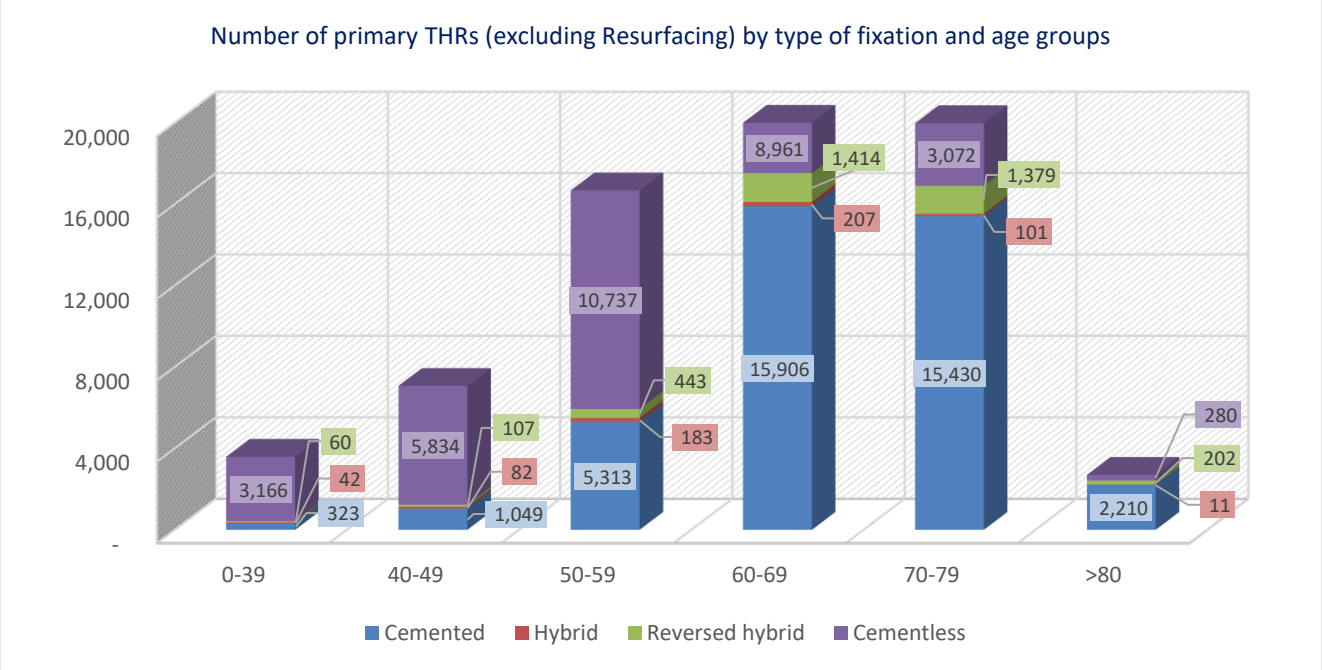


Figure 38 – Number of primary THRs (excluding Resurfacing) by type of fixation and age groups, 2001 – 2015

5.1.1.3.2 *Primary THRs (excluding Resurfacing) – type of fixation evolution*

Table 15 – Distribution of Primary THR by type of fixation, 2002 - 2015

Years	02-'05*	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Grand total
Cemented	11,834	2,914	2,778	3,177	3,089	2,754	2,653	2,809	2,790	2,883	2,579	**40,260**
Hybrid	267	53	50	49	58	27	23	26	28	20	26	**627**
Reversed hybrid	112	58	63	60	83	273	517	478	633	612	718	**3,607**
Cementless	4,731	1,711	2,099	2,806	2,790	2,654	2,414	2,572	3,086	3,563	3,645	**32,071**
Grand total	**16,944**	**4,736**	**4,990**	**6,092**	**6,020**	**5,708**	**5,607**	**5,885**	**6,537**	**7,078**	**6,968**	**76,565**

**'01-'03 - Fixation type field was introduced in RAR forms starting with 2002*

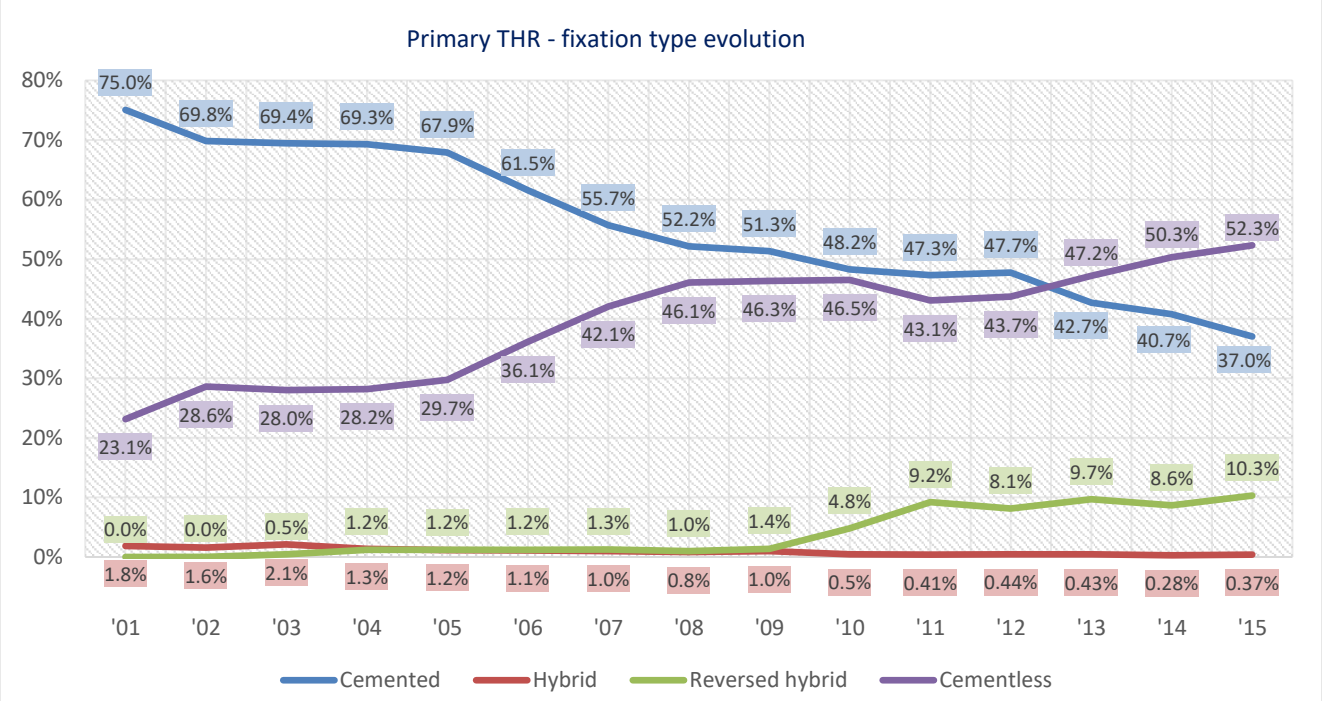


Figure 39 - Evolution of fixation type for primary THR (excluding Resurfacing), 2001 – 2015

A continuous increase in terms of cementless fixation share in THR has been registered between 2001-2010, with a twofold share in 2010 (46.5%), comparative to 2001 (23.1%). After 2010, due to the economic factors impacted by the economic crisis context, the share of cementless THRs reached a plateau with a slight increase until 2015 (52.3%). Meanwhile, the general trend of cemented THRs share is descending (37% in 2015). As the graph shows, during 2012 cementless and cemented THR procedures being equally performed in terms of relative figures.

The incidence of procedures using hybrid fixation was reduced to a constant share of 0.4% of the total number of THR procedures performed during 2010-2015. A higher incidence of 10.3% in 2015 is met for reversed hybrid endoprostheses.

5.1.1.3.3 *Trend in type of fixation for male patients in primary THR (excluding Resurfacing)*

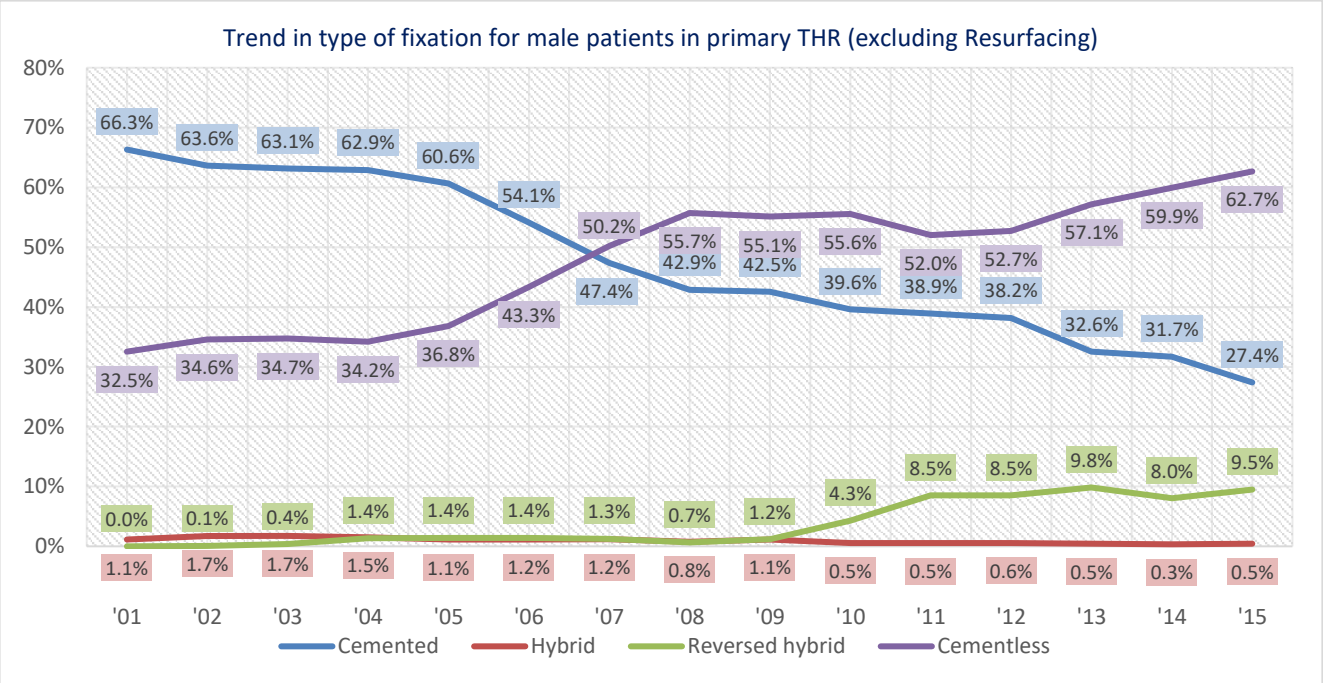


Figure 40 – Trend in type of fixation for male patients in primary THR, 2001 – 2015

5.1.1.3.4 *Trend in type of fixation for female patients in primary THR (excluding Resurfacing)*

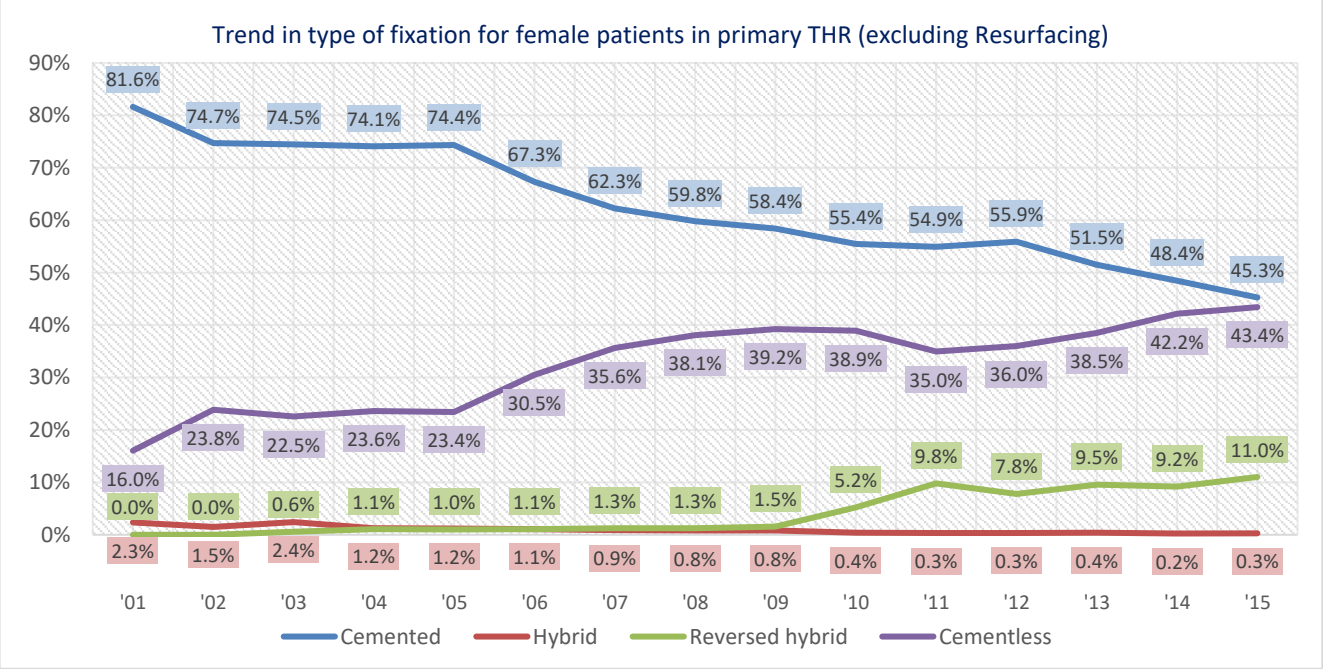


Figure 41 – Trend in type of fixation for female patients in primary THR, 2001 – 2015

The proportion of male and female patients with cementless endoprosthesis has constantly increased, at the same time cemented prosthesis proportion indicates a decreasing evolution. For both male and female patients, the reversed hybrid fixation type shows a sharp rise from 2009. In 2015, most predominant type of fixation for male patients is cementless (62.7%). Meanwhile, for female patients a lower cementless THR incidence is recorded in 2015 (43.4%).

5.1.1.3.5 *Mean age for each type of fixation in THR – yearly evolution*

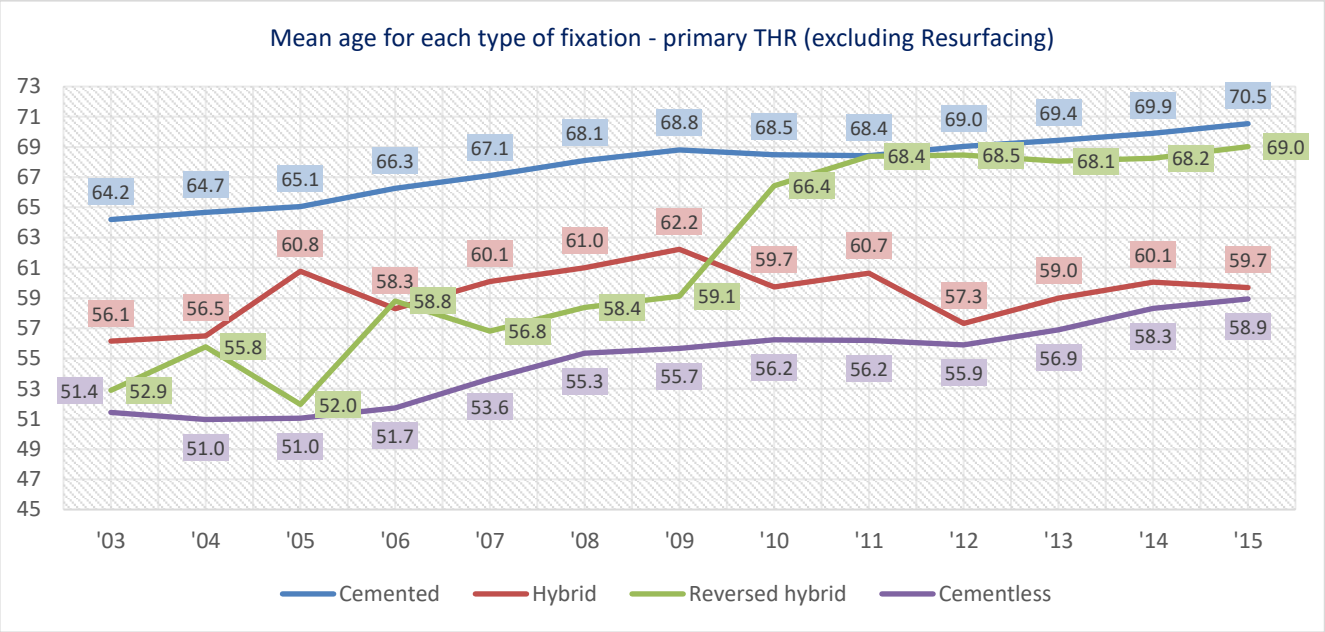


Figure 42 – Mean age for each type of fixation for primary THR, 2003-2015

**Fixation type field was introduced in RAR forms starting with 2002-2003.*

5.1.1.3.6 *Cementing techniques (2005-2015)*

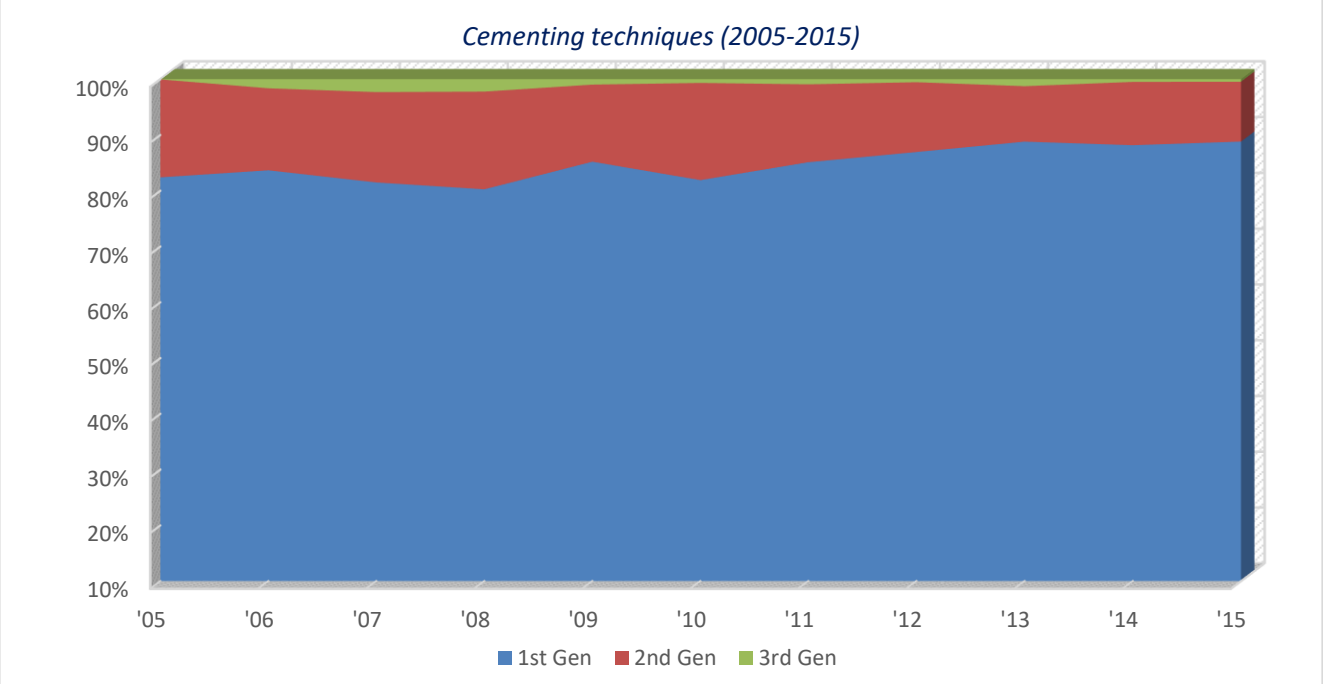


Figure 43 – Distribution of cementing techniques, 2005 – 2015

The cementing techniques used in Romania don't follow the same classifications as the ones described in the international literature. Most cementing techniques are from the first and second generation, only rarely using techniques from the 3rd generation. The pulsatile lavage, vacuum mixing, centrifugation, use of proximal and distal centralizers of the femoral shaft, use of adrenaline compresses or hydrogen peroxide for preparation of the receiving cavities or cement pressurization are seldom used.

5.1.1.3.7 Most frequent cement brands in acetabular and femoral component fixation

The most common cement brand is Surgical Simplex P used for both the acetabular and femoral components.

Table 16 – Most frequent cement types used in acetabular component fixation

Brand	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total	Percentages
Surgical Simplex P	2,041	1,237	1,299	1,357	1,375	1,063	981	978	1,100	1,074	923	**13,428**	**32.84%**
Palamed 40 (G 40)	105	2	1	1	0	258	521	573	658	754	789	**3,662**	**8.96%**
Aminofix 1	2	165	389	513	286	228	276	390	447	466	388	**3,550**	**8.68%**
Cemfix 1	741	302	280	224	332	198	86	82	19	24	42	**2,330**	**5.70%**
Fix 1	1	38	238	513	275	355	323	256	106	72	49	**2,226**	**5.44%**
Antibiotic Simplex	252	246	146	146	128	74	81	118	142	112	70	**1,515**	**3.71%**
Plus Bone Cement 40x2	1	4	29	99	127	150	136	145	118	156	110	**1,075**	**2.63%**
SmartSet MV Endurance	0	107	221	131	154	79	36	25	23	0	0	**776**	**1.90%**
SmartSet GMV	60	87	45	24	31	42	53	112	28	47	0	**529**	**1.29%**
Cemex ISO 40g	3	0	1	0	16	107	91	44	18	0	5	**285**	**0.70%**
Other	8,895	779	179	218	423	227	92	112	159	198	229	**11,511**	**28.15%**
Total	**12,101**	**2,967**	**2,828**	**3,226**	**3,147**	**2,781**	**2,676**	**2,835**	**2,818**	**2,903**	**2,605**	**40,887**	**100%**

Table 17 - Most frequent cement types used in in femoral component fixation

Brand	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total	Prop.
Surgical Simplex P	2,048	1,244	1,299	1,360	1,366	1,083	1,071	1,033	1,176	1,111	971	**13,762**	**31.37%**
Aminofix 1	2	159	376	493	287	227	269	387	436	461	378	**3,475**	**7.92%**
Cemfix 1	831	511	363	280	404	218	169	177	201	159	130	**3,443**	**7.85%**
Fix 1	1	40	231	502	276	356	323	252	100	69	49	**2,199**	**5.01%**
Palamed G 40	38	-	1	1	-	111	202	267	365	416	493	**1,894**	**4.32%**
Palamed 40	68	2	-	-	-	155	316	293	295	335	288	**1,752**	**3.99%**
Plus Bone Cement 40x2	1	3	29	97	127	151	135	146	117	156	95	**1,057**	**2.41%**
SmartSet MV Endurance	-	107	220	132	158	79	35	26	20	-	-	**777**	**1.77%**
Cemfix 3	166	44	75	104	71	94	61	39	-	1	3	**658**	**1.50%**
SmartSet GMV	61	88	46	24	31	42	50	117	29	47	1	**536**	**1.22%**
Other	8,730	774	201	244	452	511	539	550	684	740	889	**14,314**	**32.63%**
Total	**11,946**	**2,972**	**2,841**	**3,237**	**3,172**	**3,027**	**3,170**	**3,287**	**3,423**	**3,495**	**3,297**	**43,867**	**100%**

5.1.1.4 Endoprosthesis components – models and brands used in THR (excluding Resurfacing)

Table 18 - 15 most commonly used cemented acetabular and femoral component combinations

Cup - Model [Manufacturer]	Stem - Model [Manufacturer]	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
ZCA All-Poly Cup [Zimmer]	Metabloc Cemented Stem [Zimmer]	101	480	752	1,066	1,067	861	987	1,177	1,323	1,122	1,039	**9,975**
Polyethylene Acetabular Cup (Omnifit) [Stryker Howmedica Osteonics]	Omnifit Normalized Stem [Stryker Howmedica Osteonics]	2434	760	600	525	336	378	344	231	220	289	276	**6,393**
Muller-Type Acetabular Cup [Biomet]	Taperloc Femoral Stem (cemented) [Biomet]	773	274	200	283	230	347	443	393	401	545	240	**4,129**
Rim Acetabular Cup [Biotechni]	Filler-3ND Titanium Cemented Femoral Stem [Biotechni]	789	254	244	228	300	155	10	61	1	4	3	**2,049**
Exeter Acetabular Cup [Stryker Howmedica Osteonics]	Exeter Stem [Stryker Howmedica Osteonics]	1012	226	94	82	146	104	40	39	48	52	19	**1,862**
Coriolis Cup [Fournitures Hospitalieres]	Luer Stem [Fournitures Hospitalieres]	86	80	102	145	134	168	134	106	185	178	140	**1,458**
Coriolis Cup [Fournitures Hospitalieres]	Autobloquante [Fournitures Hospitalieres]	43	105	90	129	96	103	107	195	157	158	138	**1,321**
ZCA All-Poly Cup [Zimmer]	CPT Femoral Stem [Zimmer]	16	45	62	74	74	84	93	91	125	147	170	**981**
MK III Kerboull Cup [Stryker Howmedica Osteonics]	Legend V40 Stem [Stryker Howmedica Osteonics]	95	111	92	75	106	76	55	52	49	64	3	**778**
Coriolis Cup [Fournitures Hospitalieres]	Self Locking Femoral Stem [Permedica]	199	124	86	101	64	58	55	35	2	21	24	**769**
Polyethylene Acetabular Cup (Omnifit) [Stryker Howmedica Osteonics]	Legend V40 Stem [Stryker Howmedica Osteonics]	72	48	82	107	87	71	49	6	6	6	0	**534**
Muller Type Cup [Surgival]	Selflocking (Muller Type) [Surgival]	29	63	85	45	56	79	67	36	0	0	0	**460**
Elite Plus LPW Cup [De Puy (Johnson&Johnson)]	Elite Plus Stem [De Puy (Johnson&Johnson)]	301	23	7	2	2	1	0	0	0	0	0	**336**
Polyethylene Acetabular Cup (Omnifit) [Stryker Howmedica Osteonics]	Exeter Stem [Stryker Howmedica Osteonics]	0	1	1	1	2	20	44	35	34	58	138	**334**
Elite Plus LPW Cup [De Puy (Johnson&Johnson)]	FJORD [De Puy (Johnson&Johnson)]	3	37	48	40	72	48	24	1	0	0	0	**273**

Table 19 - 15 most commonly used cemented THR acetabular components

Cup	Manufacturer	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
ZCA All-Poly Cup	Zimmer	125	529	815	1153	1148	951	1084	1274	1452	1272	1211	**11014**
Polyethylene Acetabular Cup (Omnifit)	Stryker Howmedica Osteonics	2610	858	721	674	454	474	442	278	263	355	418	**7547**
Muller-Type Acetabular Cup	Biomet	792	287	210	285	233	351	443	394	401	545	241	**4182**
Coriolis Cup	Fournitures Hospitalieres	482	314	284	395	303	339	335	392	347	399	396	**3986**
Rim Acetabular Cup	Biotechni	838	259	254	233	303	158	20	78	2	6	17	**2168**
Exeter Acetabular Cup	Stryker Howmedica Osteonics	1048	228	97	101	221	126	40	45	49	52	20	**2027**
MK III Kerboull Cup	Stryker Howmedica Osteonics	187	156	127	87	111	76	56	52	50	64	10	**976**
Muller Type Cup	Surgival	56	76	118	103	108	107	69	38	3	3	16	**697**
Elite Plus LPW Cup	De Puy (Johnson&Johnson)	325	62	58	43	75	50	40	2	0	0	0	**655**
Elite Plus Ogee LPW Cup	De Puy (Johnson&Johnson)	207	106	53	32	53	35	45	0	1	0	0	**532**
Muller Polyethylene Cup	Gruppo Bioimpianti	0	0	6	48	52	56	20	26	11	22	25	**266**
Contemporary	Stryker Howmedica Osteonics	141	2	2	2	1	2	0	0	0	68	12	**230**
FAL Acetabular Cup	Waldemar Link	0	0	0	0	0	0	0	96	61	2	7	**166**
Muller Acetabular Cup	Hipokrat As	0	1	1	0	2	3	22	25	34	35	17	**140**
MY Cup	Protetim	125	4	3	0	0	0	0	0	0	0	0	**132**

Table 20 - 15 most commonly used cemented THR (excluding Resurfacing) femoral components

Stem	Manufacturer	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
Metabloc Cemented Stem	Zimmer	104	484	754	1067	1075	873	988	1183	1324	1127	1041	**10020**
Omnifit Normalized Stem	Stryker Howmedica Osteonics	2805	773	614	537	358	388	344	258	241	325	295	**6938**
Taperloc Femoral Stem (cemented)	Biomet	904	275	205	288	230	350	448	395	403	547	241	**4286**
Exeter Stem	Stryker Howmedica Osteonics	1083	230	96	83	149	125	85	77	86	144	191	**2349**
Filler-3ND Titanium Cemented Femoral Stem	Biotechni	859	269	275	285	353	183	11	62	1	5	4	**2307**
Legend V40 Stem	Stryker Howmedica Osteonics	348	164	182	207	263	163	104	65	56	73	3	**1628**
Luer Stem	Fournitures Hospitalieres	87	80	103	145	134	169	134	106	186	179	140	**1463**
Autobloquante	Fournitures Hospitalieres	43	108	90	130	97	104	108	196	158	159	139	**1332**
CPT Femoral Stem	Zimmer	17	45	62	76	74	85	93	93	125	147	170	**987**
Self Locking Femoral Stem	Permedica	209	125	89	104	66	60	55	47	17	22	24	**818**
FJORD	De Puy (Johnson&Johnson)	5	40	98	79	122	86	63	21	4	0	0	**518**
Selflocking (Muller Type)	Surgival	50	65	93	49	58	82	75	42	1	0	0	**515**
Elite Plus Stem	De Puy (Johnson&Johnson)	386	57	15	3	6	1	1	0	0	0	0	**469**
Self-Locking Stem	Gruppo Bioimpianti	0	0	6	48	52	58	20	26	11	22	25	**268**
Ultima Femoral Stem	De Puy (Johnson&Johnson)	170	71	1	0	0	0	0	0	0	0	0	**242**

Table 21 - 15 most commonly used cementless acetabular and femoral component combinations

Cup - Model [Manufacturer]	Stem - Model [Manufacturer]	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
Trilogy Cup [Zimmer]	Metabloc Uncemented Stem [Zimmer]	96	338	309	455	587	547	602	805	1047	1174	1247	**7207**
Secur-Fit PSL Cup [Stryker Howmedica Osteonics]	Omnifit HA Stem [Stryker Howmedica Osteonics]	1485	349	339	287	250	141	120	48	2	5	0	**3026**
Trilogy Cup [Zimmer]	VerSys Fiber Metal Taper [Zimmer]	6	80	218	397	305	391	232	216	295	391	352	**2883**
Mallory-Head Acetabular Shell [Biomet]	Taperloc Femoral Stem (uncemented) [Biomet]	0	0	1	0	195	339	260	233	286	401	333	**2048**
Duraloc 300 [De Puy (Johnson&Johnson)]	Corail Standard Stem(Collarless) [De Puy (Johnson&Johnson)]	89	108	295	375	322	267	258	70	27	4	0	**1815**
Atlas [Fournitures Hospitalieres]	PAVI Standard Stem (necim) [Groupe Lepine]	0	11	69	145	162	146	146	200	138	149	126	**1292**
Trident PSL Acetabular Shell [Stryker Howmedica Osteonics]	Omnifit HA Stem [Stryker Howmedica Osteonics]	40	170	65	17	91	98	52	93	130	162	169	**1087**
L-Cup	Mallory-Head [Biomet]	401	204	128	152	44	9	16	3	7	16	0	**980**
ABG II Cup [Stryker Howmedica Osteonics]	ABG II Stem [Stryker Howmedica Osteonics]	22	61	152	174	199	104	64	52	36	29	0	**893**
Swing Acetabular Cup (Cotyle Swing) [Biotechni]	Filler-3ND Ti+HA Femoral stem [Biotechni]	302	116	85	74	107	109	55	32	7	0	0	**887**
Igloo (Cotyle Igloo) [Biotechni]	Filler-3ND Ti+HA Femoral stem [Biotechni]	12	12	50	79	98	88	97	83	67	51	63	**700**
Atlas [Fournitures Hospitalieres]	Thira [Fournitures Hospitalieres]	0	0	0	27	9	6	43	79	110	165	155	**594**
Pinnacle 300 [De Puy (Johnson&Johnson)]	Corail Standard Stem(Collarless) [De Puy (Johnson&Johnson)]	0	0	0	0	1	31	34	161	247	87	6	**567**
ABG II Cup [Stryker Howmedica Osteonics]	Omnifit HA Stem [Stryker Howmedica Osteonics]	60	88	88	154	65	44	32	14	9	1	0	**555**
Azur Acetabular Cup (Cotyle Azur) [Biotechni]	Filler-3ND Ti+HA Femoral stem [Biotechni]	53	33	24	12	12	37	77	78	61	60	48	**495**

Table 22 - 15 most commonly used cementless THR (excluding Resurfacing) acetabular components

Cup	Manufacturer	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
Trilogy Cup	Zimmer	103	418	533	859	894	952	845	1031	1352	1570	1684	**10241**
Secur-Fit PSL Cup	Stryker Howmedica Osteonics	1505	352	344	312	263	146	125	51	2	5	0	**3105**
Mallory-Head Acetabular Shell	Biomet	0	0	1	0	197	340	262	233	286	401	333	**2053**
Atlas	Fournitures Hospitalieres	0	29	69	177	176	152	193	284	250	319	285	**1934**
Duraloc 300	De Puy (Johnson&Johnson)	91	117	301	380	325	270	260	70	30	7	0	**1851**
Trident PSL Acetabular Shell	Stryker Howmedica Osteonics	60	174	67	19	95	129	127	156	203	225	262	**1517**
ABG II Cup	Stryker Howmedica Osteonics	86	151	240	330	265	148	96	66	45	30	0	**1457**
Igloo (Cotyle Igloo)	Biotechni	15	31	89	136	110	96	109	94	153	133	119	**1085**
Swing Acetabular Cup (Cotyle Swing)	Biotechni	320	123	107	96	113	121	76	33	8	2	0	**999**
L-Cup / Mallory-Head	Biomet	405	207	129	153	44	9	16	3	7	16	0	**989**
Azur Acetabular Cup (Cotyle Azur)	Biotechni	55	34	24	12	12	37	135	160	189	151	111	**920**
Multi Acetabular Cup	Biotechni	0	0	0	0	0	0	0	28	129	223	279	**659**
Pinnacle 300	De Puy (Johnson&Johnson)	0	0	0	0	1	32	34	173	254	97	8	**599**
Trilogy Cup (Shell Spiked)	Zimmer	0	0	9	75	75	48	27	40	34	60	126	**494**
L-Cup Press Fit	Biomet	6	33	118	162	91	40	16	2	0	2	3	**473**

Table 23 - 15 most commonly used cementless THR (excluding Resurfacing) femoral components

Stem	Manufacturer	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
Metabloc Uncemented Stem	Zimmer	96	338	334	524	663	606	632	839	1073	1226	1348	**7679**
Omnifit HA Stem	Stryker Howmedica Osteonics	1646	610	493	465	410	286	208	156	141	171	171	**4757**
Taperloc Femoral Stem	Biomet	466	238	248	314	333	409	300	258	308	576	437	**3887**
VerSys Fiber Metal Taper	Zimmer	6	80	229	453	371	439	256	266	324	441	400	**3265**
Corail Standard Stem(Collarless)	De Puy (Johnson&Johnson)	156	115	324	412	358	311	309	269	300	102	9	**2665**
Filler-3ND Ti+HA Femoral stem	Biotechni	394	161	159	165	217	238	231	202	161	162	152	**2242**
PAVI Standard Stem	Groupe Lepine	0	11	72	149	167	146	148	202	139	149	126	**1309**
ABG	Stryker Howmedica Osteonics	23	64	153	174	203	133	139	115	108	92	71	**1275**
Filler-3ND Ti Femoral Stem	Biotechni	0	0	0	0	0	9	87	116	214	263	276	**965**
Thira	Fournitures Hospitalieres	0	0	0	27	9	6	43	79	110	166	155	**595**
Fortress	Biotechni	0	0	14	52	18	9	5	1	51	23	13	**186**
Cleveland Femoral Stem	C2F Implants	0	0	0	0	0	0	0	0	14	93	64	**171**
Synergy	Smith & Nephew	0	0	1	11	18	26	14	11	26	18	30	**155**
Karey-HA Femoral Stem	Surgival	0	0	0	0	0	0	0	2	24	41	37	**104**
Standard C Stem	Waldemar Link	0	0	0	0	0	0	0	1	2	16	81	**100**

Table 24 - 15 most commonly used hybrid acetabular and femoral component combinations

Cup - Model [Manufacturer]	Stem - Model [Manufacturer]	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
Trilogy Cup [Zimmer]	Metabloc Cemented Stem [Zimmer]	0	2	4	9	10	8	12	15	7	5	21	**93**
Duraloc 300 [De Puy (Johnson&Johnson)]	FJORD [De Puy (Johnson&Johnson)]	5	21	19	20	20	2	1	0	0	0	0	**88**
Secur-Fit PSL Cup [Stryker Howmedica Osteonics]	Omnifit Normalized Stem [Stryker Howmedica Osteonics]	55	5	3	4	7	3	0	0	0	0	0	**77**
L-Cup	Mallory-Head [Biomet]	13	3	1	1	0	0	0	0	0	0	0	**18**
T.O.P. Acetabular Cup [Waldemar Link]	Lubinus Classic Plus Hip Stem [Waldemar Link]	0	0	0	0	0	0	0	6	8	1	0	**15**
ABG II Cup [Stryker Howmedica Osteonics]	Legend V40 Stem [Stryker Howmedica Osteonics]	5	5	0	1	1	0	1	0	0	0	0	**13**
Plasmacup SC (uncemented) [Aesculap (B Braun)]	Bicontact CoCr Stem (cemented) [Aesculap (B Braun)]	7	3	0	0	0	0	0	0	0	0	0	**10**
Allofit S Shell [Zimmer]	Metabloc Cemented Stem [Zimmer]	0	0	0	1	2	1	2	1	1	1	0	**9**
Trilogy Cup [Zimmer]	CPT Femoral Stem [Zimmer]	0	0	0	3	1	1	0	0	3	0	0	**8**
Trilogy Cup [Zimmer]	Autobloquante [Fournitures Hospitalieres]	0	2	6	0	0	0	0	0	0	0	0	**8**
ABG II Cup [Stryker Howmedica Osteonics]	ABG II Cemented Stem [Stryker Howmedica Osteonics]	0	0	4	0	3	0	0	0	0	0	0	**7**
Trilogy Cup [Zimmer]	Omnifit Normalized Stem [Stryker Howmedica Osteonics]	0	1	1	0	0	1	0	0	0	2	1	**6**
Trident PSL Acetabular Shell [Stryker Howmedica Osteonics]	Omnifit Normalized Stem [Stryker Howmedica Osteonics]	0	0	2	0	0	0	1	0	3	0	0	**6**
Swing Acetabular Cup (Cotyle Swing) [Biotechni]	Filler-3ND Titanium Cemented Femoral Stem [Biotechni]	1	0	0	1	1	2	0	0	0	0	0	**5**
Exceed ABT [Biomet]	Taperloc Femoral Stem (cemented) [Biomet]	0	0	0	0	0	0	1	2	0	1	1	**5**

Table 25 - 15 most commonly used reversed hybrid acetabular and femoral component combinations

Cup - Model [Manufacturer]	Stem - Model [Manufacturer]	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
Rim Acetabular Cup [Biotechni]	Filler-3ND Ti Femoral Stem [Biotechni]	0	0	0	0	1	28	393	356	379	376	504	**2037**
Muller II Cup [OHST Medizintechnik AG]	Filler-3ND Ti Femoral Stem [Biotechni]	0	0	0	0	0	0	0	8	120	157	134	**419**
Rim Acetabular Cup [Biotechni]	Filler-3ND Ti+HA Femoral stem [Biotechni]	12	0	1	0	0	167	34	5	20	4	14	**257**
ZCA All-Poly Cup [Zimmer]	Metabloc Uncemented Stem [Zimmer]	2	4	6	17	15	18	16	26	29	22	16	**171**
Polyethylene Acetabular Cup (Omnifit) [Stryker Howmedica Osteonics]	Omnifit HA Stem [Stryker Howmedica Osteonics]	36	22	23	5	9	4	4	3	4	1	0	**111**
Muller Type Cup [Surgival]	Filler-3ND Ti Femoral Stem [Biotechni]	0	0	0	0	0	2	32	54	15	5	2	**110**
Muller Type Cup [Surgival]	Filler-3ND Ti+HA Femoral stem [Biotechni]	0	0	0	0	0	26	4	1	0	0	0	**31**
Rim Acetabular Cup [Biotechni]	Cleveland Femoral Stem [C2F Implants]	0	0	0	0	0	0	0	0	10	17	3	**30**
Muller-Type Acetabular Cup [Biomet]	Taperloc Femoral Stem (uncemented) [Biomet]	6	5	0	2	4	0	0	1	1	5	2	**26**
Exeter Acetabular Cup [Stryker Howmedica Osteonics]	Omnifit HA Stem [Stryker Howmedica Osteonics]	6	2	5	2	7	0	0	0	0	0	0	**22**
FAL Acetabular Cup [Waldemar Link]	Standard C Stem [Waldemar Link]	0	0	0	0	0	0	0	0	0	1	17	**18**
Elite Plus LPW Cup [De Puy (Johnson&Johnson)]	Corail Standard Stem(Collarless) [De Puy (Johnson&Johnson)]	1	2	3	1	3	5	2	0	0	0	0	**17**
ZCA All-Poly Cup [Zimmer]	Revitan (DE REVIZIE) [Zimmer]	0	0	0	0	0	0	3	0	4	4	6	**17**
Polyethylene Acetabular Cup (Omnifit) [Stryker Howmedica Osteonics]	Metabloc Uncemented Stem [Zimmer]	0	0	1	0	0	1	5	2	2	2	3	**16**
Coriolis Cup [Fournitures Hospitalieres]	PAVI Standard Stem (necim) [Groupe Lepine]	0	0	0	0	4	2	5	0	1	1	3	**16**

5.1.1.5 Surgical approach used in THRs (excluding Resurfacing)

5.1.1.5.1 Number of THR implants - evolution by type of approach

Table 26 - Number of THR implants by type of approach, 2001 - 2015

Approach	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
Clasic Approach												
Lateral	12,876	3,574	3,699	4,030	4,207	3,989	3,948	4,280	4,813	5,248	5,285	**55,949**
Anterolateral	2,028	683	889	1,301	1,188	1,015	1,008	969	952	842	782	**11,657**
Posterolateral	1,372	394	368	577	517	613	587	533	647	773	691	**7,072**
Anterior	41	11	10	112	37	9	3	8	11	11	19	**272**
Trohanterotomy	11	0	0	1	0	1	0	0	0	0	0	**13**
MIS Approach*												
Posteriolateral	n/a	1	15	84	67	74	50	74	103	76	49	**593**
Anterolateral	n/a	5	14	2	8	2	11	18	13	46	20	**139**
Double Incision	n/a	n/a	0	1	2	0	2	0	0	0	1	**6**
Direct anterior	n/a	n/a	0	0	2	4	0	1	0	42	65	**114**
Others	0	0	0	0	0	3	4	4	1	40	60	**112**
n/a **												**638**
Total	**16,328**	**4,668**	**4,995**	**6,108**	**6,028**	**5,710**	**5,613**	**5,887**	**6,540**	**7,078**	**6,972**	**75,927**

** Minimally invasive approach documentation in RAR forms was introduced in 2007-2008*

*** approach type not available*

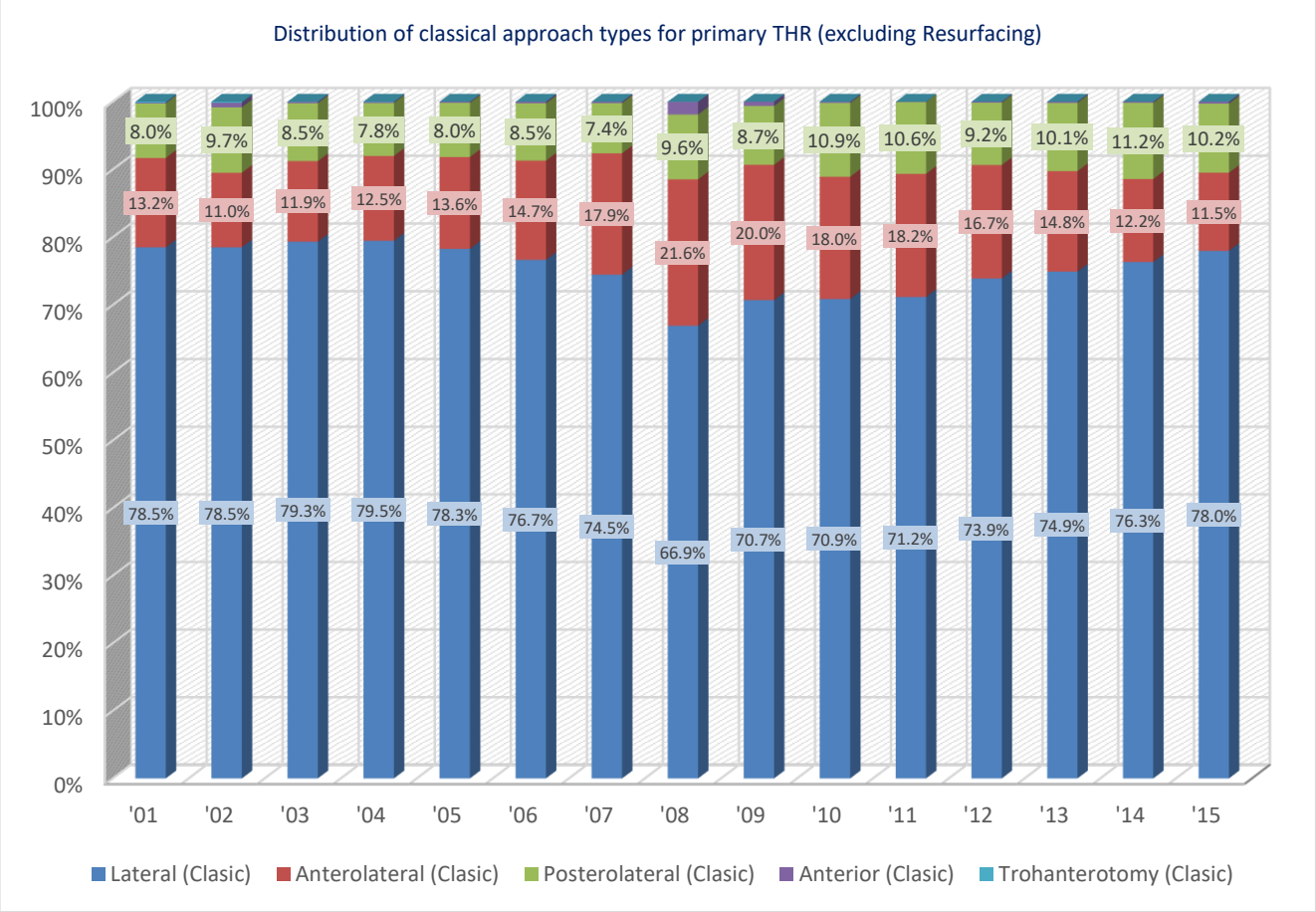


Figure 44 – Distribution of classical incision types for primary THR, 2001 – 2015

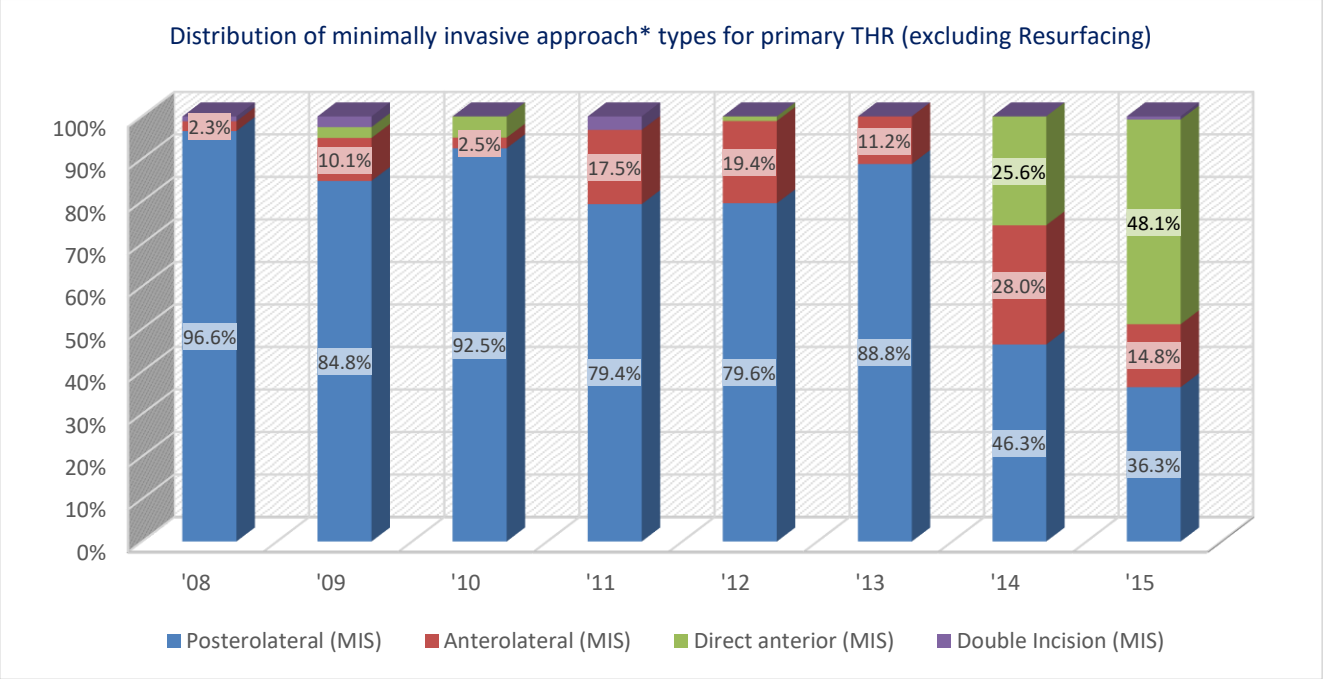


Figure 45 – Distribution of minimally invasive surgical types for primary THR, 2001 – 2015

**Minimally invasive approach documentation in RAR forms was introduced in 2007-2008*

After volatile fluctuations, posterolateral minimally invasive approach was performed with 50% more in 2013 than in 2015. It was the most used approach out of all minimally invasive surgical approaches between 2008 and 2013 (96.6% and 88.8%). Proceeded by anterolateral approach, direct anterior approach was used especially during 2014-2015, with 25.6% and 48.1%, respectively.

5.1.1.5.2 Classic versus minimal invasive approach

Minimally invasive approach documentation in RAR forms was introduced in 2007-2008, and ever since registered a slightly yearly increasing rate with less than 3% in 2015.

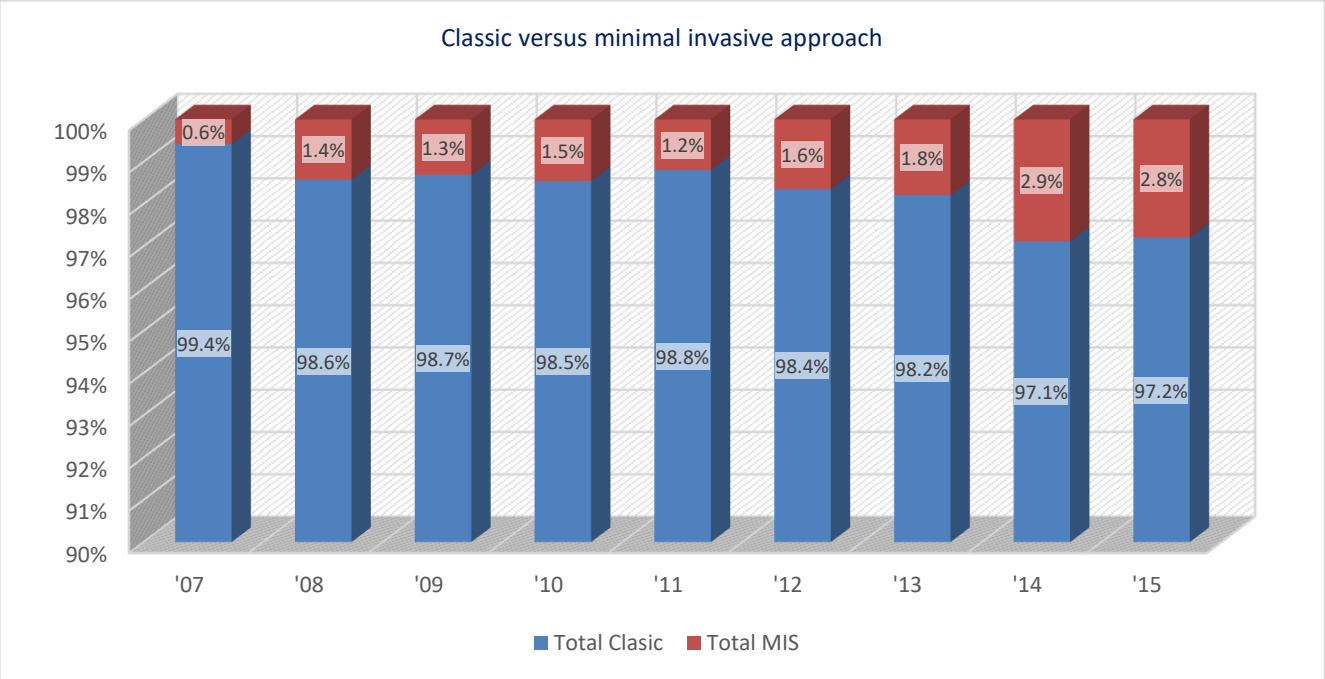


Figure 46 - Classic versus minimal invasive approach, 2001 – 2015

5.1.1.6 Antibiotic prophylaxis

To reduce the incidence of post-operative sepsis, the accepted method is the antibiotic prophylaxis, so it is surprising that this method is not used in 100% of the cases. The last decade brought a transition from a wide variety of antibiotics to a more standard and reduced list of antibiotics used in antibiotic prophylaxis.

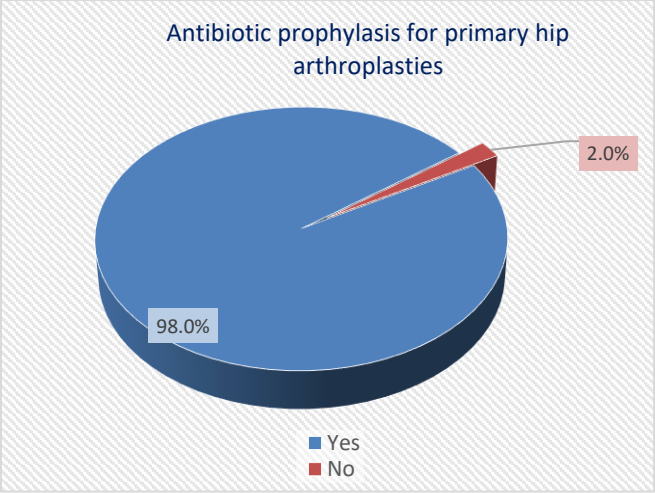


Figure 47 – Antibiotic prophylaxis for primary hip arthroplasties, 2001 – 2015

In 85.14% of cases, antibiotic prophylaxis was performed with cephalosporins sole antibiotic (64.43%) or cephalosporins combinations with aminoglycoside, sulbactam or glycopeptide (20.71%). 1st and 2nd generation cephalosporins were used in 36.87% of cases and in 48.27% of cases were used cephalosporins of 3rd generation. In 12.35% of cases, the cephalosporin used was not specified. Among the most common cephalosporins, Axetine (2nd generation) was used as sole antibiotic in 22.2% of cases, associated with Gentamicin in 5% of cases or associated with Vancomycin in 1.21% of cases.

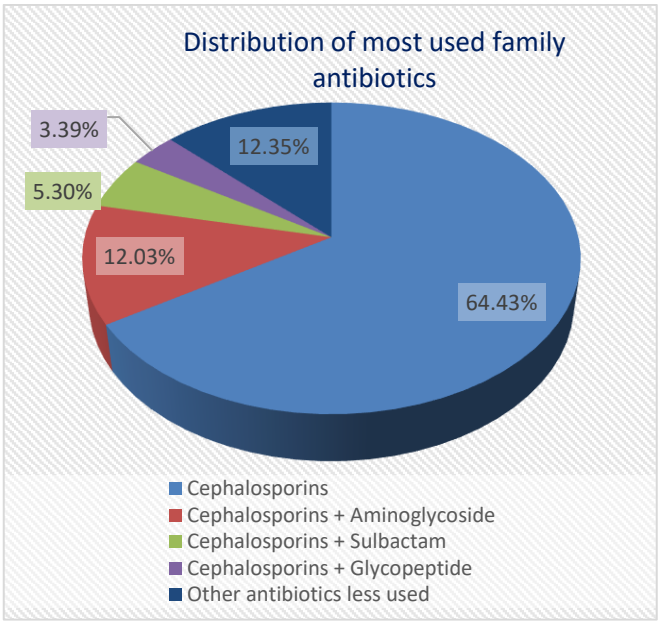


Figure 48 – Distribution of used antibiotics by family, 2001 – 2015

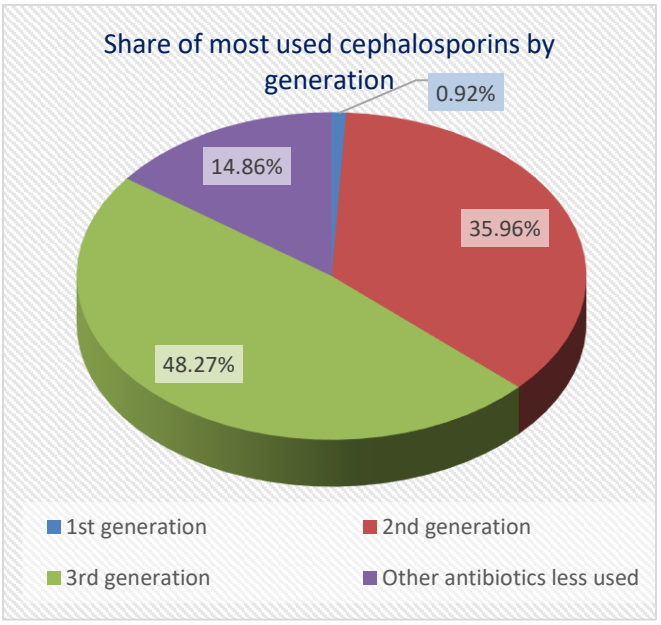


Figure 49 – Distribution of cephalosporins by generation, 2001 – 2015

Considering the distribution of the used antibiotics, Axetine and Cefort were the most used antibiotics with 22.20%, respectively 19.66%. Following, a combination of Gentamicina and Cefort antibiotics was used, with 5.41% from the total and Cefuroxim antibiotic with 5.38%. Subsequently, this confirms that cephalosporins are the most used antibiotic family in THR (excluding Resurfacing) hip arthroplasty (85.14% of the total).

5.1.1.7 Reasons for "early" failure in THR (excluding Resurfacing) implants during 2001-2015

Table 27 - Reasons for early failure in THR (excl. Resurfacing), 2001 - 2015

Years	Main reason of "early" failure	Percentages
0-1	Luxation	36.79%
1-2	Acetabular loosening	19.76%
2-3	Acetabular loosening	20.00%
3-4	Acetabular loosening	18.80%
4-5	Acetabular loosening	19.86%
5-6	Acetabular loosening	23.64%

5.1.1.8 Discussions on Total Hip Replacements (THRs) (excluding Resurfacing)

Five manufacturers add up to the threshold of 90% of all THRs in Romania between 2001 - 2015: Zimmer (29%), Stryker (26%), Biomet (12%), Biotechni (11%), Fournitures Hospitaliers (7%) and De Puy (Johnson&Johnson) (5%).

The evolution of the patients' mean age at time of primary intervention indicates a general increase in both male and female patients with approximately 5 years for both genders.

The most common THR pre-operative diagnosis from all reported diagnosis between 2001-2015 was primary OA (60%) of patients followed by secondary OA (28.4%), femoral neck fracture (7.5%) and other diagnoses (4.1%).

Cementless THR is predominant in patients under 59 years old, in average for about 78.3% of cases, while Cemented THR prevales in 73% of patients over 60 years.

There has been a tendency to increase the proportion of cementless implants in recent years, partially reversed in 2011. It is possible that economic factors have had a contribution as well. Cemented implants currently continue to hold the majority, cementless being prevalent in male patients.

Between 2001 and 2015, the surgical options for femoral neck fractures were ostheosinthesis and arthroplasty with cervicocephalic implants. Between 2008 throughout 2013, there was an increased incidence in THRs as curative choice.

If we analyze the number of total hip prosthesis implantation for post-traumatic disorders, thereby understanding pseudarthrosis, necrosis of the femoral head, secondary or post-traumatic arthritis, we find that THRs used in femoral neck fractures have decreased the number of THRs in late post-traumatic complications for this condition.

Most total hip prostheses were implanted by conventional surgical approaches and even if the incidence of prostheses implanted through posterolateral or anterolateral approach has shown some growth, lateral approach is still preponderant (78% in 2015).

Even if the number of prostheses implanted through minimally invasive surgical approaches is below 3%, the surgical technique has changed significantly during this period, total hip moving from a "heroic operation" that required special preparation of the entire health staff, to routine surgery. Postoperative and mid-surgery blood loss has been reduced significantly, surgery time was reduced, and incision length is much smaller today than 10 years ago.

5.1.2 Resurfacing implants

Taking in consideration the low number of implants and the short period of time of their usage, this type of procedure does not hold statistical significance for an elaborate analysis.

Table 28 - Most commonly used resurfacing implants

Implant	Manufacturer	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
BHR (Birmingham Hip Resurfacing)	Smith & Nephew	11	15	60	65	38	48	33	14	7	4	1	296
BHR (Birmingham Hip Resurfacing)	Midland Medical Technologies	40	7	1	0	0	0	0	0	0	0	0	48
Recap/Magnum Acetabular Shell	Biomet	0	1	4	3	7	7	3	1	0	0	0	26
ASR Total Acetabular Implant*	De Puy (Johnson&Johnson)	0	0	6	11	2	0	0	0	0	0	0	19
Other	Other	52	0	0	0	0	0	0	0	0	0	0	52
Total		**103**	**23**	**71**	**79**	**47**	**55**	**36**	**15**	**7**	**4**	**1**	**441**

** withdrawn from market*

5.1.2.1 Resurfacing procedures for specific diagnoses and by age groups

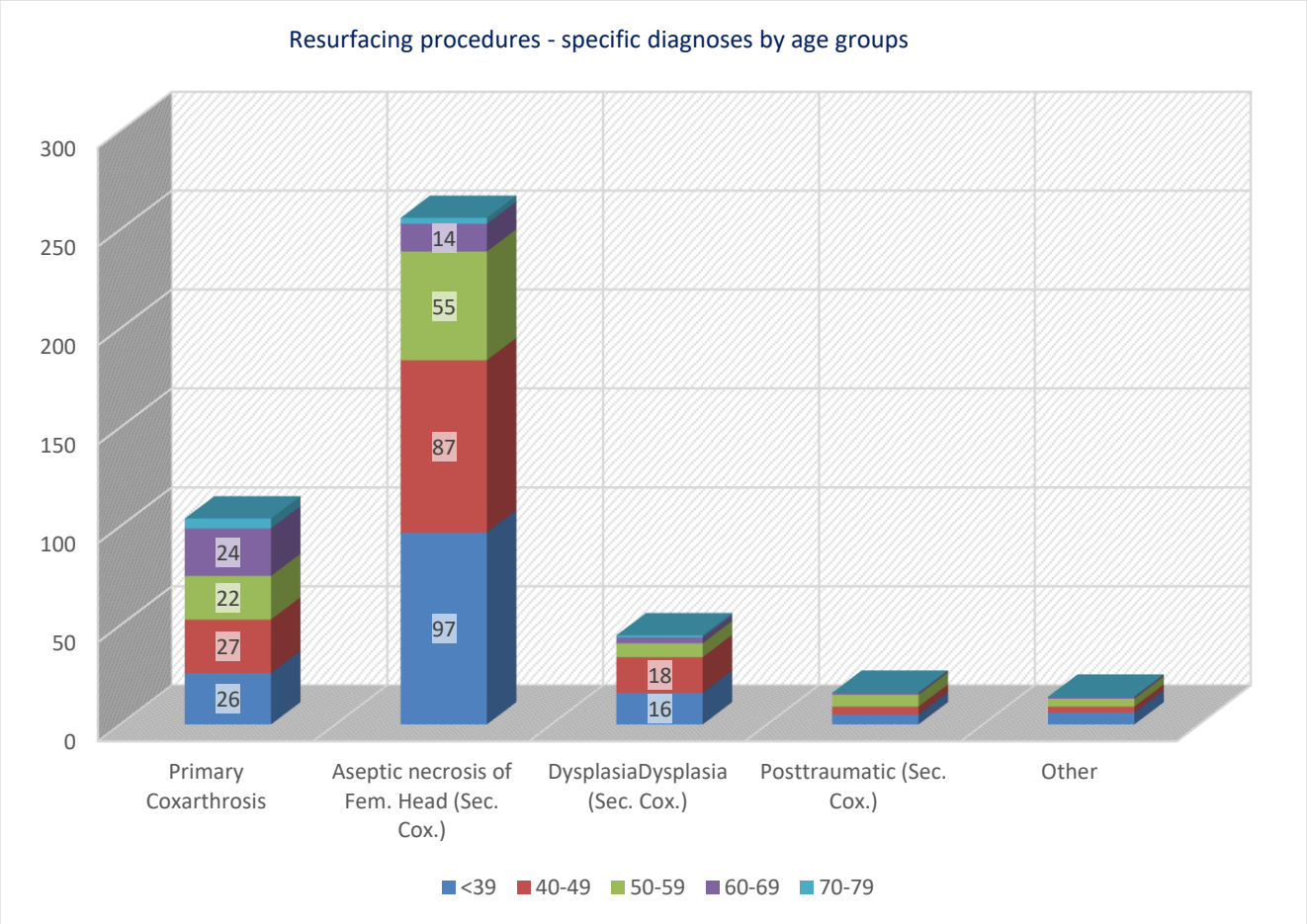


Figure 50 – Resurfacing procedures for specific diagnoses and by age groups, 2001 – 2015

5.1.2.2 *Resurfacing procedures for main age groups and by diagnoses*

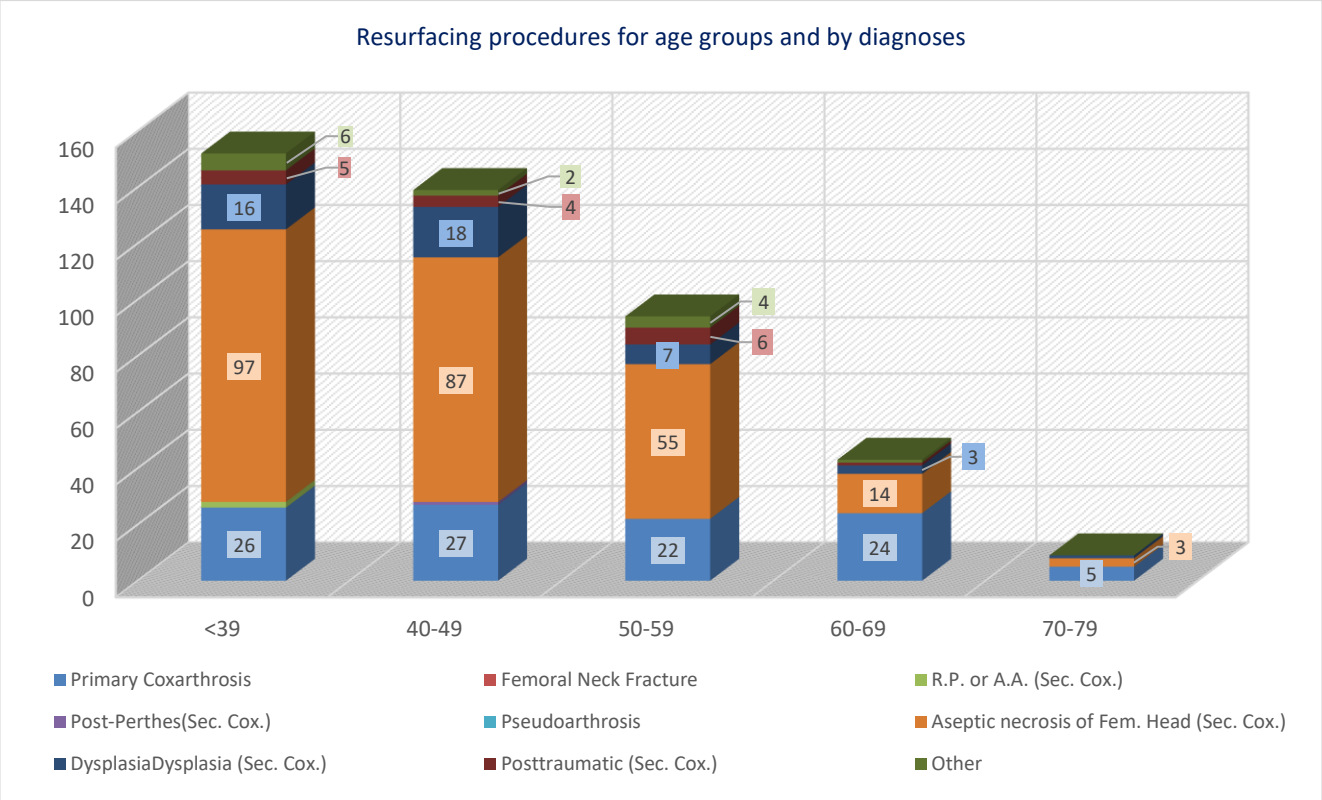


Figure 51 – Resurfacing procedures for age groups and by specific diagnoses, 2001 - 2015

5.1.2.3 *Percent of primary resurfacing procedures by age groups and gender*

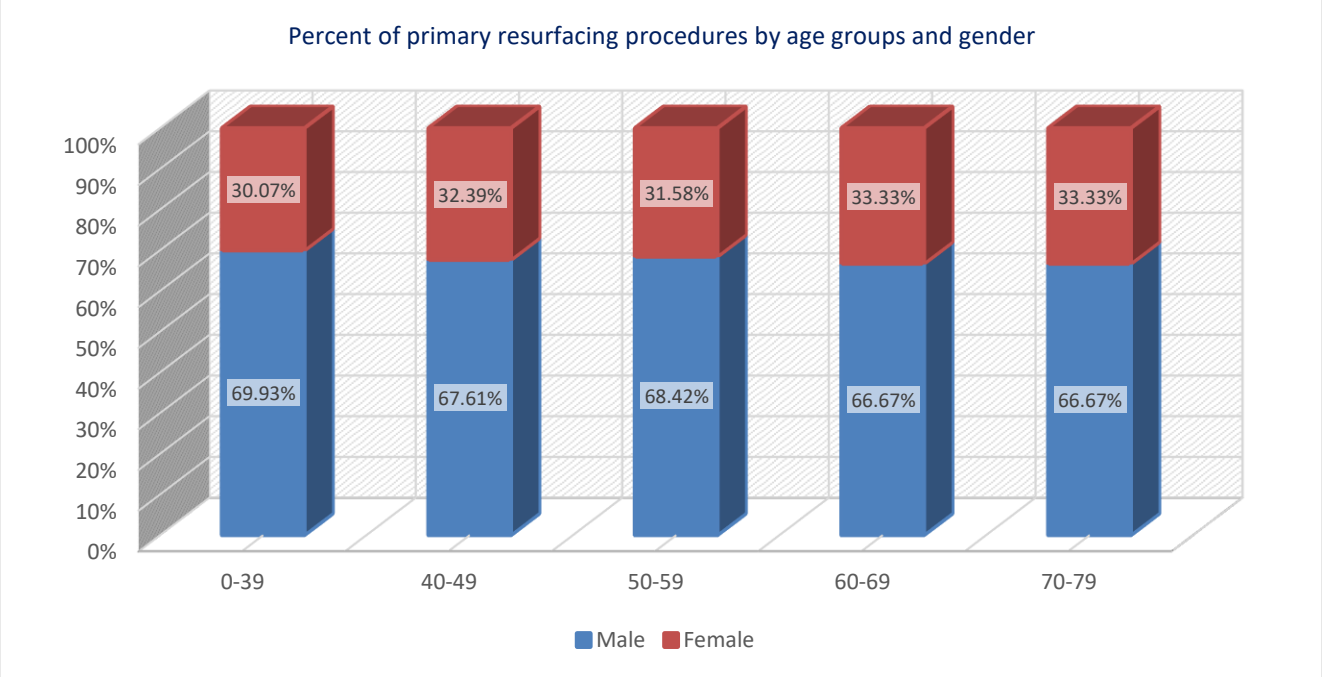


Figure 52 – Primary Resurfacing by age groups and gender, 2001 – 2015

5.1.2.4 *Resurfacing procedures by diagnosis and gender*

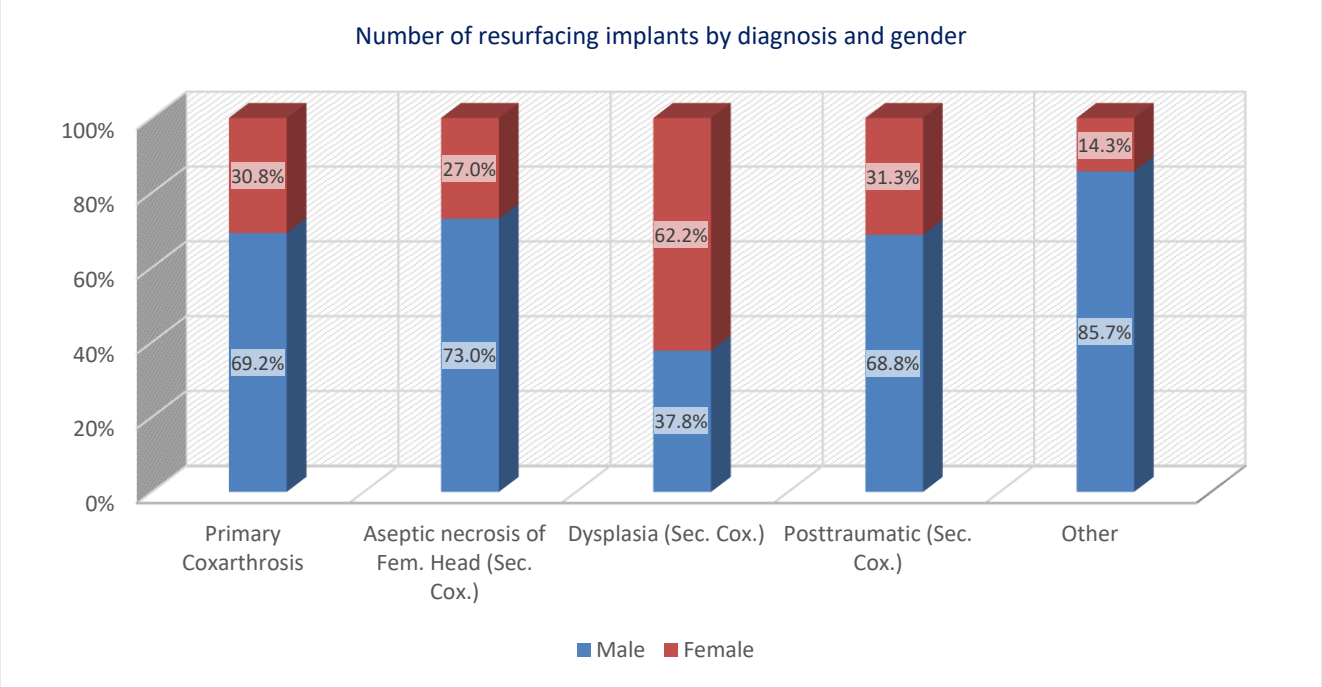


Figure 53 – Number of Resurfacing implants by diagnosis and gender, 2001 – 2015

5.1.2.5 *Mean age at time of primary procedure for each gender (resurfacing)*

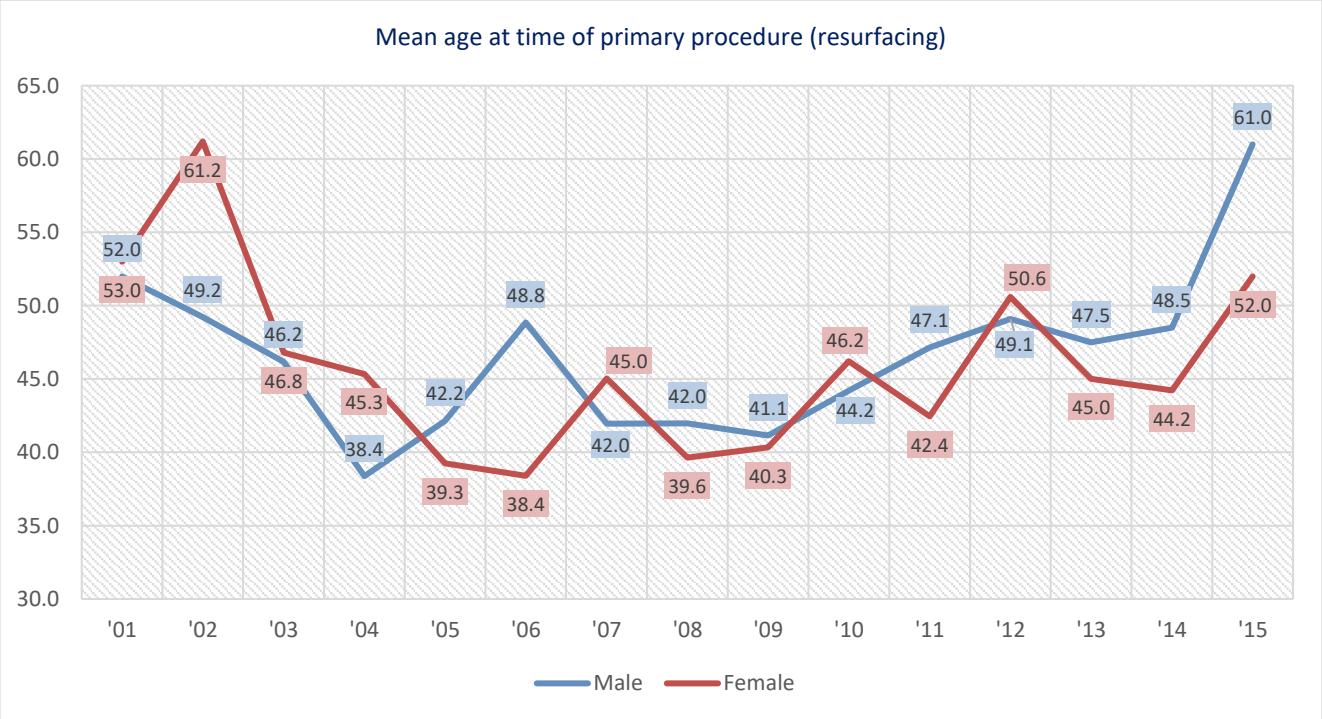


Figure 54 – Mean age at time of primary procedure (resurfacing) for each gender, 2001 – 2015

5.1.2.6 Mean age at time of primary procedure by diagnosis and gender (resurfacing)

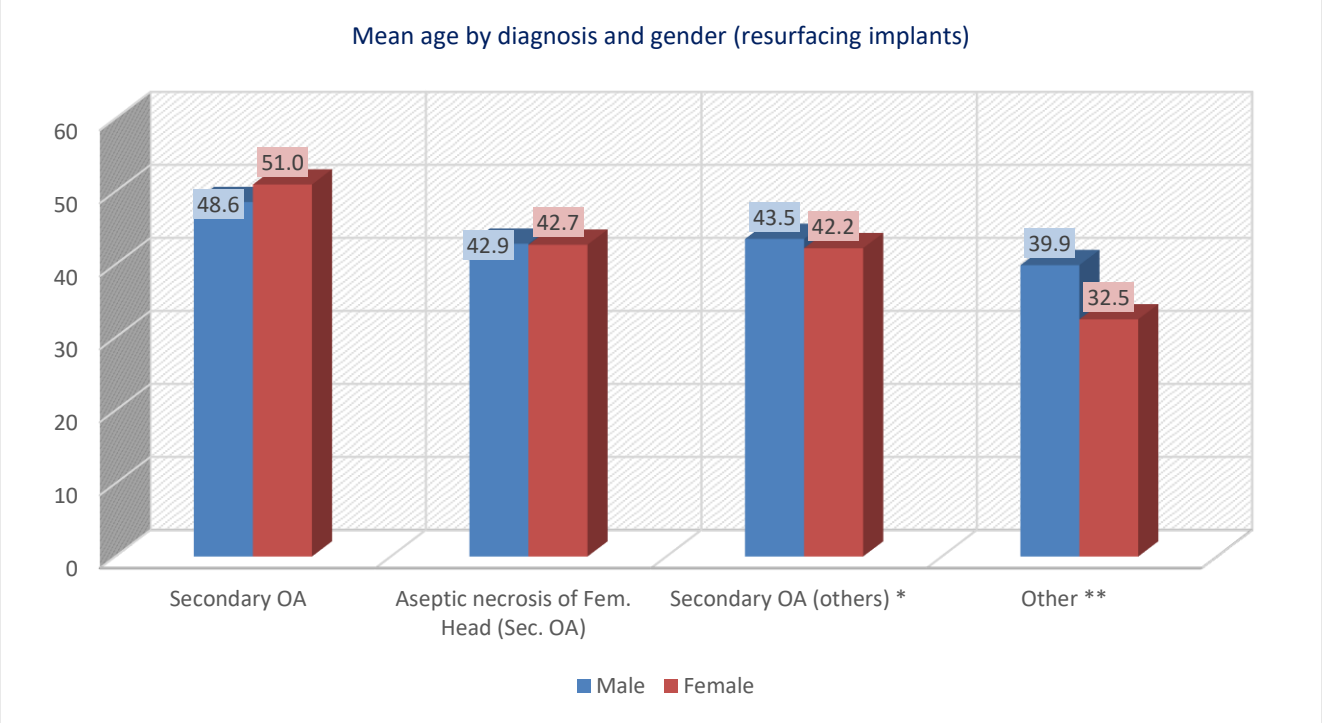


Figure 55 – Mean age at time of primary procedure (resurfacing) by diagnosis and gender, 2001 – 2015

**includes: Posttraumatic (Sec.Cox.), Dysplasia (Sec.Cox.)*

*** custom input provided by surgeon*

5.1.2.7 Reasons for "early" failure in Resurfacing implants

Table 29 – Reasons for "early" failure in Resurfacing implants – 2001 – 2015

Years	Main reasons of "early" failure	Percentages
0-1	Periprostethic fracture	38.46%
1-2	Late Infection	50.00%
2-3	Others*	40.00%
3-4	Acetabular loosening and Femoral loosening	57.14%
4-5	Femoral osteolysis and Periprostethic fracture	100.00%
5-6	Late Infection, Femoral osteolysis and Periprostethic fracture	75.00%

* custom input provided by surgeon

5.1.2.8 Discussion on resurfacing implants

The low number of resurfacing implants and the lack of long-term results make a detailed analysis impossible and allows the RAR to give only a brief overview on type of endoprostheses.
The limited range of surgical indication, plus the high cost of this implant type, accounts for its limited use. The number of complications is relatively high (37 implants revised out of 441 implanted, 12 failed in the first year), but the survival results lack statistical significance.
The most frequent diagnosis was the aseptic necrosis of the femoral head (58,6%), followed by primary OA (23.8%) and dysplasia (10,3%).
Except for dysplasia, the resurfacing implant was used mostly in male patients (65% male), and under 49 years old (66% male and female below 49 years old).

5.2 Primary hip hemi-arthroplasty

Table 30 – Distribution of primary hip hemi-arthroplasty by years, 2001 - 2015

	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
Hemiarthroplasty	**9,713**	**2,379**	**2,189**	**2,733**	**2,820**	**3,103**	**3,187**	**3,071**	**3,263**	**3,288**	**3,317**	**39,063**
Bipolar	1,878	493	353	528	516	506	587	563	574	652	622	7,272
Moore/Thompson type	7,783	1,883	1,836	2,205	2,304	2,597	2,600	2,508	2,689	2,636	2,695	31,736
Unipolar modular	52	3	0	0	0	0	0	0	0	0	0	55

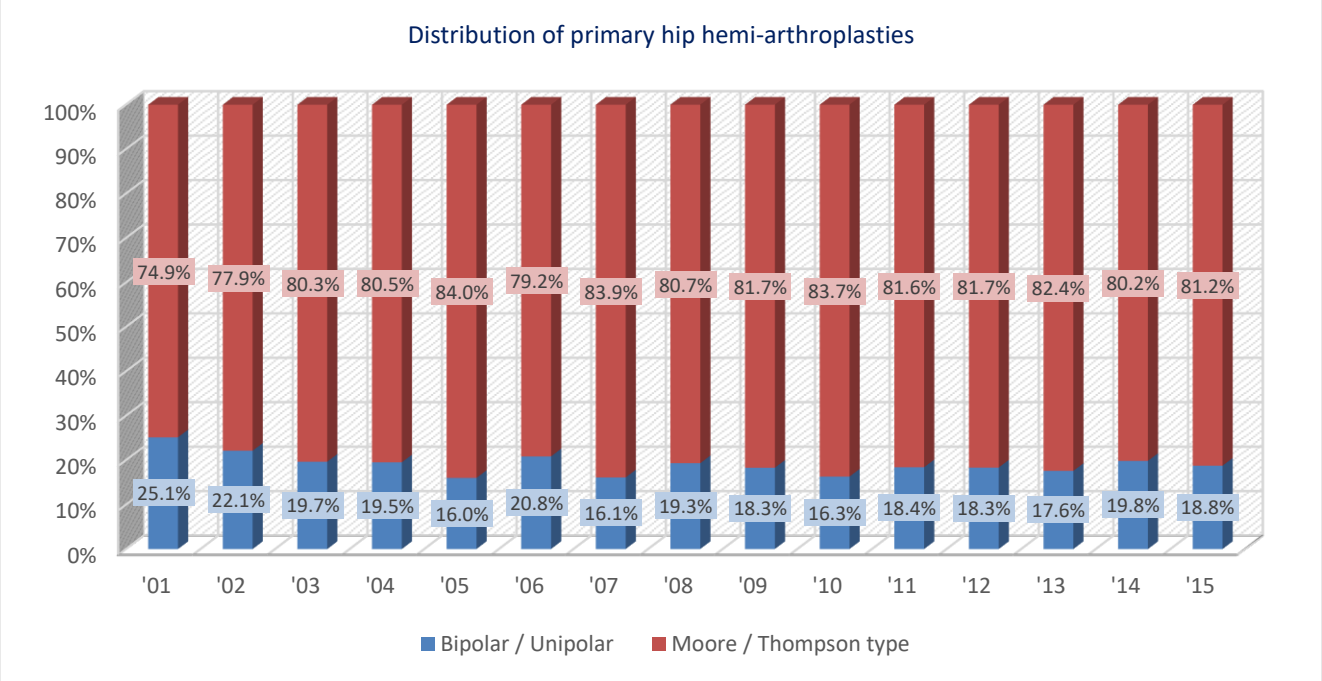


Figure 56 – Distribution of primary hip hemi-arthroplasties, 2001 – 2015

5.2.1 Bipolar/Unipolar

Table 31 – 15 most common bipolar/unipolar modular acetabular components

Head / Cup	Manufacturer	01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
UHR Universal Head	Stryker Howmedica Osteonics	452	319	250	322	230	191	229	192	175	204	174	**2738**
UHL Bipolar Cup	Groupe Lepine	0	0	3	44	81	84	86	128	205	219	170	**1020**
Multipolar Bipolar Cup	Zimmer	3	14	22	63	87	136	132	73	19	22	16	**587**
Variokonus Bipolar Head (Duo-Polar)	Biomet	189	53	45	58	89	34	7	0	0	0	0	**475**
Bi-Polar Acetabular Cup	Biomet	0	9	0	0	0	40	59	53	73	83	125	**442**
Bipolar Cup	Hipokrat As	0	0	0	2	0	3	47	84	76	70	22	**304**
Bipolar Cup (Cupule Mobile)	Biotechni	110	33	4	7	1	1	0	0	0	0	1	**157**
Bipolar Head	Aesculap (B Braun)	82	9	1	4	4	1	0	0	0	0	0	**101**
PHARO (Bipolar Acetabular Cup)	Fournitures Hospitalieres	0	0	1	12	4	6	10	25	22	20	0	**100**
Biarticular Cup	Permedica	4	20	26	10	3	0	8	0	0	0	0	**71**
Bipolar Modular Head	aap Implantate AG	0	0	0	0	2	10	9	8	4	0	1	**34**
Unitrax Unipolar Head	Stryker Howmedica Osteonics	24	0	0	0	0	0	0	0	0	0	0	**24**
Ring Loc Bi-Polar Acetabular Cup	Biomet Orthopedics USA]	0	3	0	0	11	0	0	0	0	0	0	**14**
Ultima Monk	De Puy (Johnson&Johnson)	0	0	0	5	0	0	0	0	0	0	0	**5**
Kirschner Bipolar Cup	Biomet Orthopedics USA	0	0	1	0	2	0	0	0	0	0	0	**3**

Table 32 – 15 most common bipolar/unipolar modular femoral components

Stem	Manufacturer	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
Omnifit HA Stem	Stryker Howmedica Osteonics	183	159	127	161	96	62	118	87	87	98	98	**1276**
Taperloc Femoral Stem (uncemented)	Biomet	139	45	43	55	84	72	63	46	63	71	109	**790**
Legend V40 Stem	Stryker Howmedica Osteonics	105	43	46	72	64	77	51	47	34	36	0	**575**
PAVI Standard Stem (necim)	Groupe Lepine	0	0	4	30	59	58	52	59	60	74	20	**416**
Omnifit Normalized Stem	Stryker Howmedica Osteonics	173	50	16	21	12	12	16	25	24	30	20	**399**
Exeter Stem	Stryker Howmedica Osteonics	50	29	41	39	28	12	23	18	25	27	46	**338**
Metabloc Cemented Stem	Zimmer	0	10	15	39	60	81	72	34	3	12	9	**335**
Metabloc Uncemented Stem	Zimmer	0	3	10	23	35	63	60	35	20	10	7	**266**
Modular Straight Stem Cemented	Hipokrat As	0	0	0	0	0	3	39	62	67	37	5	**213**
Autobloquante	Fournitures Hospitalieres	0	13	11	8	5	6	14	25	27	36	38	**183**
Self Locking Femoral Stem	Permedica	2	5	1	0	3	6	2	16	60	41	32	**168**
Selflocking (Muller Type)	Surgival	4	27	15	25	14	21	18	8	0	0	0	**132**
Taperloc Femoral Stem (cemented)	Biomet	61	9	3	3	5	1	2	4	9	12	16	**125**
ABG II Stem	Stryker Howmedica Osteonics	0	1	1	7	20	14	17	13	8	7	4	**92**
Filler-3ND Ti Femoral Stem	Biotechni	0	0	0	0	0	0	1	8	27	28	26	**90**

5.2.1.1 *Bipolar/unipolar modular implants by diagnosis and age groups*

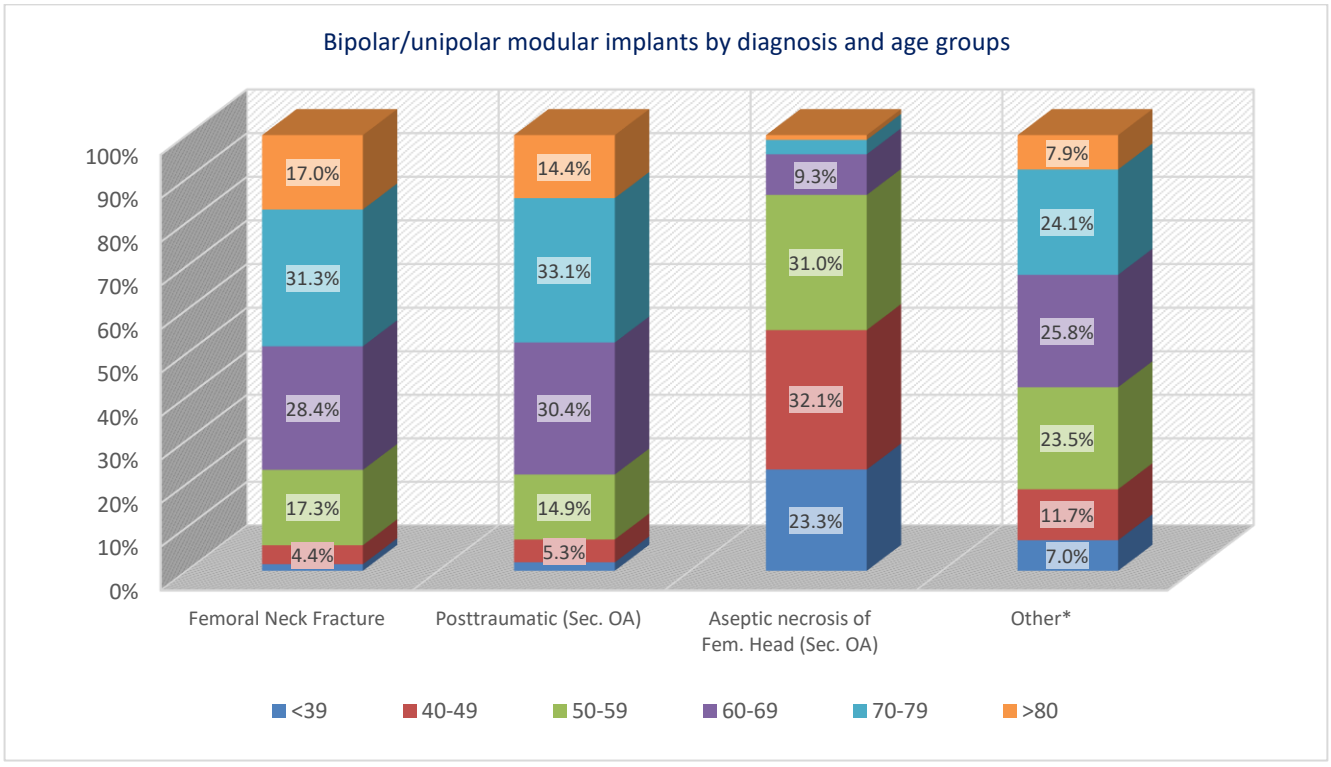


Figure 57 – Bipolar/unipolar modular implants by diagnosis and age groups, 2001 – 2015

5.2.1.2 Bipolar/unipolar implants by age groups and diagnoses

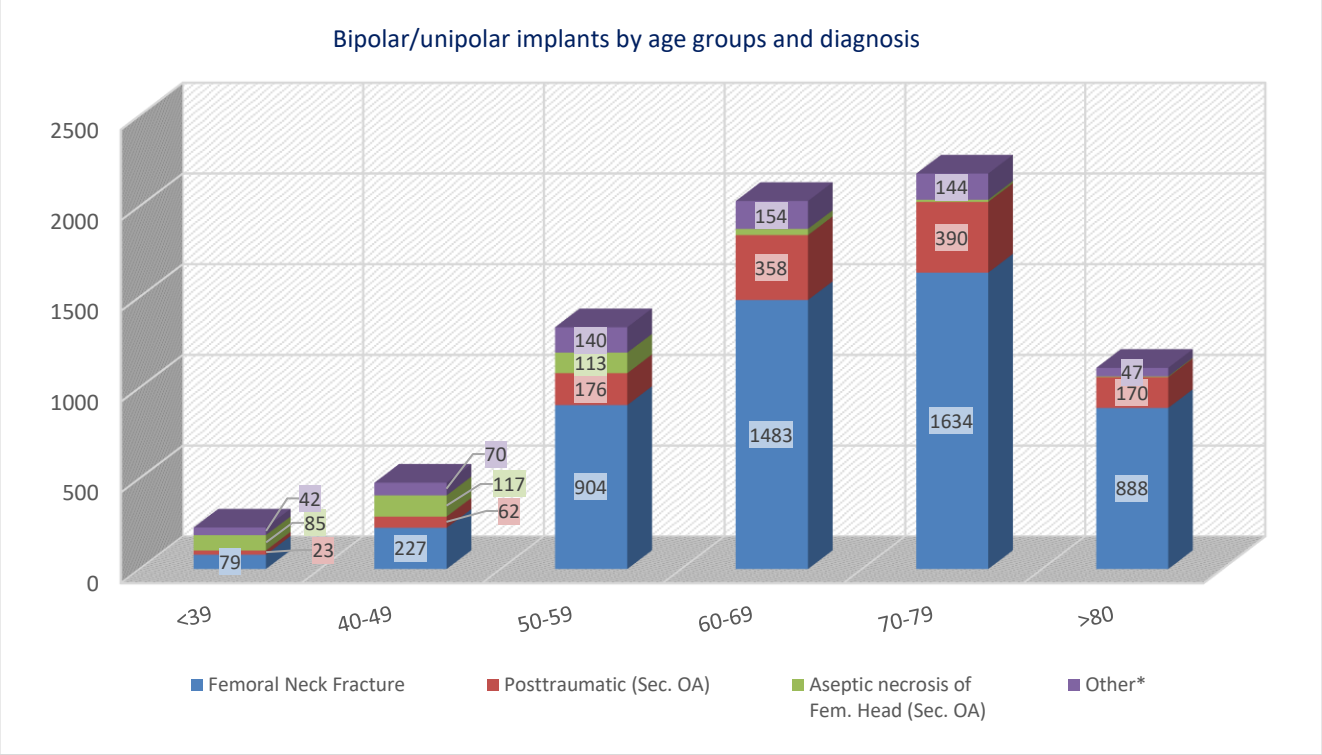


Figure 58 – Bipolar/unipolar procedures by age groups and diagnosis, 2001 – 2015

5.2.1.3 Bipolar/unipolar implants by diagnoses and gender

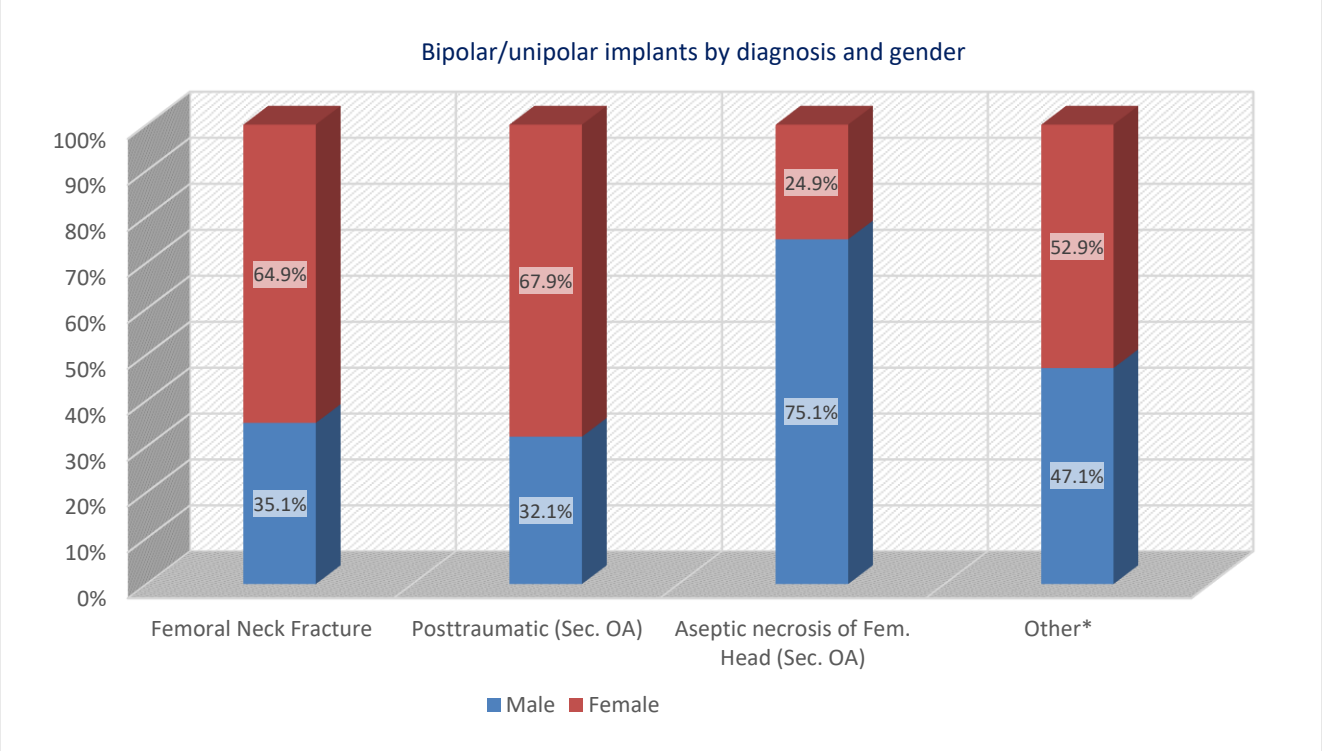


Figure 59 – Share of bipolar/unipolar modular implants by diagnosis and gender, 2001 – 2015

**other – custom input provided by surgeon, including primary OA, dysplasia (Sec.OA), R.P. or A.A. (Sec.OA), Pseudarthrosis*

5.2.1.4 *Mean age at time of primary procedure by gender (bipolar/unipolar modular)*

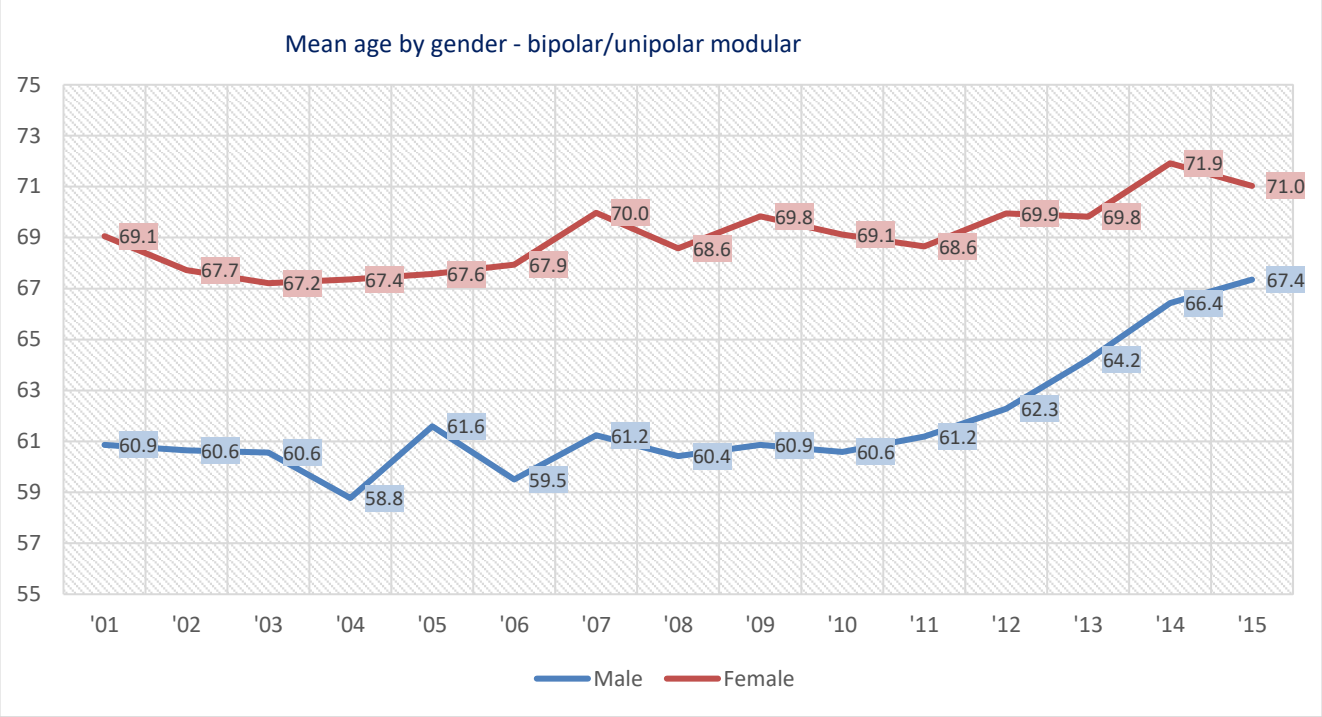


Figure 60 – Mean age by gender - bipolar/unipolar modular implants, 2001 – 2015

5.2.1.5 *Mean age at time of primary procedure by diagnosis and gender (bipolar/unipolar)*

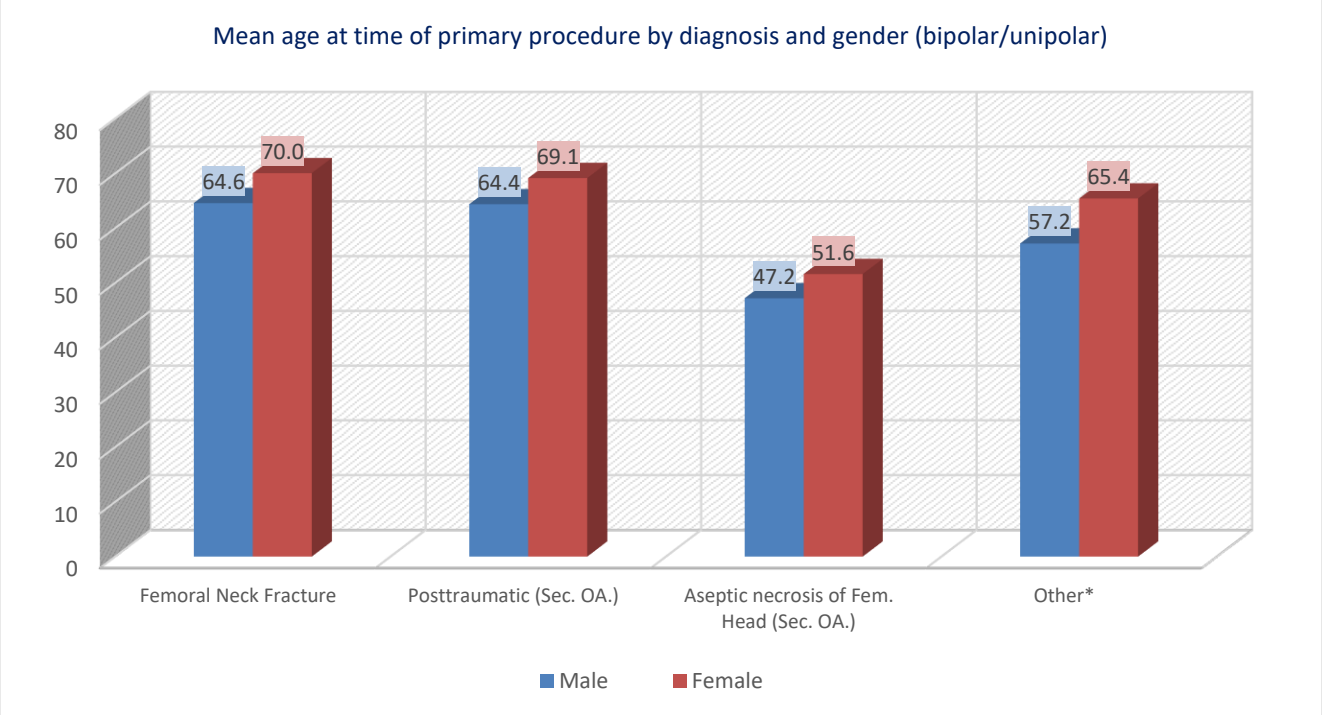


Figure 61 – Mean age at time of primary intervention by diagnosis and gender – bipolar/unipolar, 2001 – 2015

5.2.1.6 Fixation type evolution (bipolar/unipolar)

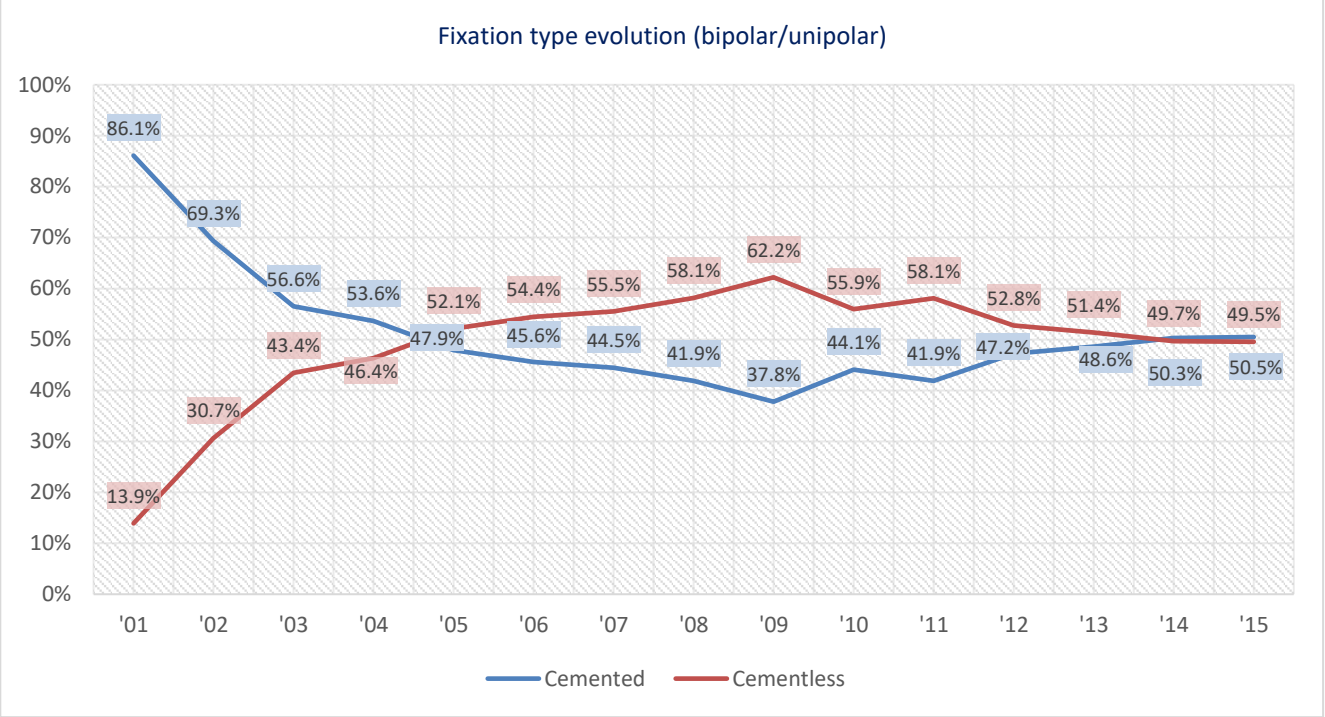


Figure 62 – Bipolar type of fixation evolution, 2001 – 2015

5.2.1.7 Reasons for "early" failure in Bipolar (incl. Unipolar) implants

Table 33 - "Early" failure in Bipolar (including Unipolar) implants

Years	Main reason of "early" failure	Percentages
0-1 years	Luxation	29.09%
1-2 years	Acetabular erosion	16.67%
2-3 years	Acetabular erosion	30.56%
3-4 years	Acetabular erosion	23.33%
4-5 years	Acetabular erosion	28.57%
5-6 years	Acetabular erosion	27.78%

5.2.2 Moore type implants

5.2.2.1 The „Moore" social economic phenomena

Table 34 – Number of THR and Moore type implants from other registers

Implant type	Romania (2014)	Australia (2014)	Great Britain (2014)	Norway (2014)	Sweden (2013)
Moore	2,695	690	0	0	0
THR	6969	35,320	83,886	8,099	16,609

**Data extracted from each country's most recent report at time of publication*

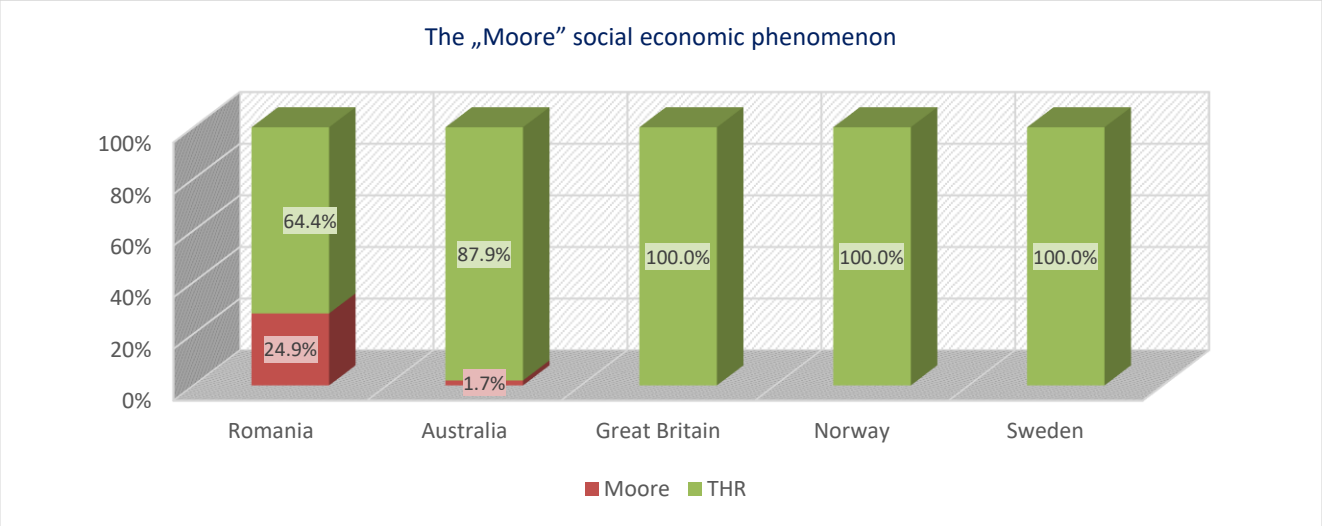


*Figure 63 – Share of Unipolar Monobloc (Moore type) vs. THR – country comparison based on the year 2015**

In Romania 2695 primary hip arthroplasties were performed using Moore type implants, even though studies have shown that this is a compromised option and has a high failure rate on the long run. Meanwhile in other countries Moore type endoprosthesis is no longer used or the usage is under 2%, R.A.R. data indicates a 24.9% Moore usage from the total number of primary arthroplasties performed in 2015.

5.2.2.2 Use of Moore type implants in Femoral Neck Fracture

Table 35 – Use of Moore type endoprostheses in Femoral Neck Fracture, 2001 - 2015

	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
Use of Moore in Femoral Neck Fracture	2871	1482	1744	2142	2212	2538	2548	2464	2645	2588	2623	**25857**
Total number of Moore	7783	1883	1836	2205	2304	2597	2600	2508	2689	2636	2695	**31736**
% of Femoral Neck Fracture from Moore	36.90%	78.70%	95.00%	97.10%	96.00%	97.70%	98.00%	98.20%	98.40%	98.20%	97.30%	**81.50%**
Use of Moore in Femoral Neck Fracture for elder patients (>70 years)	73.60%	77.10%	78.80%	78.30%	80.40%	79.00%	83.40%	84.50%	85.10%	87.40%	87.40%	**81.60%**

* Most recent data for the values.

The social and economic considerations that lead to the use of the Moore type hemiarthroplasty in time reveals a direct correlation between Femoral Neck Fracture and the procedures using Moore endoprostheses. In 2015, 97.3% of all Moore endoprostheses reported to the RAR were used for the treatment of the Femoral Neck Fracture.

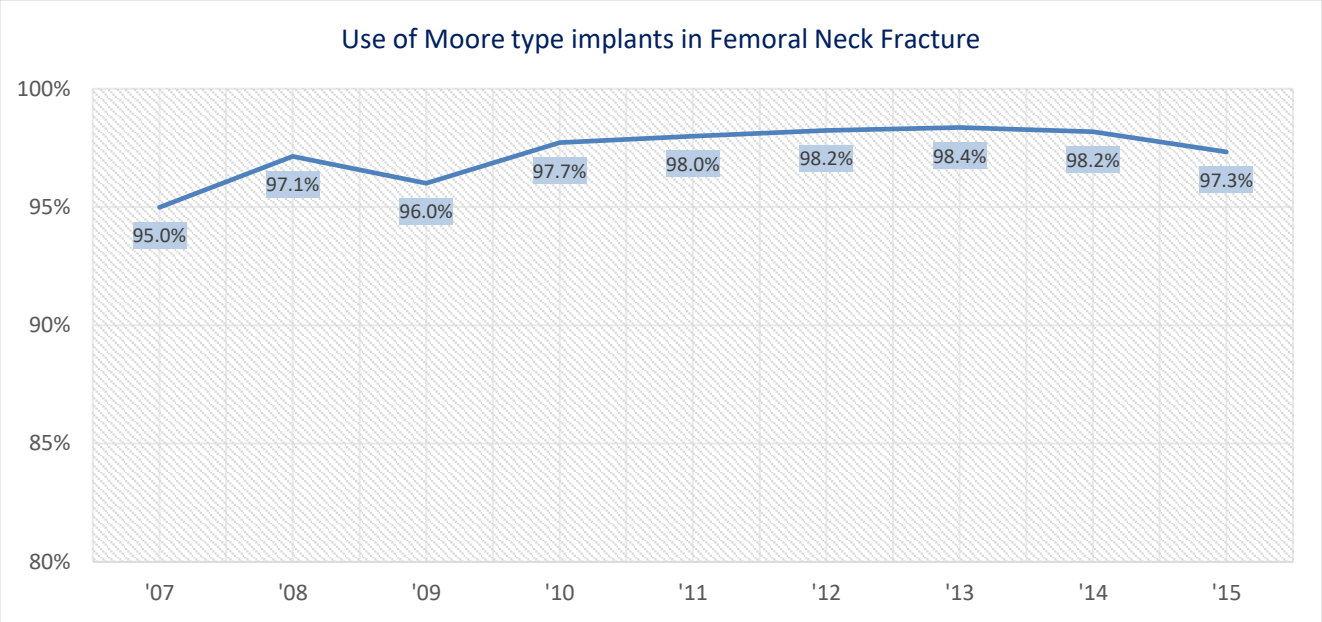


Figure 64 – Femoral Neck Fracture frequency as diagnosis in arthroplasties with Moore type implants, 2001 – 2015

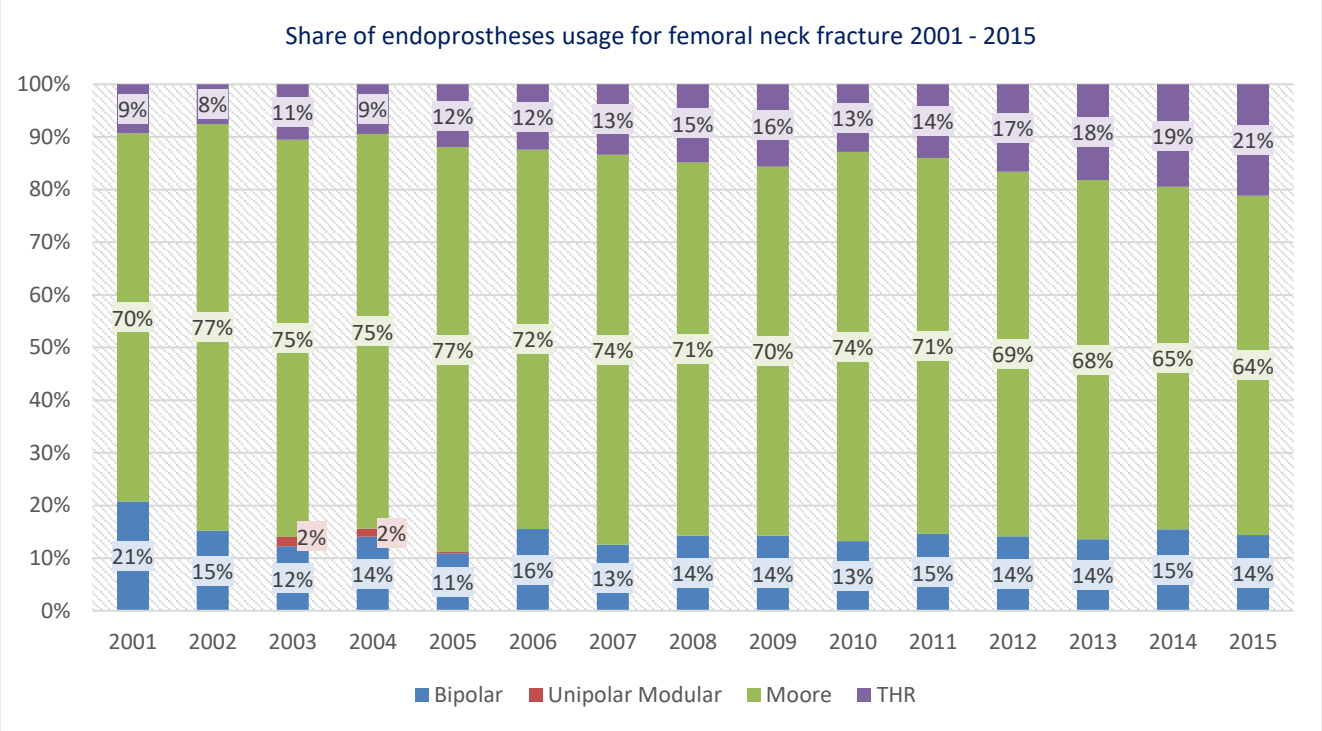


Figure 65 - Share of endoprostheses usage for femoral neck fracture diagnosis, 2001 - 2015

5.2.2.3 Most common Moore type implants

Table 36 - 15 most common Moore type implants, 2001-2015

Model	Manufacturer	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
Austin Moore-Step Ball	Auxein Medical	0	0	0	0	0	267	1101	1281	1149	1153	923	**5874**
Austin Moore Prosthesis	Reda Instrumente	1492	1095	981	514	357	127	31	26	10	1	1	**4635**
Austin Moore	Stryker Howmedica Osteonics	1999	241	165	138	168	181	142	159	65	91	96	**3445**
Austin Moore 118.1	ASCO	0	27	235	754	929	910	197	58	16	11	10	**3147**
Austin Moore	Adler	0	0	0	70	197	252	224	283	591	510	550	**2677**
Austin Moore	Tipmed	0	0	0	71	160	396	329	234	396	447	414	**2447**
Austin Moore Prosthesis	Surgival	227	135	120	135	147	151	174	190	199	164	251	**1893**
Moore Hip Prosthesis	TST Medical Devices	0	141	213	241	93	36	23	2	9	3	0	**761**
Austin Moore Prosthesis	Biomet	212	8	15	47	42	43	44	54	74	87	23	**649**
Austin Moore	Global Products Corporation	0	10	29	42	51	38	47	16	3	24	285	**545**
Austin Moore Prosthesis	Narang Medical	0	2	65	125	19	24	137	73	6	3	0	**454**
Austin Moore	Shakti	0	0	0	5	53	74	36	4	59	110	96	**437**
Austin Moore Prosthesis	V2-Evren	278	77	4	7	10	2	3	2	0	0	0	**383**
Austin Moore	Hipokrat As	0	0	0	0	0	39	83	89	50	8	7	**276**
Austin Moore 117.1	ASCO	0	0	2	29	40	0	0	0	0	1	0	**72**

5.2.2.4 Moore type implants by main diagnosis and age groups

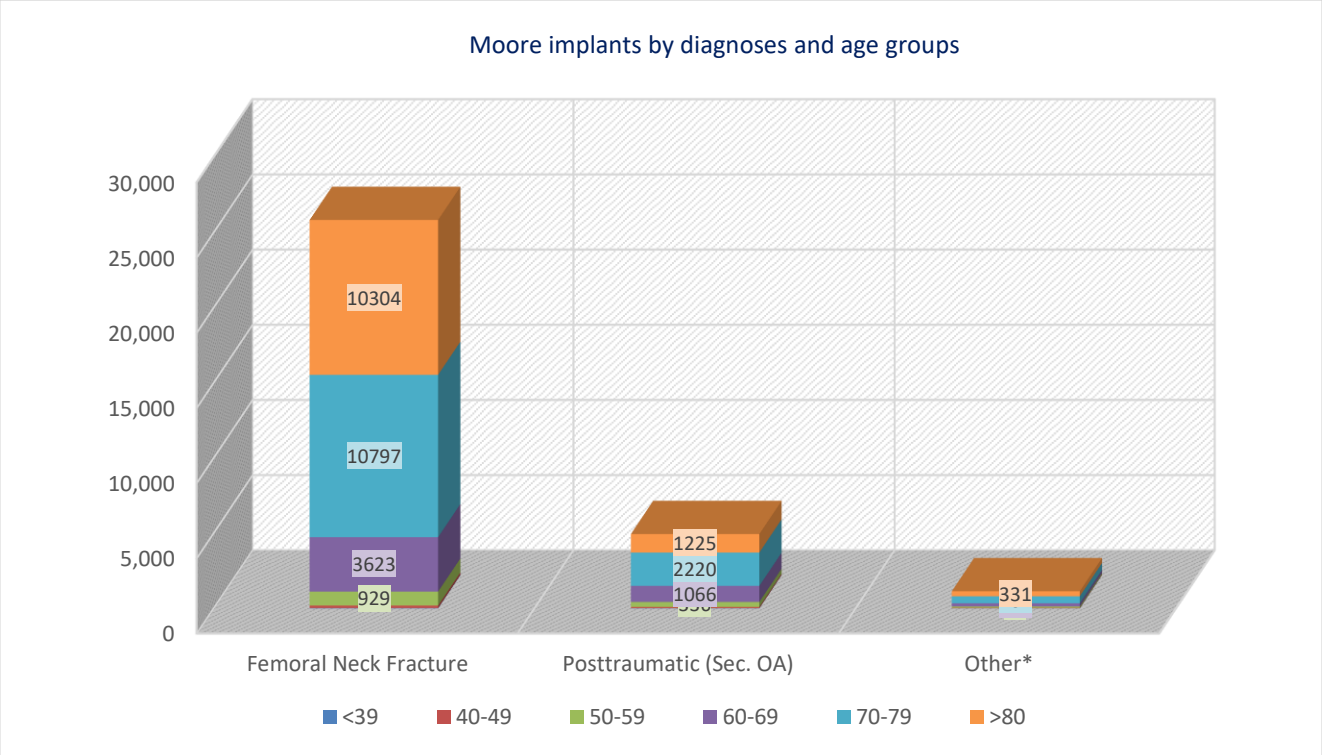


Figure 66 – Moore type implants by diagnosis frequency and age groups, 2001 – 2015

**un-standardized diagnosis (custom input provided by surgeon) incl. Post-Perthes, primary OA & secondary OA*

5.2.2.5 Moore type implants by age groups and diagnoses

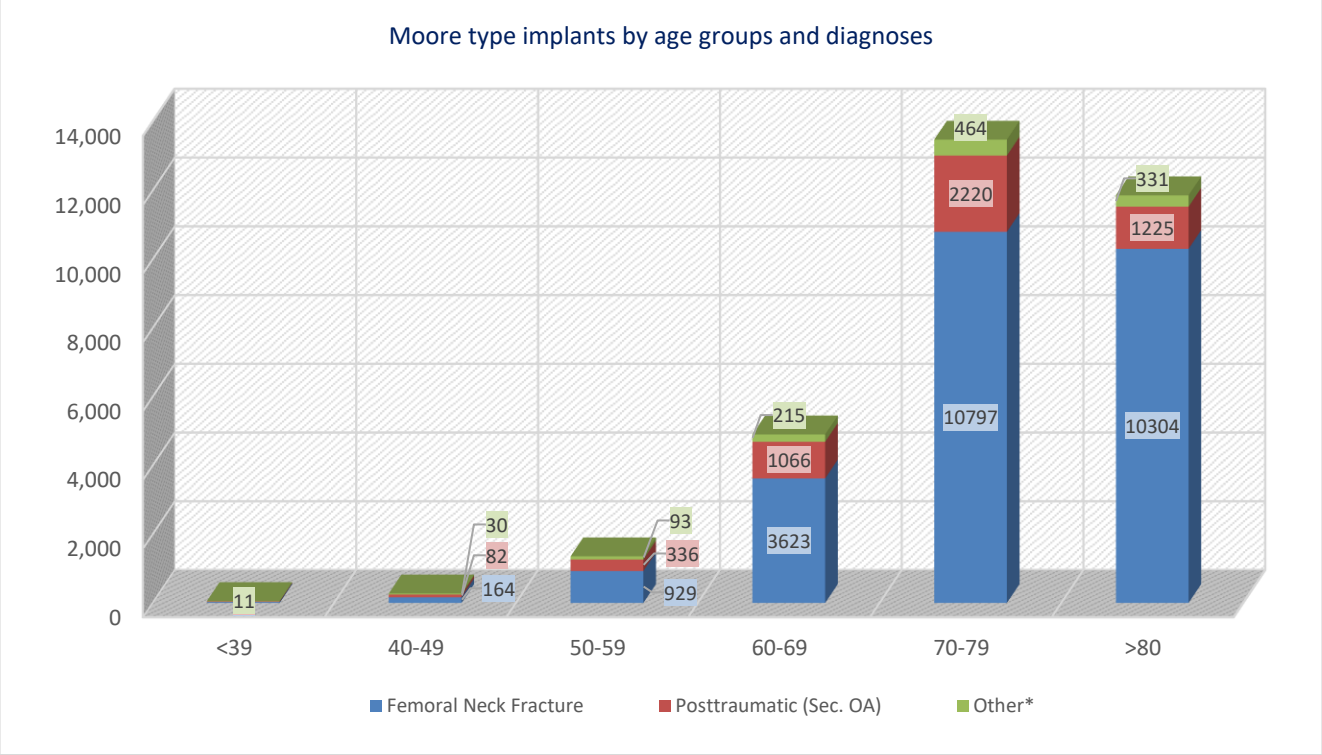


Figure 67 – Moore type HA by age group and diagnoses frequencies, 2001 – 2015

**un-standardized diagnosis (custom input provided by surgeon) incl. Post-Perthes, primary & secondary OA*

5.2.2.6 Distribution of Moore type implants by diagnosis and gender

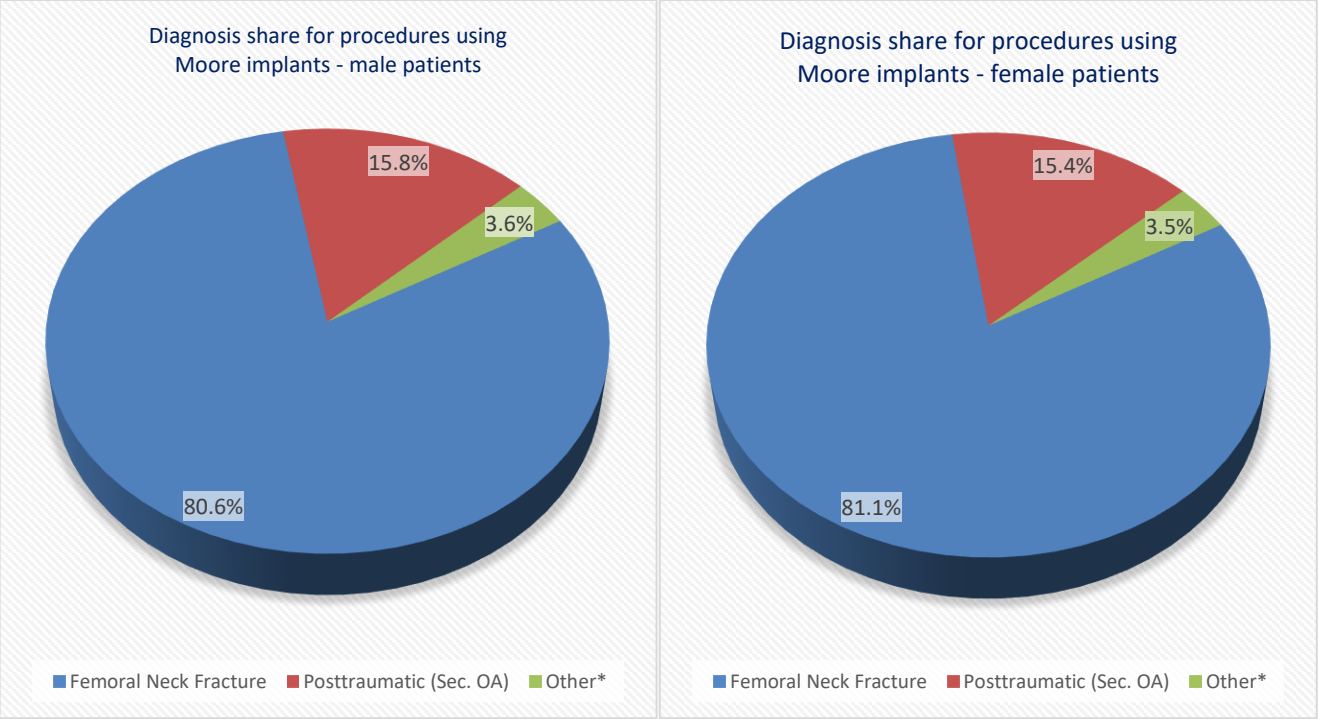


Figure 68 - Distribution of Moore type implants by diagnosis frequency and gender, 2001 – 2015

**Including primary OA, R.P. or A.A., Post-Perthes, Pseudarthrosis, Aseptic necrosis of Fem. Head, Dysplasia.*

5.2.2.7 *Mean age at time of primary procedure by gender (Moore type implants)*

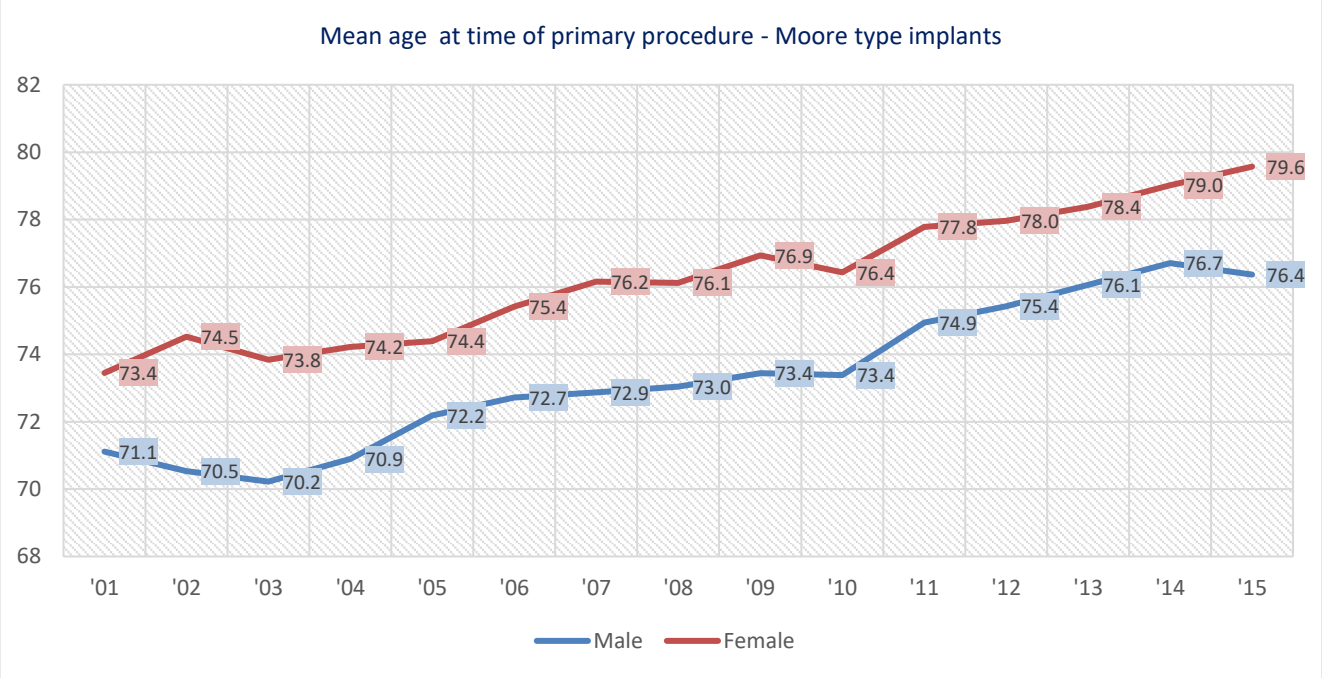


Figure 69 – Mean age at time of primary procedure (Moore type implants), 2001 – 2015

5.2.2.8 *Distribution by age groups and gender in Moore type implants*

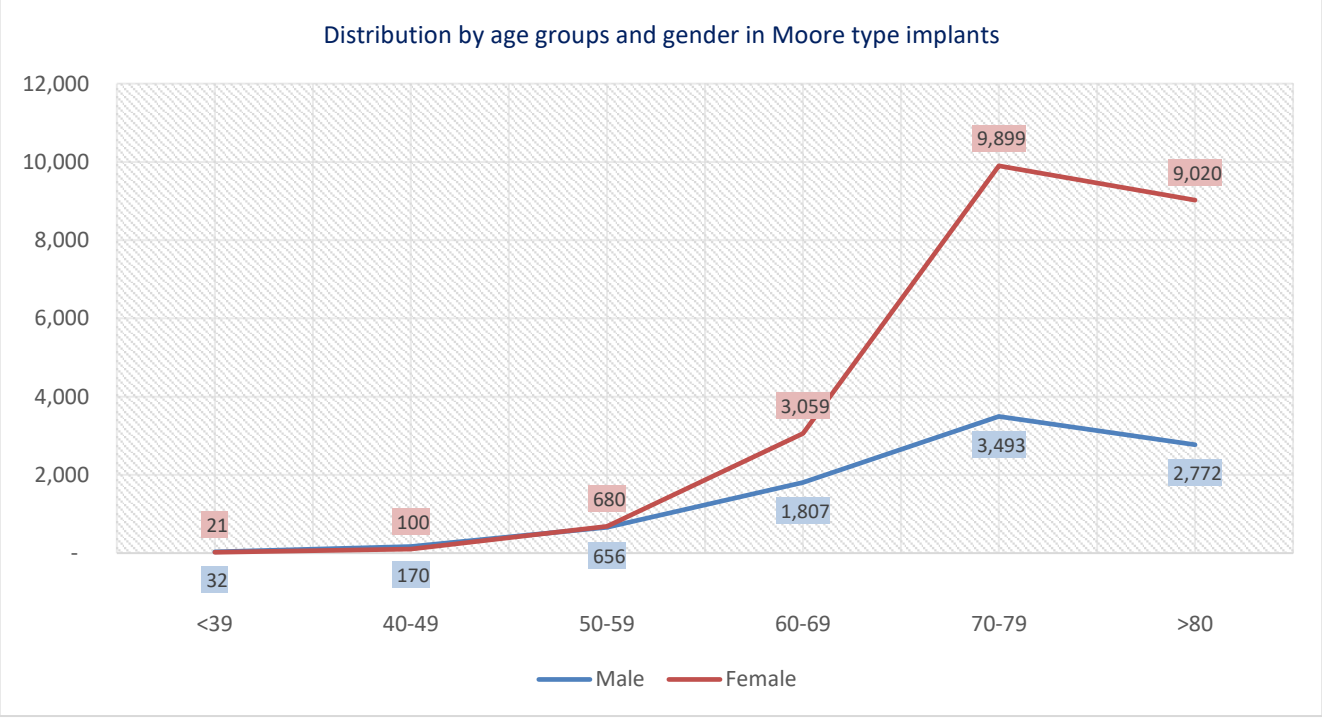


Figure 70 - Distribution by age groups and gender in Moore type implants, 2001 – 2015

5.2.2.9 Mean age at time of primary procedure using Moore type implants by diagnosis and gender

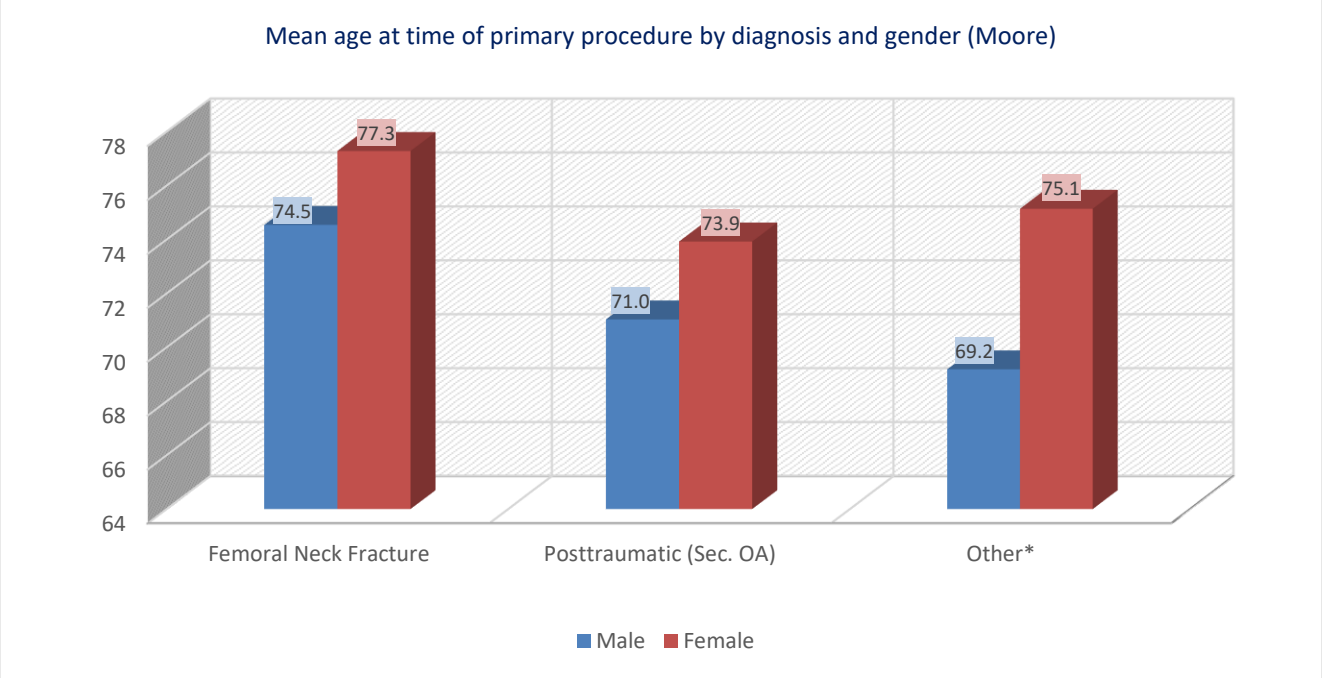


Figure 71 - Mean age at time of primary procedure using Moore type implants by diagnosis and gender, 2001 – 2015

**un-standardized diagnosis (custom input provided by surgeon) incl. Post-Perthes, primary and secondary OA*

5.2.2.10 Moore implants share in primary hip arthroplasties

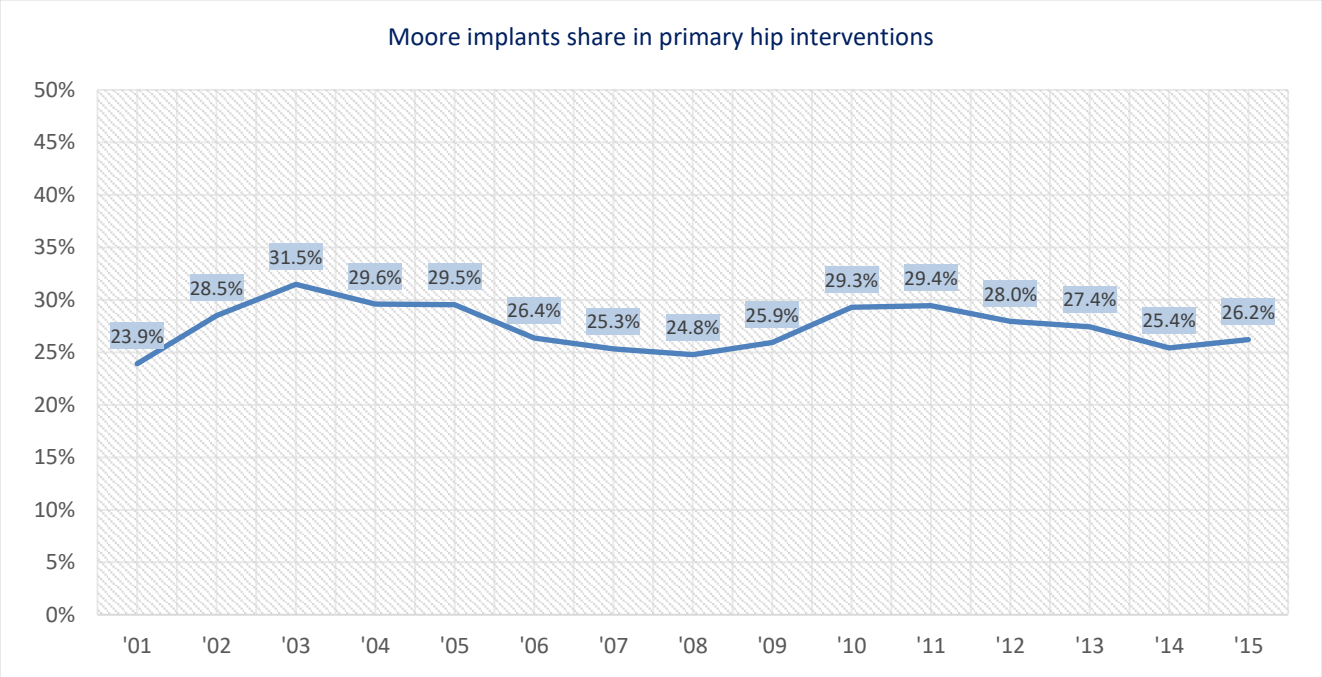


Figure 72 - Moore implants share in primary hip arthroplasties, 2001 – 2015

The percent of Moore type implants in primary hip interventions shows that over a 14-years observational period remains at an alarming rate (26.2% in 2015).

5.2.2.11 Reasons for "early" failure for Moore type implants

Table 37 - "Early" failure in Moore type implants, 2001-2015

Years	Main reason of "early" failure	Percentages
0-1 years	Acetabular erosion	41.67%
1-2 years	Acetabular erosion	55.60%
2-3 years	Acetabular erosion	65.25%
3-4 years	Acetabular erosion	71.62%
4-5 years	Acetabular erosion	61.33%
5-6 years	Acetabular erosion	51.79%

5.2.3 Discussion on hemiarthroplasties

Considering the results of an observational period of 14 years, it is shown that Romania has a large number of hemiarthroplasties (32.2% in 2015), especially Moore type implants (26.2% in 2015) out of all primary implants. This fact is most likely due to an imbalanced medical and financial system where the lack of resources put pressure on the medical act and the surgeon must consider rather cheap implants for treating emergencies.

For the procedures where Moore type implants were used, female patients are predominant for age groups over 60 years old, with a peak of 73.9% of all patients in age group 70-79.

Femoral neck fractures represent the main Diagnosis in Hemi-Arthroplasties (68.2%), only 16.1% of them are treated using a Bipolar/Unipolar modular type implant, with a clear majority of 80.2% treated with Moore type implants. Almost 98% of all Moore type implants are used in Femoral Neck Fractures.

The main reason for “Early Failure” is Acetabular Erosion for both Bipolar (16-30%) and Moore Type (55%-70%) implants, except for 0-1 years in Bipolar Implants (Luxation).

In the post-traumatic group of patients treated with a hemiarthroplasty, we assume that the correct diagnosis is a femoral neck fracture, poorly reported to RAR between 2001 and 2006.

6 Arthroplasty re-operations

Definitions:

- **Re-operations** are comprised of the total number of revisions, plus the total number of complications that did not necessarily require re-implantation (e.g. soft tissue). Any form of open procedure after hip arthroplasty.
- **Revisions** are re-operations that require partial or total implant exchange.
- **Total Revision** are re-operations that require the exchange of both acetabular and femoral components.
- **Conversion type revisions** are total revisions that originate from hemiarthroplasties (Bipolar or Moore type). This sub-category was created to underline the hemiarthroplasty phenomena, without influencing the Total or Partial revisions originating from primary total hip replacements.
- **Partial revisions** are re-operations that require the exchange of only one of either the acetabular or femoral components.
- **Complications** are re-operations that do not use immediate re-implantation of a new implant (e.g. soft tissue debridement, cement spacer, short-term re-interventions, etc.).
- **Revision burden** represents the proportion of revisions from total number of arthroplasties

6.1 Revisions

6.1.1 Introduction to hip revision

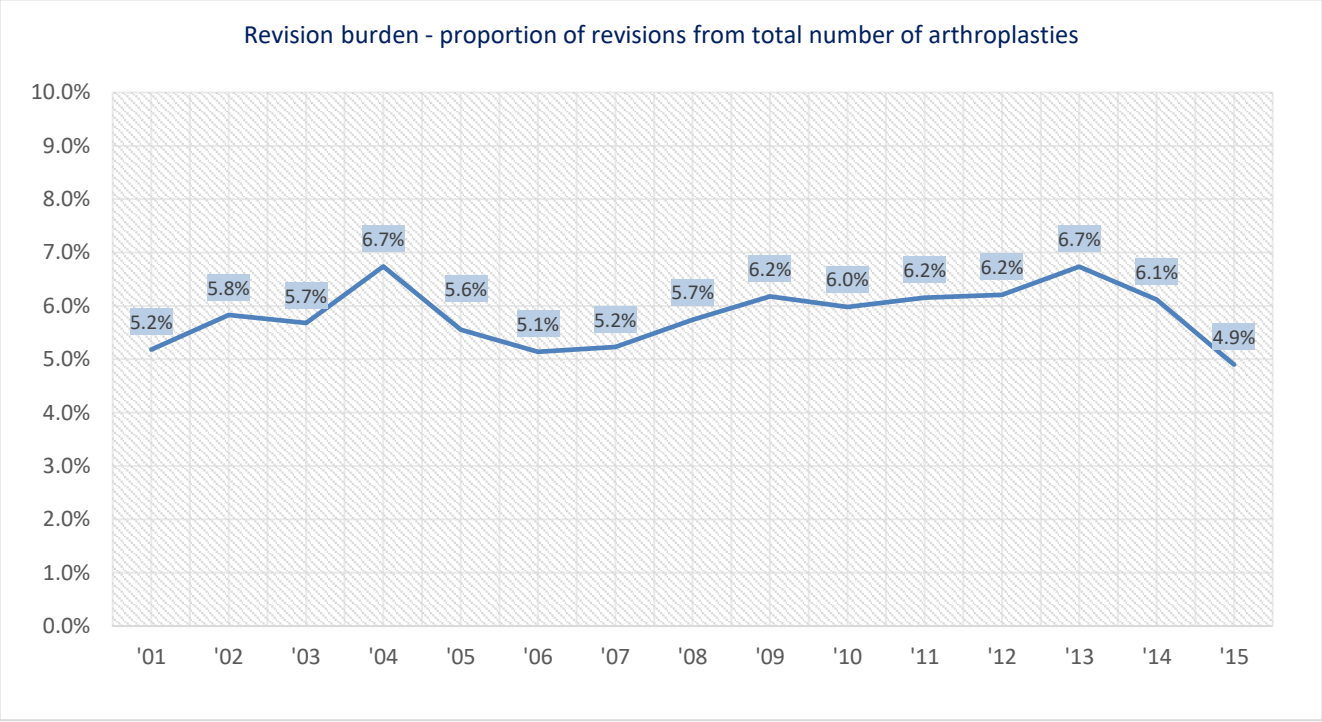


Figure 73 – Revision arthroplasties percentage out of all arthroplasties performed in Romania, from 2001 – 2015

6.1.1.1 Number of primary hip arthroplasties per 1 revision

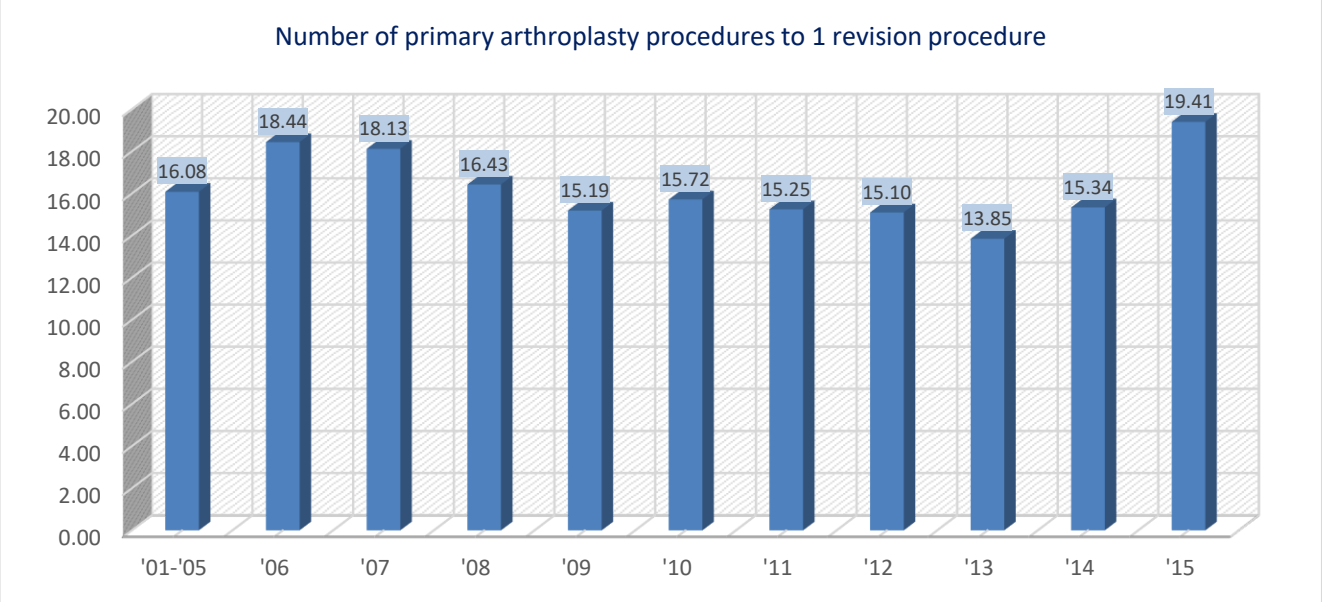


Figure 74 - Number of primary hip arthroplasties per 1 revision , 2001 – 2015

Table 38 – Number of primary to revision implants, 2001-2015

	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Grand Total
Primary hip	26,760	7,138	7,250	8,904	8,887	8,866	8,830	8,971	9,807	10,370	10,286	**116,069**
Revision hip	1,664	387	400	542	585	564	579	594	708	676	530	**7,229**
Ratio of primary to revision	16.1	18.4	18.1	16.4	15.2	15.7	15.3	15.1	13.9	15.3	19.4	**16.1**

6.1.1.2 Hip Revisions by type of revision

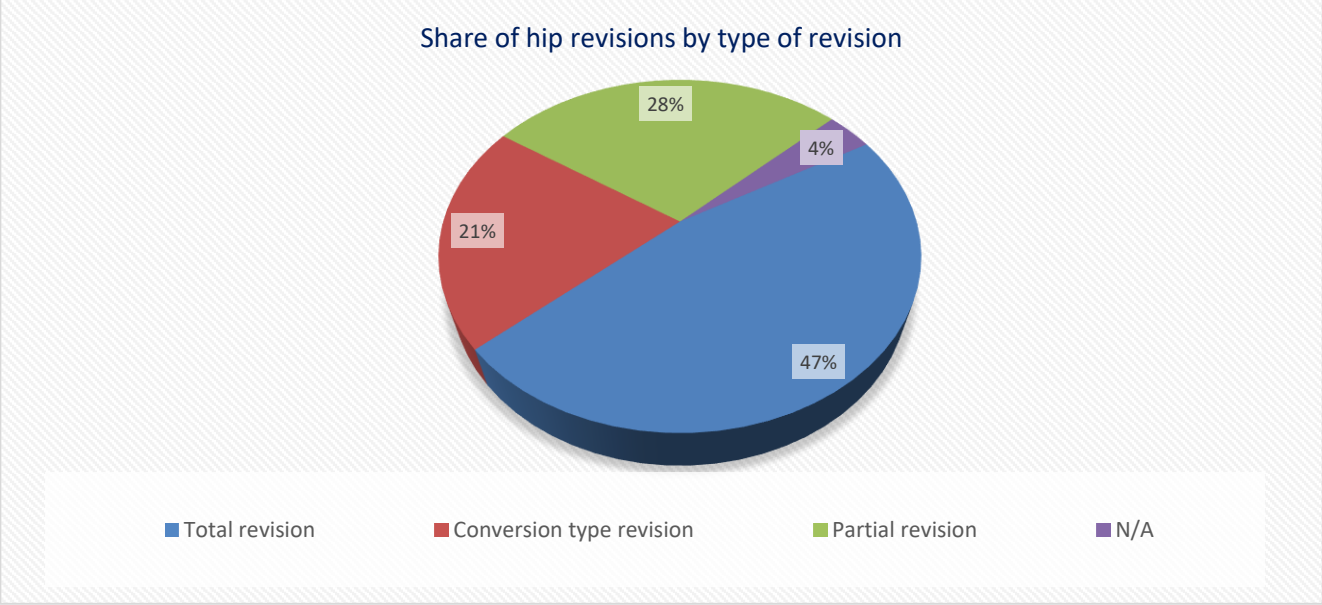


Figure 75 – Share of Hip Revisions by type of revision, 2001 - 2015

Table 39 – Number of hip revisions by type of revision, 2001-2015

Revision type	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
Total revision	824	159	167	253	268	243	225	240	273	261	225	**3,138**
Partial revision	449	122	129	142	177	170	164	196	217	242	188	**2,196**
Conversion type revision	342	84	85	123	114	114	137	114	134	116	84	**1,447**
Other*	49	22	19	24	26	37	53	44	84	57	33	**448**
Total	**1,664**	**387**	**400**	**542**	**585**	**564**	**579**	**594**	**708**	**676**	**530**	**7,229**

**Other – information on type of revision not available.*

6.1.1.3 Use of primary and revision type components in revision arthroplasty

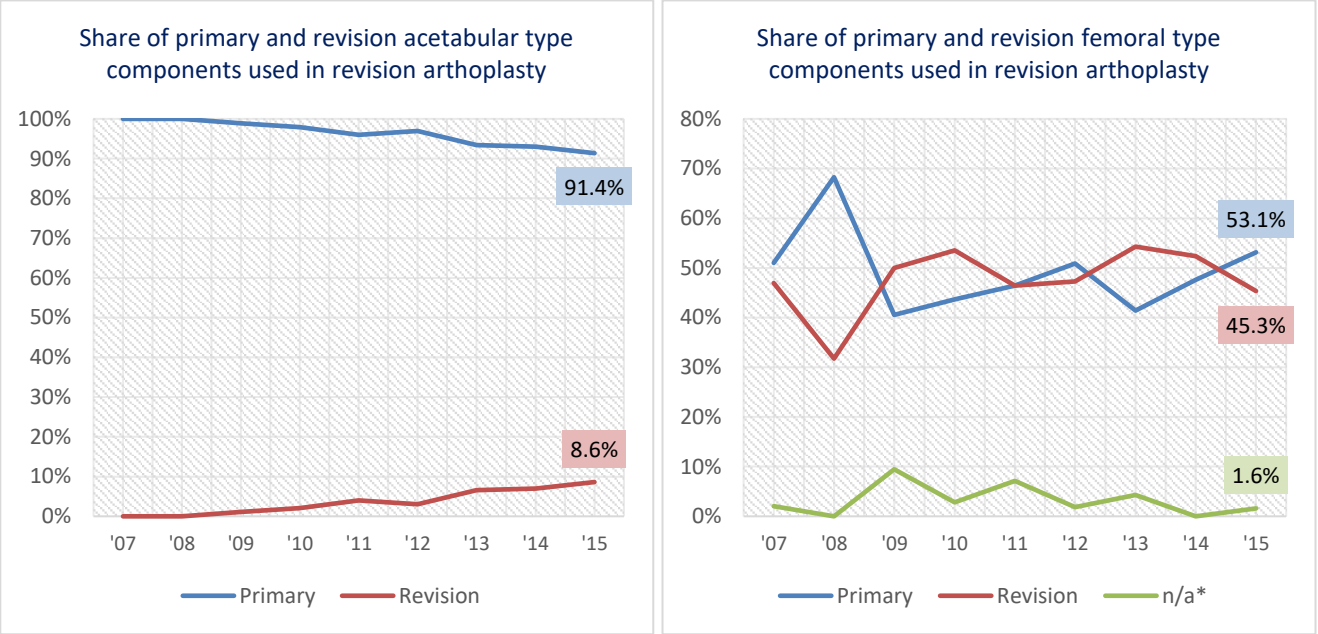


Figure 76 - Use of primary and revision type components in revision arthroplasty (acetabular and femoral components), 2007 – 2015

Note: Data is not available until 2007.

**n/a – information about femoral type components is missing*

6.1.1.4 Hip revisions by age group and gender

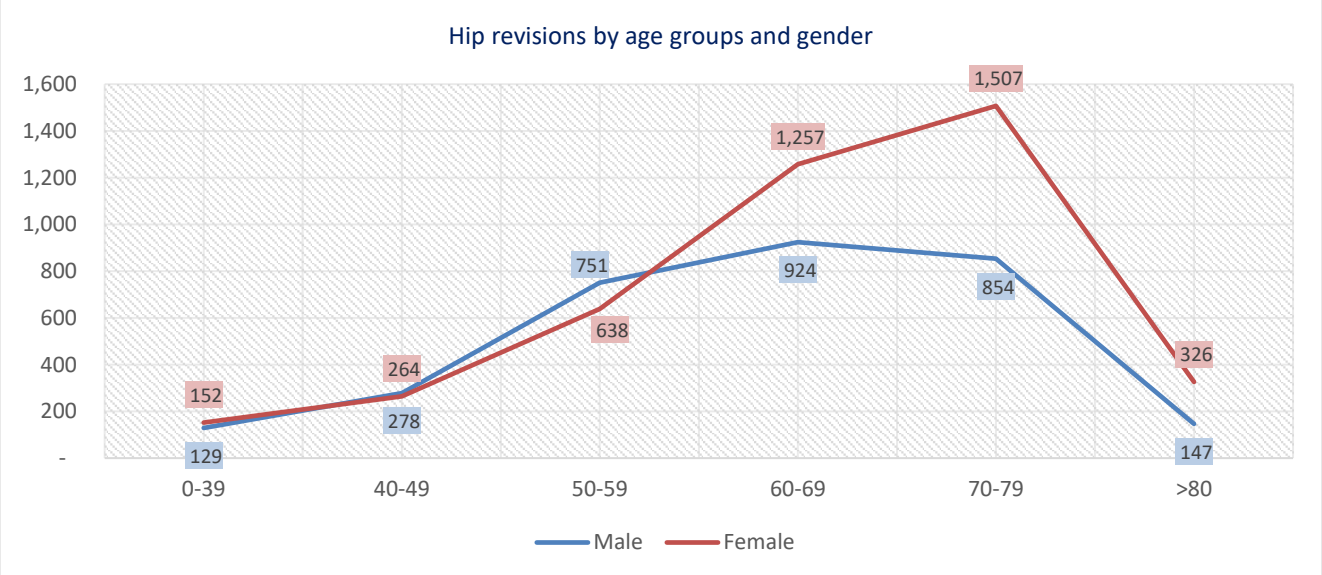
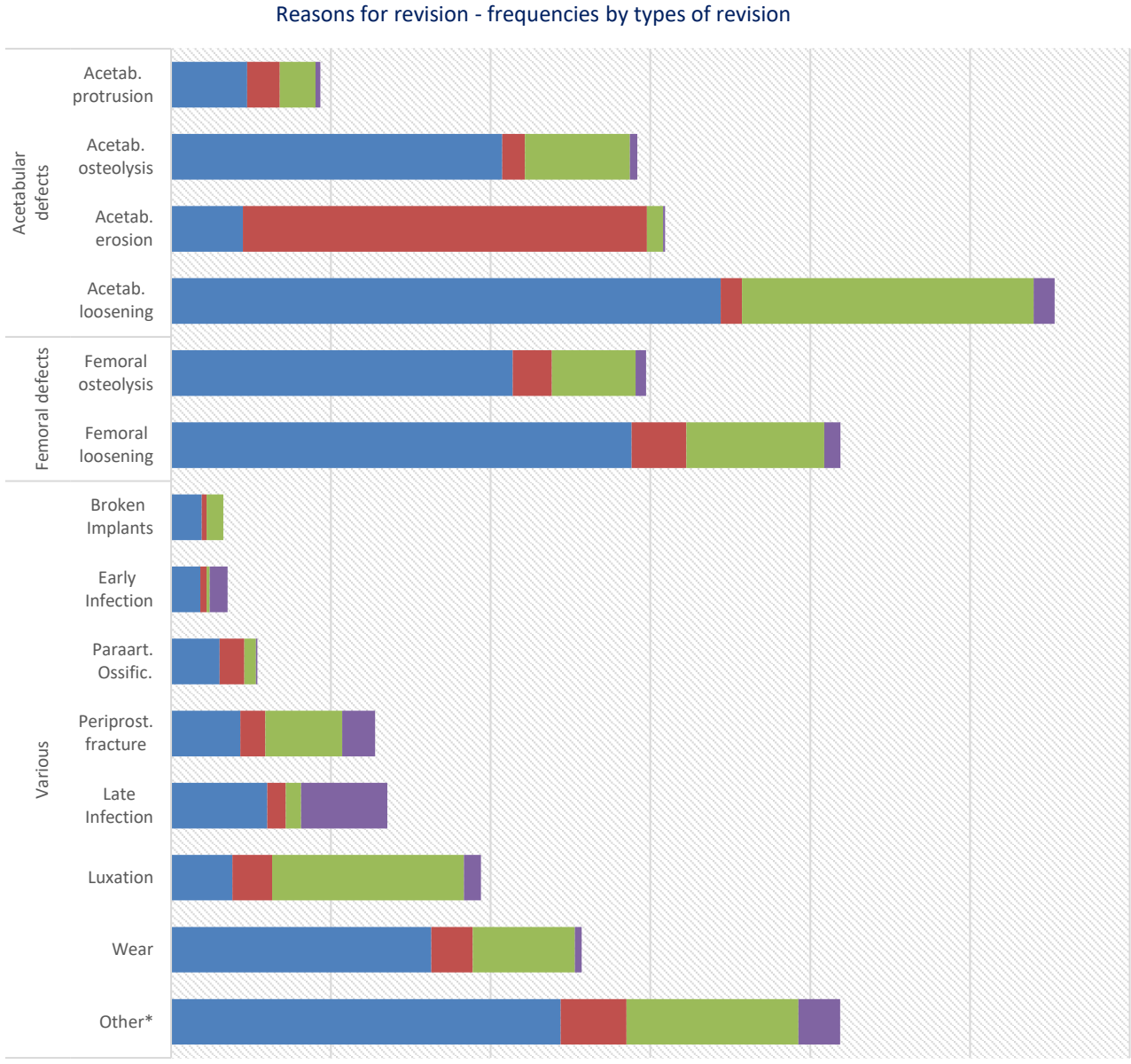


Figure 77 - Hip revisions by age group and gender, 2001 – 2015

6.1.1.5 Reasons for revision – occurrence frequency by types of revision



	Various								Femoral defects		Acetabular defects			
	Other*	Wear	Luxation	Late Infection	Periprost. fracture	Paraart. Ossific.	Early Infection	Broken Implants	Femoral loosening	Femoral osteolysis	Acetab. loosening	Acetab. erosion	Acetab. osteolysis	Acetab. protrusion
Total revision	12.19%	8.14%	1.92%	3.01%	2.16%	1.52%	0.92%	0.96%	14.41%	10.69%	17.19%	2.25%	10.36%	2.38%
Conversion revision	2.06%	1.30%	1.25%	0.58%	0.78%	0.77%	0.19%	0.15%	1.71%	1.23%	0.67%	12.65%	0.71%	1.01%
Partial revision	5.38%	3.19%	6.00%	0.48%	2.41%	0.37%	0.10%	0.52%	4.32%	2.62%	9.12%	0.51%	3.29%	1.12%
N/A*	1.30%	0.22%	0.53%	2.70%	1.03%	0.04%	0.56%	0.00%	0.51%	0.33%	0.66%	0.05%	0.23%	0.15%

Figure 78 - Occurrence frequency of revision reasons in the total number of revisions (N=7229) by type of procedure, 2001 – 2015

**un-standardized reason for revision (custom input provided by surgeon)*

6.1.1.6 Hip revisions by revised elements

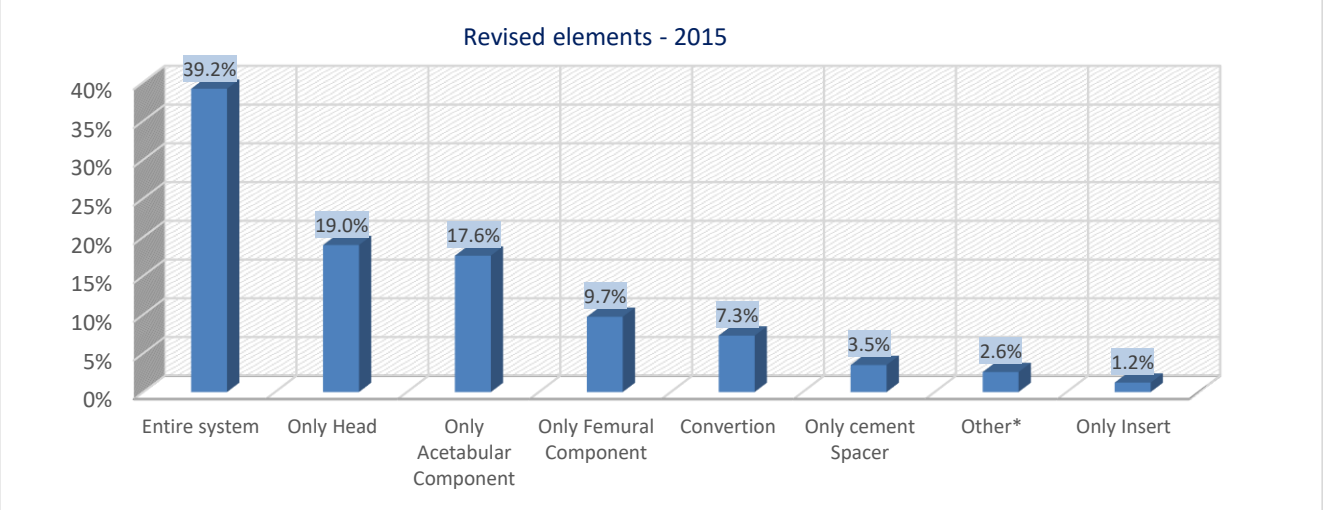


Figure 79 - Revised elements proportion, 2015

** Un-standardized revised element (custom input provided by surgeon/ possibility of multiple elements revised)*

***The percentages were calculated from the total number of revised elements, not from the total number of revisions*

6.1.1.7 Hip revisions that required acetabular or femoral reconstructions

Table 40 – Number of acetabular and femoral reconstructions, 2001-2015

	Structural bone grafts	Morselized bone grafts	Ring	Net	Reconstructions
Number of acetabular reconstructions	398	791	452	0	**1243**
Number of femoral reconstructions	168	248	0	72	**460**
Total number of revisions with reconstruction	566	1039	452	72	**1703**

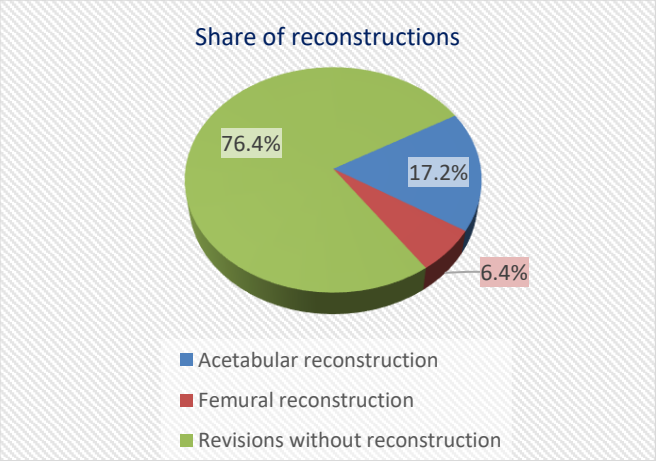


Figure 80 – Share of reconstructions, 2001 – 2015

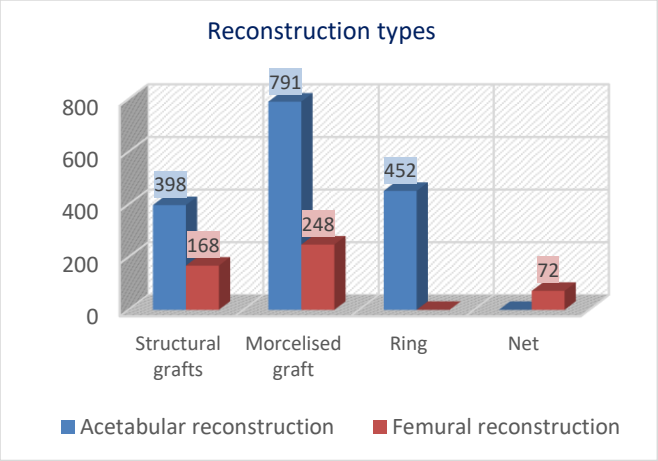


Figure 81 – Reconstruction types, 2001 – 2015

**Ring is available only for acetabular reconstruction and net is available only for femoral reconstruction*

Table 41 – Number of femoral and acetabular reconstructions by revision type, 2001 -2015

	Acetabular reconstruction	Femoral reconstruction	Revisions
Total revision	834	312	3138
Conversion type revision	71	34	1447
Partial revision	331	93	2196
n/a*	7	21	448
Grand Total	**1243**	**460**	**7229**

** data on previous implant not available*

6.1.1.8 *Revision procedures by County – percentage of total number of revisions performed in Romania*

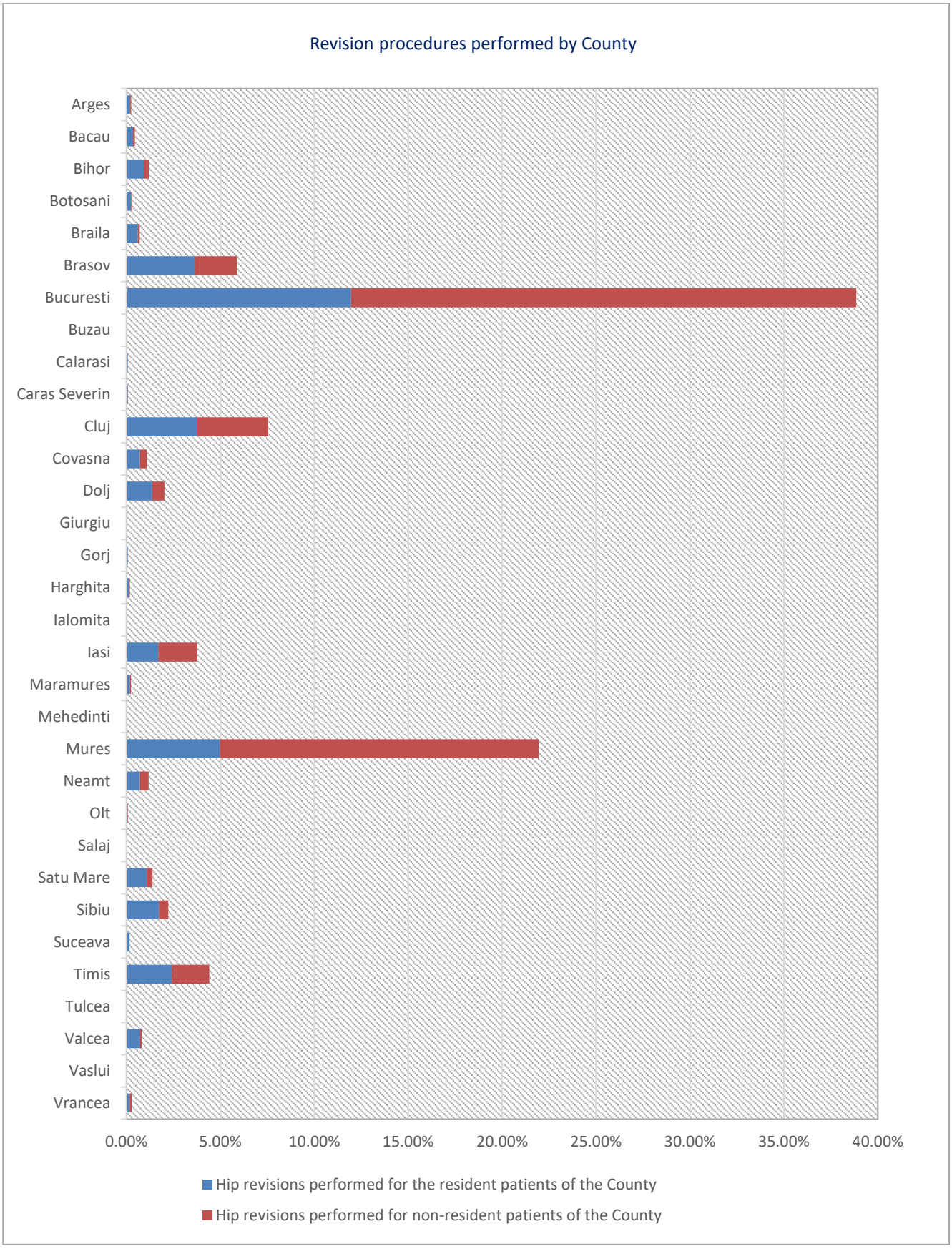


Figure 82 - Revision procedures - % of total number of revisions performed in Romania between 2001 - 2015

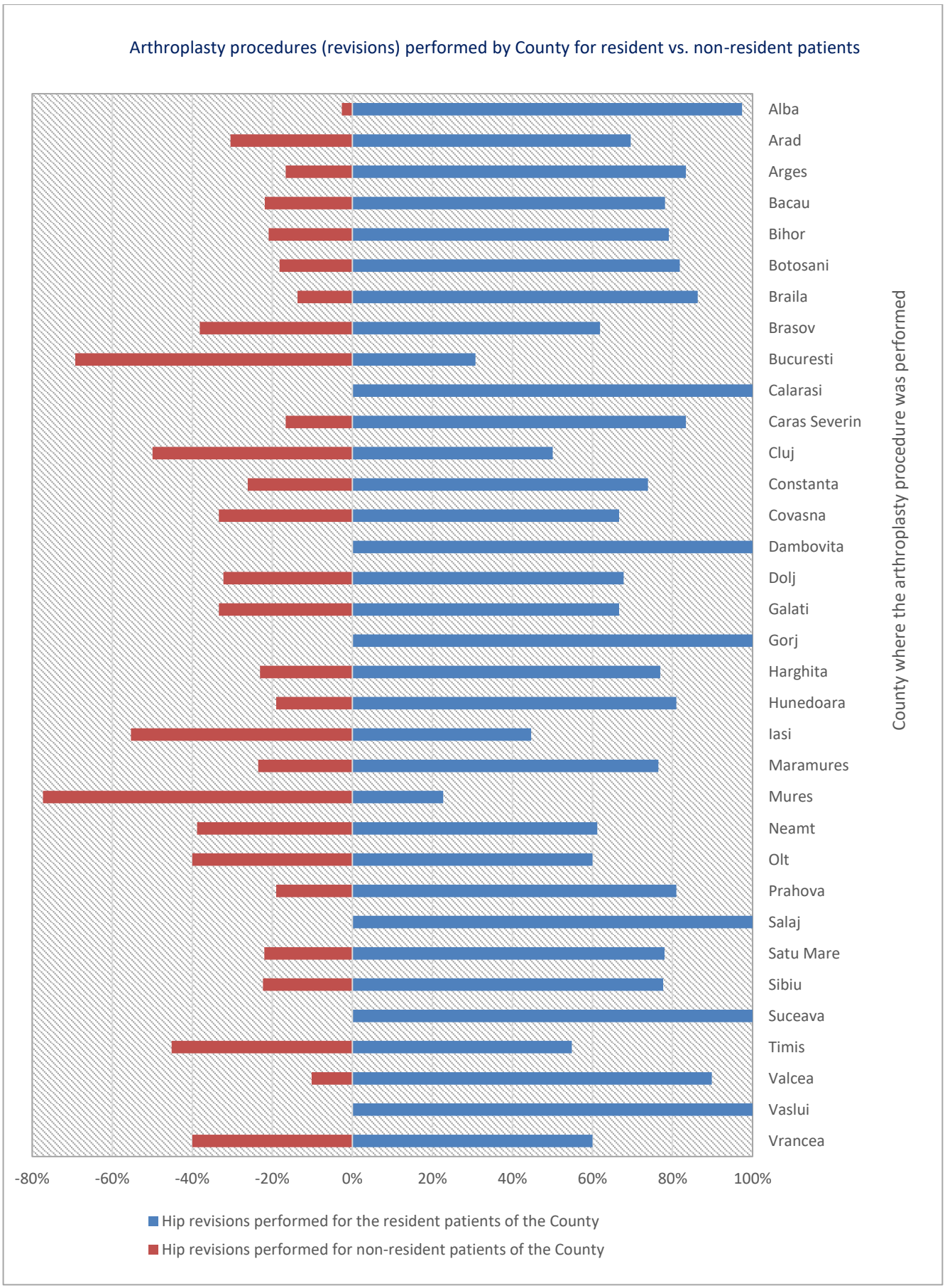


Figure 83 - Arthroplasty procedures (revisions) performed by County for resident vs. non-resident patients in Romania, 2001 – 2015

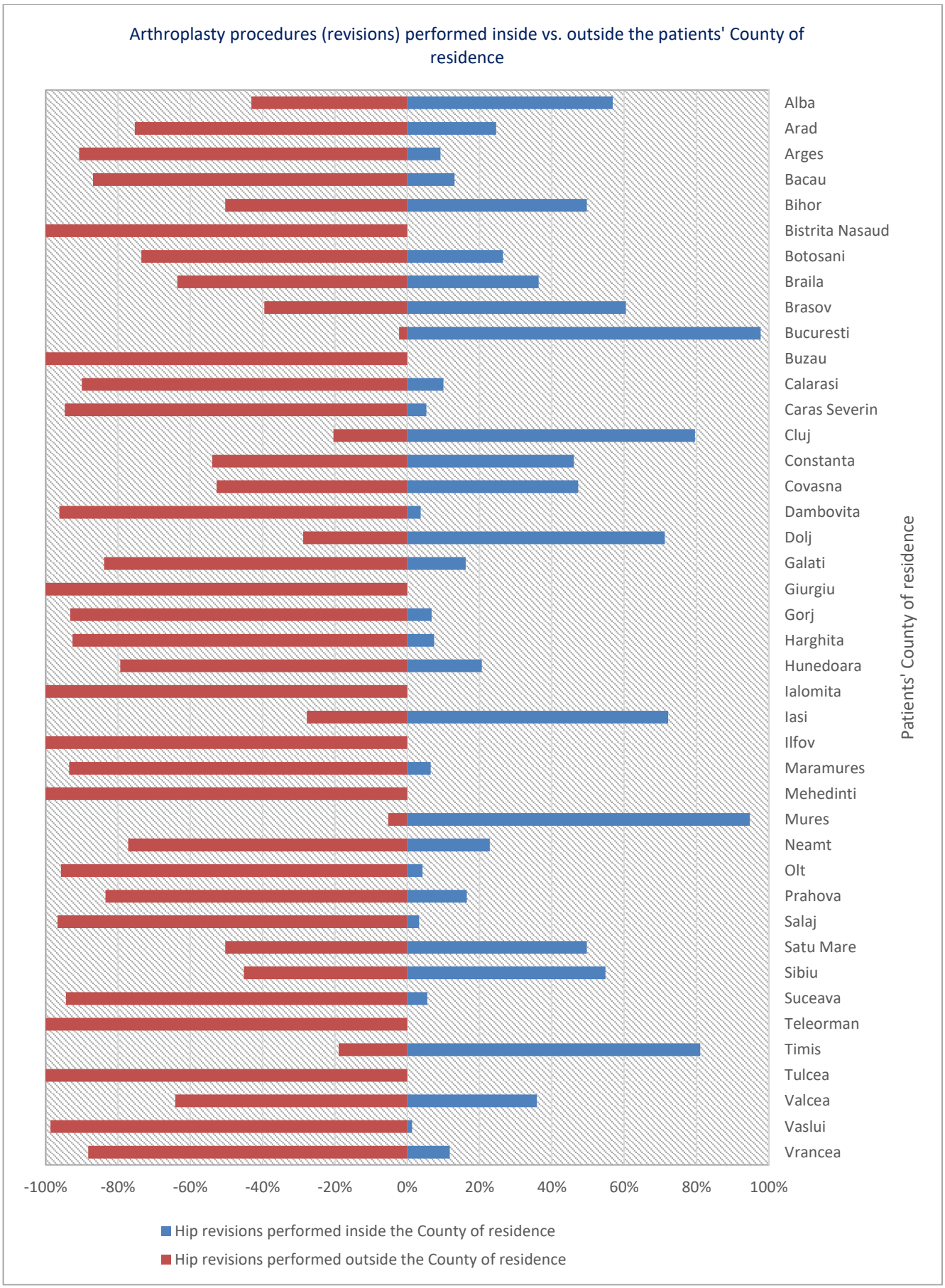


Figure 84 - Arthroplasty procedures (revisions) performed inside vs. outside the patients' County of residence in Romania, 2001 - 2015

6.1.2 Total revisions

6.1.2.1.1 Total type revisions – reasons for revision percentage frequency

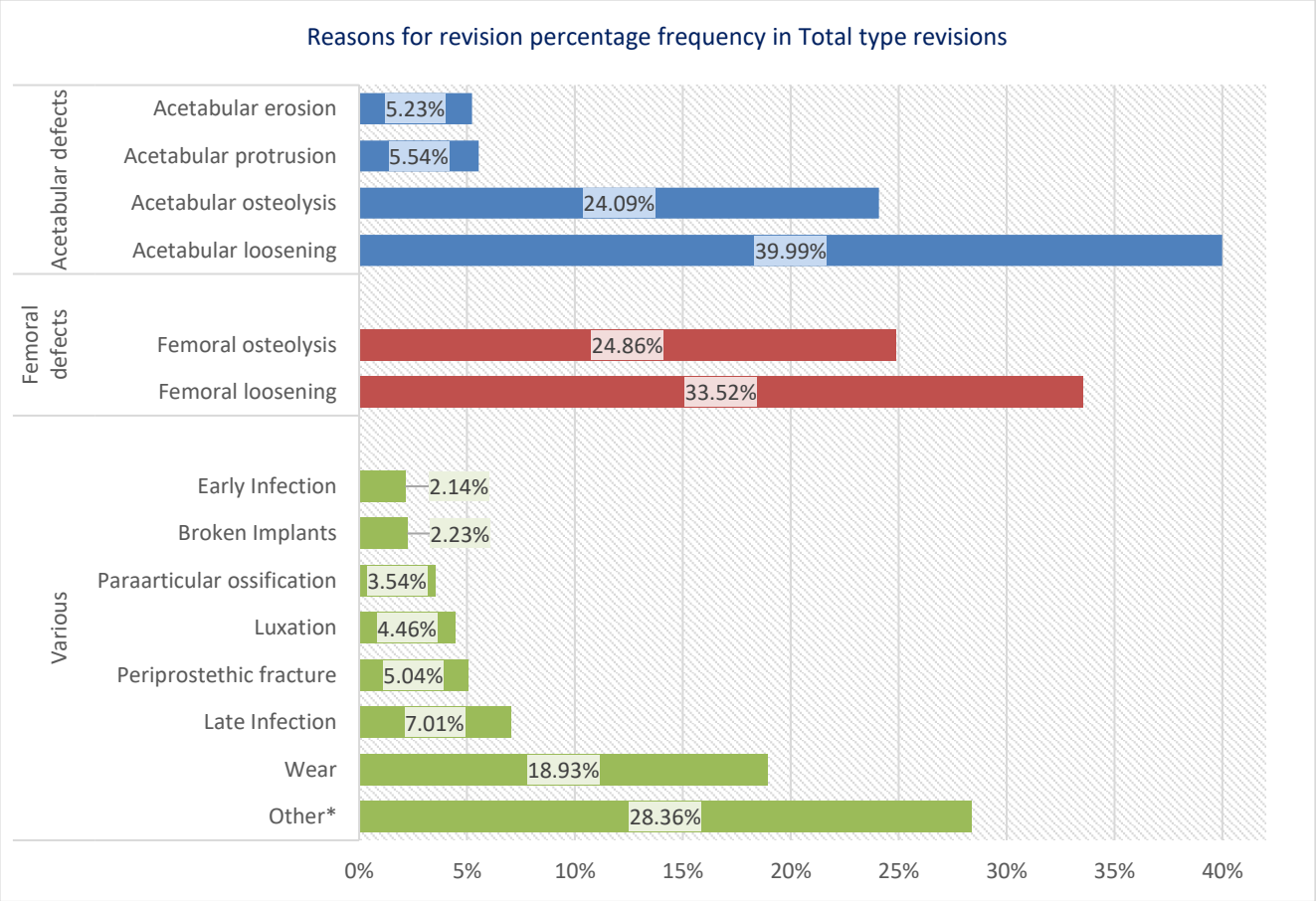


Figure 85 – Reasons for revision percentage frequency in all Total type revisions, 2001 – 2015

**un-standardized reasons for reoperation (custom input provided by surgeon)*

6.1.2.1.2 Total revisions - types of fixation share

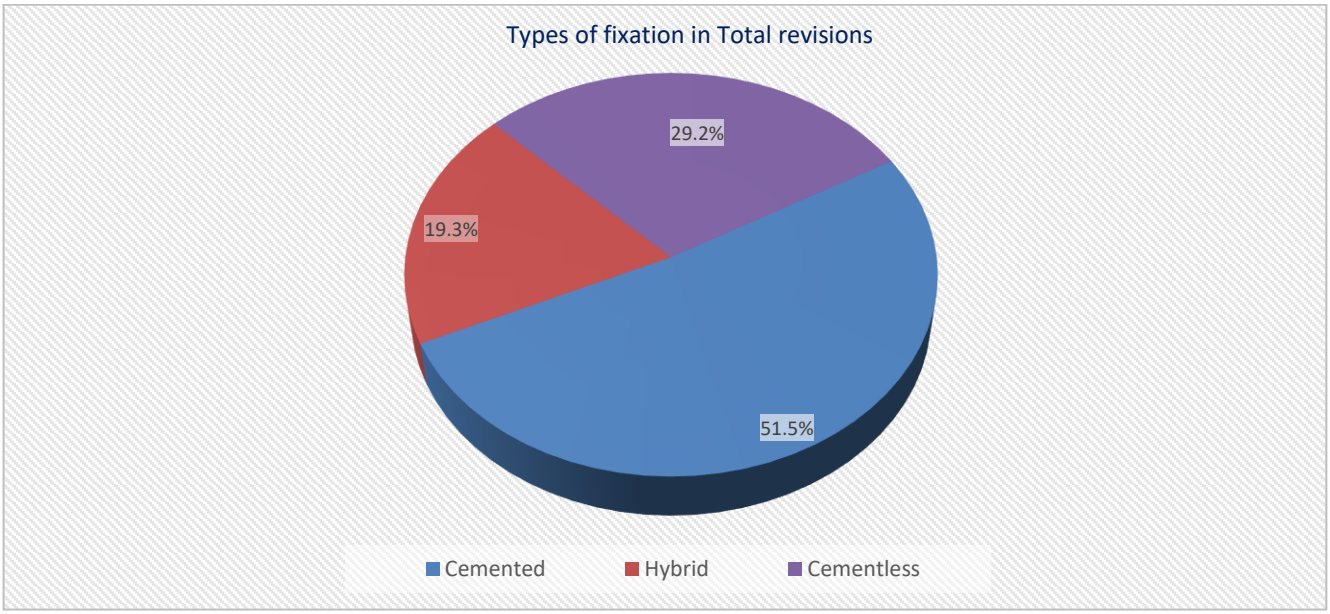


Figure 86 – Share of all types of fixation in Total revisions, 2001 – 2015

6.1.2.1.3 15 most common acetabular components implanted in total revision

Table 42 – 15 most common cemented acetabular components implanted in total revision, 2001 -2015

Cup	Manufacturer	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
Polyethylene Acetabular Cup (Omnifit)	Stryker Howmedica Osteonics	219	30	41	63	69	38	50	49	38	40	36	**673**
ZCA All-Poly Cup	Zimmer	4	14	17	38	64	53	46	50	73	55	36	**450**
Rim Acetabular Cup	Biotechni	55	11	8	9	10	18	15	17	19	18	27	**207**
Muller-Type Acetabular Cup	Biomet	72	14	9	16	20	11	11	14	6	22	6	**201**
Coriolis Cup	Fournitures Hospitalieres	34	15	6	17	18	14	4	13	8	9	13	**151**
Exeter Acetabular Cup	Stryker Howmedica Osteonics	77	5	8	6	3	2	4	2	1	2	0	**110**
MY Cup	Protetim	53	2	0	0	0	0	1	0	0	0	0	**56**
Elite Plus LPW Cup	De Puy (Johnson&Johnson)	21	1	0	2	3	4	2	1	0	0	0	**34**
Muller Type Cup	Surgival	3	4	4	12	2	3	1	2	0	0	2	**33**
Elite Plus Ogee LPW Cup	De Puy (Johnson&Johnson)	14	2	0	0	2	0	9	0	0	0	0	**27**
Igloo (Cotyle Igloo)	Biotechni	1	2	1	0	1	2	2	4	1	2	1	**17**
PE-CUP (cemented)	Aesculap (B Braun)	11	2	1	0	0	0	0	0	0	0	0	**14**
Polyethylene Acetabular Cup	Stryker Howmedica Osteonics	0	0	0	1	1	1	0	5	2	0	2	**12**
Secur-Fit PSL Cup	Stryker Howmedica Osteonics	3	0	1	2	1	1	1	2	0	0	0	**11**
Retentive Acetabular Cup	Groupe Lepine	0	0	0	0	1	1	2	0	2	3	2	**11**

Table 43 – 15 most common cementless acetabular components implanted in total revision, 2001 -2015

Cup	Manufacturer	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
Trilogy Cup	Zimmer	2	7	26	36	26	44	30	31	58	41	41	**342**
Trabecular Metal Revision Shell	Zimmer	0	0	0	0	2	11	15	10	12	26	22	**98**
Igloo (Cotyle Igloo)	Biotechni	2	0	7	8	6	10	10	14	12	10	12	**91**
Secur-Fit PSL Cup	Stryker Howmedica Osteonics	43	4	3	2	3	3	2	3	0	0	0	**63**
Mallory-Head Acetabular Shell	Biomet	0	0	0	0	5	9	2	2	6	4	4	**32**
Espace B2C	Groupe Lepine	14	1	3	5	5	1	1	0	0	0	0	**30**
Swing Acetabular Cup (Cotyle Swing)	Biotechni	19	0	2	0	1	1	2	0	0	0	0	**25**
Trilogy Cup (Shell Spiked)	Zimmer	0	1	2	2	2	3	1	4	3	2	5	**25**
L-Cup / Mallory-Head	Biomet	14	3	3	3	0	0	0	0	0	0	0	**23**
ABG II Cup	Stryker Howmedica Osteonics	4	2	2	9	3	1	0	0	0	0	0	**21**
Duraloc 300	De Puy (Johnson&Johnson)	1	1	5	5	4	0	1	1	2	0	0	**20**
Azur Acetabular Cup (Cotyle Azur)	Biotechni	3	3	5	3	2	0	0	2	2	0	0	**20**
Trident PSL Acetabular Shell	Stryker Howmedica Osteonics	3	5	2	0	3	1	2	0	3	0	0	**19**
Allofit S Shell	Zimmer	0	0	2	3	2	2	5	0	0	1	2	**17**
Atlas	Fournitures Hospitalieres	0	0	1	2	2	1	1	1	2	2	1	**13**

6.1.2.1.4 15 most common femoral components implanted in total revisions

Table 44 – 15 most common cemented femoral components implanted in total revisions, 2001 -2015

Stem	Manufacturer	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
Omnifit Normalized Stem	Stryker Howmedica Osteonics	183	34	30	42	50	19	29	32	20	21	20	**480**
Metabloc Cemented Stem	Zimmer	3	7	7	15	30	28	16	25	54	40	18	**243**
Omnifit Cemented Long Stem (DE REVIZIE)	Stryker Howmedica Osteonics	11	1	6	8	12	12	14	20	16	15	15	**130**
Filler-3ND Titanium Cemented	Biotechni	52	10	9	10	11	17	7	3	2	1	2	**124**
Exeter Stem	Stryker Howmedica Osteonics	63	7	6	8	1	6	5	2	1	11	7	**117**
Taperloc Femoral Stem	Biomet	21	2	2	8	11	10	8	9	5	22	6	**104**
MY Stem	Protetim	46	2	0	0	0	0	2	0	0	0	0	**50**
CPT Femoral Stem	Zimmer	1	4	8	8	6	8	1	1	3	4	2	**46**
Virtec	Zimmer	0	0	0	4	9	8	9	3	0	0	0	**33**
Elite Plus Stem	De Puy (Johnson&Johnson)	23	2	0	0	0	0	0	0	0	0	0	**25**
Luer Stem	Fournitures Hospitalieres	0	1	1	2	4	3	0	3	3	2	1	**20**
Legend V40 Stem	Stryker Howmedica Osteonics	4	0	0	6	2	3	1	1	1	1	0	**19**
Self Locking Femoral Stem	Permedica	9	5	0	2	0	0	0	0	0	0	0	**16**
Autobloquante	Fournitures Hospitalieres	0	2	2	4	3	1	0	3	0	0	1	**16**
FJORD	De Puy (Johnson&Johnson)	0	0	1	0	6	2	5	0	0	0	0	**14**

Table 45 - 15 most common cementless femoral components implanted in total revisions, 2001 -2015

Stem	Manufacturer	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
Revitan	Zimmer	1	11	33	52	44	58	60	53	70	72	73	**527**
Restoration DLS Stem	Stryker Howmedica Osteonics	64	17	5	11	21	9	9	5	3	2	1	**147**
Kent Femoral Stem	Biomet	71	14	2	7	8	3	4	2	1	0	0	**112**
Filler-3ND Ti Femoral Stem	Biotechni	0	0	0	0	0	0	7	19	19	21	25	**91**
Omnifit HA Stem	Stryker Howmedica Osteonics	32	9	7	10	4	6	5	2	2	2	0	**79**
Filler-3ND Ti+HA Femoral stem	Biotechni	27	3	8	4	9	12	1	3	2	6	2	**77**
Metabloc Unc	Zimmer	0	1	3	8	4	7	11	7	12	6	9	**68**
Taperloc Femoral Stem	Biomet	8	2	3	4	5	8	2	1	6	7	4	**50**
TTHR	Biotechni	0	0	2	4	0	1	9	6	7	7	12	**48**
VerSys Fiber Metal Taper	Zimmer	0	1	4	3	3	4	1	6	7	3	2	**34**
Filler-3ND Titanium Cemented	Biotechni	3	1	1	2	1	2	3	4	1	2	1	**21**
Helios (DE REVIZIE)	Biomet	0	0	8	3	5	4	1	0	0	0	0	**21**
KAR	De Puy (Johnson&Johnson)	0	0	0	2	7	0	3	5	1	0	0	**18**
Targos Stem	Groupe Lepine	0	0	0	0	0	0	0	0	2	6	3	**11**
Bicontact Stem (uncemented)	Aesculap (B Braun)	10	1	0	0	0	0	0	0	0	0	0	**11**

6.1.3 Conversion type revision

6.1.3.1 Conversion type revisions – reasons for revision percentage frequency

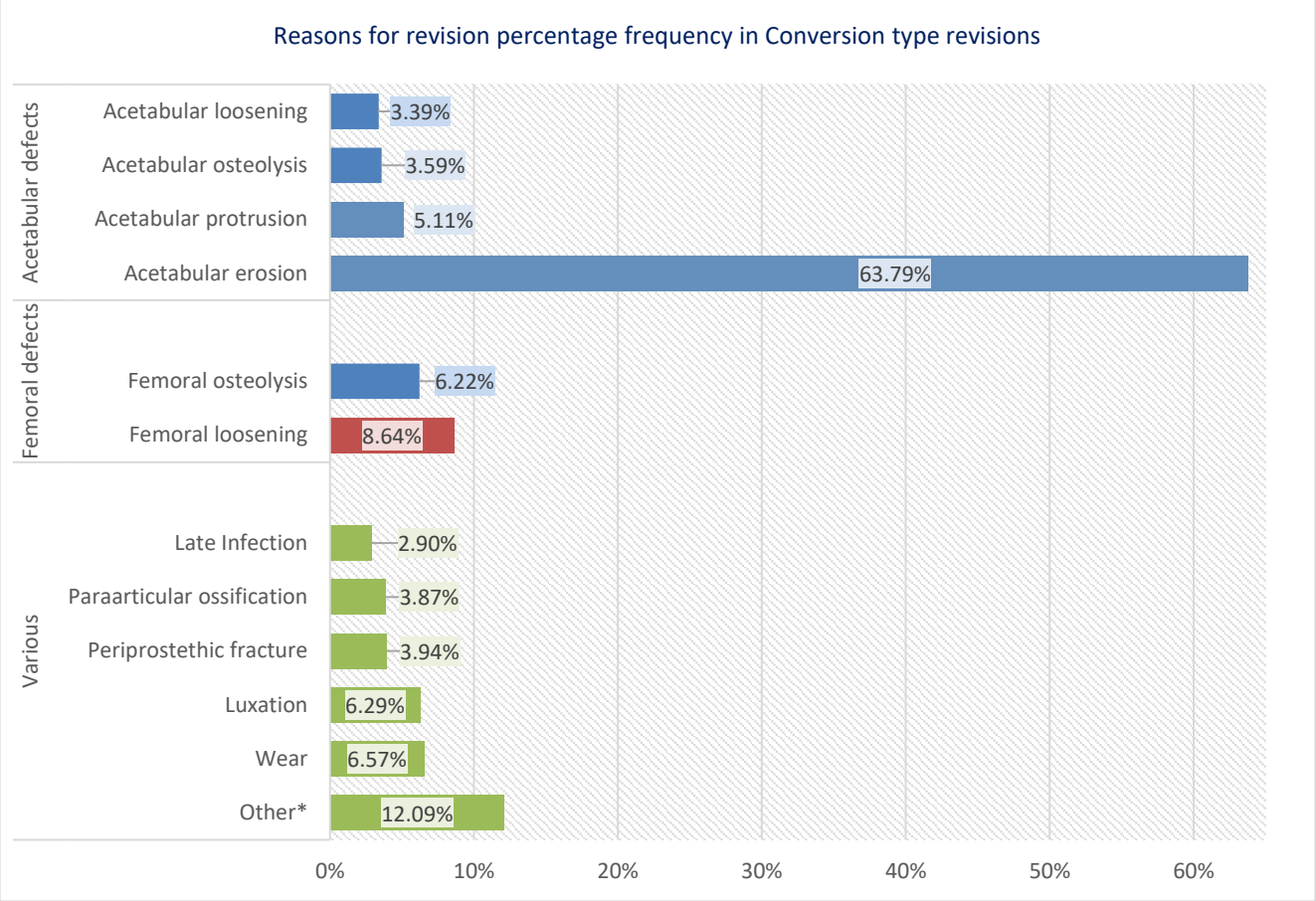


Figure 87 – Reasons for revision percentage frequency in all Conversion type revisions, 2001 – 2015

** un-standardized reasons for reoperation (custom input provided by surgeon) including diagnoses less than 1%*

6.1.3.2 Conversion revisions - types of fixation share

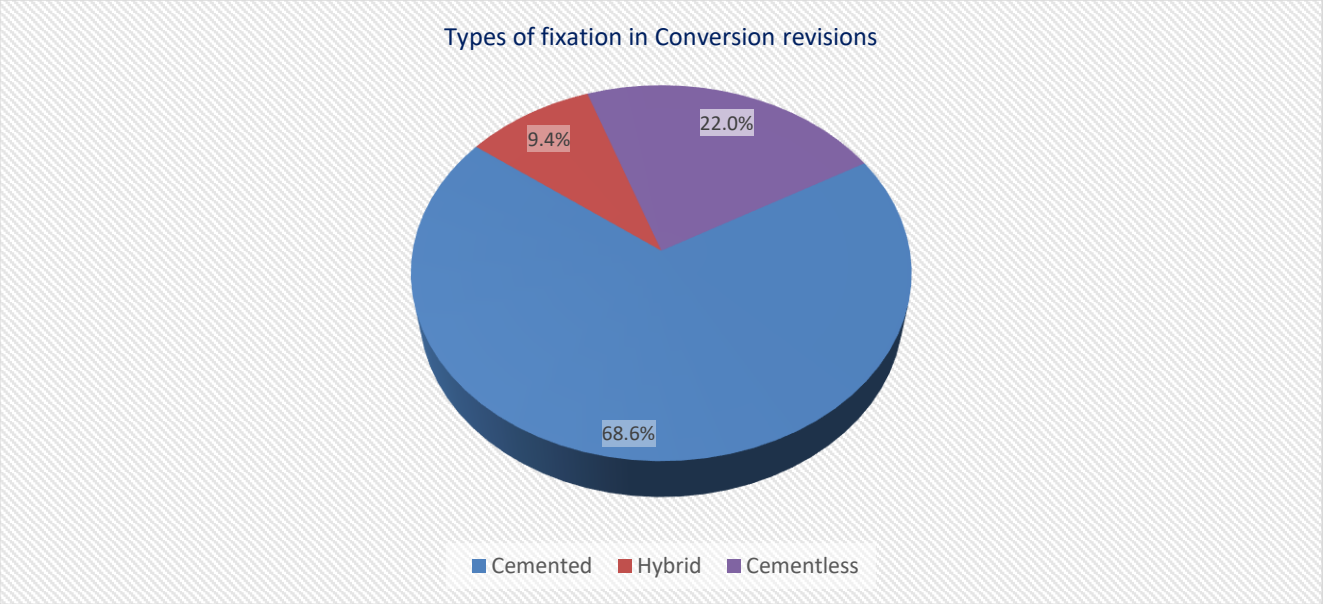


Figure 88 - Share of all types of fixation in Conversion revisions, 2001 – 2015

6.1.3.3 15 most common acetabular components implanted in conversion type revision

Table 46 – 15 most common cemented acetabular components implanted in conversion type revision, 2001 -2015

Cup	Manufacturer	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
Polyethylene Acetabular Cup (Omnifit)	Stryker Howmedica Osteonics	78	28	17	13	21	23	21	11	18	15	12	**263**
ZCA All-Poly Cup	Zimmer	0	6	13	27	25	16	24	23	40	29	12	**215**
Muller-Type Acetabular Cup	Biomet	48	4	7	14	14	15	17	14	10	15	9	**161**
Rim Acetabular Cup	Biotechni	23	5	13	12	7	14	19	14	18	6	7	**138**
Coriolis Cup	Fournitures Hospitalieres	13	13	7	11	9	5	15	11	8	10	15	**125**
Exeter Acetabular Cup	Stryker Howmedica Osteonics	43	4	2	5	4	1	0	2	2	1	0	**56**
Elite Plus LPW Cup	De Puy (Johnson&Johnson)	15	3	1	0	2	1	5	0	0	0	0	**24**
MK III Kerboull Cup	Stryker Howmedica Osteonics	7	2	0	0	3	0	0	6	0	2	0	**21**
Muller Type Cup	Surgival	0	1	4	0	2	1	4	1	2	0	0	**15**
Elite Plus Ogee LPW Cup	De Puy (Johnson&Johnson)	3	0	1	1	2	3	1	0	0	0	0	**11**
MY Cup	Protetim	9	0	0	1	0	0	1	0	0	0	0	**11**
MBA	Groupe Lepine	7	0	0	0	0	0	0	0	0	0	0	**6**
Retentive Acet	Groupe Lepine	0	0	0	0	0	1	1	0	2	1	0	**5**
Polyethylene Acetabular Cup	Stryker Howmedica Osteonics	0	0	0	1	0	0	0	0	3	0	0	**4**
PE-CUP (cemented)	Aesculap (B Braun)	3	1	1	0	0	0	0	0	0	0	0	**4**

Table 47 - 15 most common cementless acetabular components implanted in conversion type revision, 2001 -2015

Cup	Manufacturer	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
Trilogy Cup	Zimmer	1	0	5	13	8	10	7	9	16	13	12	**94**
Secur-Fit PSL Cup	Stryker Howmedica Osteonics	29	3	1	5	1	2	0	0	0	0	0	**41**
Mallory-Head Acetabular Shell	Biomet	0	0	0	0	2	5	6	4	2	6	3	**28**
Atlas	Fournitures Hospitalieres	0	0	0	0	2	0	1	3	4	5	3	**18**
L-Cup / Mallory-Head	Biomet	11	3	3	0	1	0	0	0	0	0	0	**18**
ABG II Cup	Stryker Howmedica Osteonics	2	2	1	6	2	2	1	1	0	0	0	**17**
Swing Acetabular Cup (Cotyle Swing)	Biotechni	7	2	3	1	0	0	0	0	0	0	0	**13**
Azur Acetabular Cup (Cotyle Azur)	Biotechni	3	0	1	3	1	0	1	1	0	2	0	**12**
Igloo (Cotyle Igloo)	Biotechni	0	0	2	2	1	1	1	3	0	2	0	**12**
Trident PSL Acetabular Shell	Stryker Howmedica Osteonics	0	3	0	0	1	2	1	1	0	2	2	**12**
Duraloc 300	De Puy (Johnson&Johnson)	0	0	1	3	2	2	3	0	0	0	0	**11**
Allofit S Shell	Zimmer	0	0	0	0	1	5	4	1	0	0	0	**11**
L-Cup Press Fit	Biomet	0	0	1	2	2	0	0	0	0	0	0	**5**
Pinnacle 300	De Puy (Johnson&Johnson)	0	0	0	0	0	0	0	2	1	1	0	**4**
Trabecular Metal Revision Shell	Zimmer	0	0	0	0	0	1	1	0	1	0	0	**3**

6.1.3.4 15 most common femoral components implanted in conversion type revision

Table 48 - 15 most common cemented femoral components implanted in conversion type revision, 2001 -2015

Stem	Manufacturer	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
Omnifit Normalized Stem	Stryker Howmedica Osteonics	74	24	12	10	17	16	16	10	14	14	10	**217**
Metabloc Cem	Zimmer	0	4	12	22	18	11	20	20	31	21	10	**169**
Taperloc Femoral Stem	Biomet	39	3	7	13	10	14	17	12	12	15	7	**149**
Filler-3ND Titanium Cemented Femoral Stem	Biotechni	25	5	12	12	8	14	17	4	1	0	2	**100**
Exeter Stem	Stryker Howmedica Osteonics	31	4	2	2	1	3	1	3	4	2	3	**56**
Luer Stem	Fournitures Hospitalieres	4	3	4	1	7	1	6	6	2	4	4	**42**
Autobloquante	Fournitures Hospitalieres	0	3	3	6	2	3	5	4	6	3	6	**41**
Filler-3ND Ti Femoral Stem	Biotechni	0	0	0	0	0	0	3	10	13	4	6	**36**
Legend V40 Stem	Stryker Howmedica Osteonics	5	4	1	2	4	2	1	6	0	3	0	**28**
Self Locking Femoral Stem	Permedica	6	7	0	1	1	1	1	0	0	1	2	**20**
Revitan (DE REVIZIE)	Zimmer	0	0	0	4	1	2	1	0	3	6	0	**17**
Elite Plus Stem	De Puy (Johnson&Johnson)	14	2	0	0	0	0	0	0	0	0	0	**16**
#VALUE!	De Puy (Johnson&Johnson)	0	1	2	1	3	4	3	1	0	0	0	**15**
MYSTEM	Zimmer	0	1	1	2	1	1	0	0	2	3	1	**12**
Omnifit Cemented Long Stem	Stryker Howmedica Osteonics	3	1	0	1	1	2	1	0	1	0	1	**11**

Table 49 - 15 most common cementless femoral components implanted in conversion type revision, 2001 -2015

Stem	Manufacturer	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
Revitan	Zimmer	0	0	3	4	4	7	5	4	9	6	3	**45**
Omn	Stryker Howmedica Osteonics	25	4	2	7	1	3	0	1	0	1	1	**45**
Taperloc Femoral Stem	Biomet	9	3	3	1	2	5	6	2	2	6	2	**41**
Metabloc Uncemented Stem	Zimmer	1	0	1	4	2	5	2	6	6	6	6	**39**
Filler-3ND Ti+HA Femoral stem	Biotechni	9	0	4	5	2	1	2	2	0	0	0	**25**
VerSys Fiber Metal Taper	Zimmer	0	0	0	3	2	2	3	0	1	1	1	**13**
Restoration DLS Stem	Stryker Howmedica Osteonics	4	0	0	2	2	1	0	0	0	0	0	**9**
Thira	Fournitures Hospitalieres	0	0	0	0	0	0	0	2	2	2	2	**8**
PAVI St	Groupe Lepine	0	0	0	0	1	0	1	1	1	2	0	**6**
ABG II Stem	Stryker Howmedica Osteonics	0	2	0	0	0	2	1	0	0	0	0	**5**
Kent Femoral Stem (DE REV	Biomet	1	1	1	0	1	0	0	0	0	0	0	**4**
Filler-3ND Ti	Biotechni	0	0	0	0	0	0	0	2	0	1	0	**3**
Bicontact Stem (unc	Aesculap (B Braun)	3	0	0	0	0	0	0	0	0	0	0	**3**
B2C Stem Uncemented	Groupe Lepine	2	0	0	0	0	0	0	0	0	0	0	**2**
TTHR	Biotechni	0	0	0	0	0	0	0	0	0	2	0	**2**

6.1.4 Partial revisions

6.1.4.1 Partial revisions – reasons for revision percentage frequency

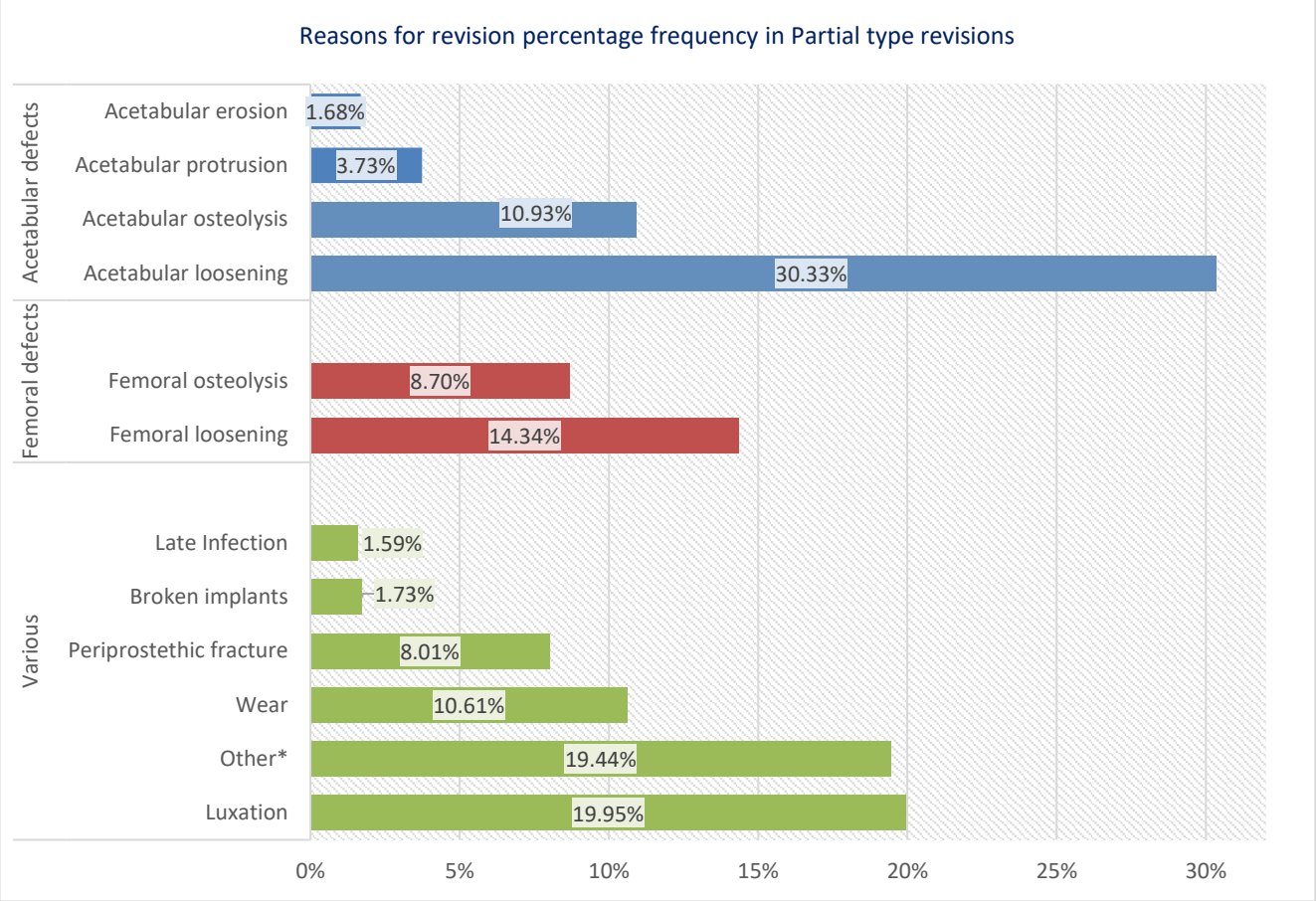


Figure 89 - Reasons for revision percentage frequency in all Partial type revisions, 2001 – 2015

**Other – un-standardized reasons for reoperation (custom input provided by surgeon) including diagnoses less than 1%.*

6.1.4.2 Partial revisions – types of fixation share

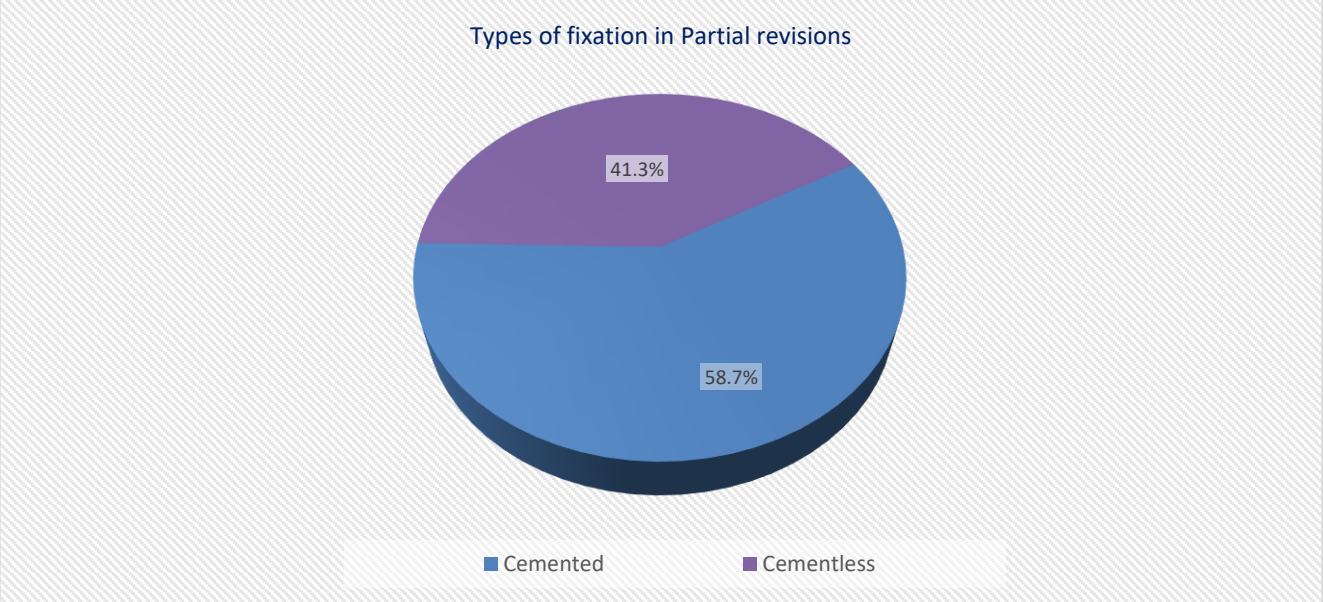


Figure 90 - Share of all types of fixation in Partial revisions, 2001 – 2015

6.1.4.3 15 most common acetabular components implanted in partial revisions

Table 50 - 15 most common cemented acetabular components implanted in partial revision, 2001 -2015

Cup	Manufacturer	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
ZCA All-Poly Cup	Zimmer	1	0	10	8	14	17	12	30	45	45	24	**206**
Polyethylene Acetabular Cup (Omnifit)	Stryker Howmedica Osteonics	41	8	10	18	9	13	3	13	10	12	11	**148**
Coriolis Cup	Fournitures Hospitalieres	11	11	11	6	6	9	10	15	13	9	12	**113**
Rim Acetabular Cup	Biotechni	9	1	1	2	9	4	9	12	10	7	9	**73**
Muller-Type Acetabular Cup	Biomet	15	8	3	5	5	4	6	6	3	6	3	**64**
Exeter Acetabular Cup	Stryker Howmedica Osteonics	16	3	2	3	5	3	2	2	2	2	2	**42**
Retentive Acetabular Cup	Groupe Lepine	0	0	3	1	5	1	5	4	6	5	8	**38**
MY Cup	Protetim	18	1	4	1	2	1	0	1	0	0	0	**28**
Muller Type Cup	Surgival	1	1	2	3	1	1	7	2	1	1	0	**20**
MK III Kerboull Cup	Stryker Howmedica Osteonics	3	3	2	1	0	0	3	1	1	0	3	**17**
Contemporary	Stryker Howmedica Osteonics	4	3	1	0	0	1	0	0	0	2	2	**13**
Elite Plus LPW Cup	De Puy (Johnson&Johnson)	3	1	3	0	1	1	1	0	0	0	0	**10**
Elite Plus Ogee LPW Cup	De Puy (Johnson&Johnson)	2	2	0	0	0	3	0	0	0	0	0	**7**
PE-CUP	Aesculap (B Braun)	4	1	1	0	0	0	0	0	0	0	0	**6**
Muller II Cup	OHST Medizintechnik AG	0	0	0	0	0	0	0	0	3	2	0	**5**

Table 51 - 15 most common cementless acetabular components implanted in partial revision, 2001 -2015

Cup	Manufacturer	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
Trilogy Cup	Zimmer	0	1	2	3	7	5	8	12	13	23	9	**83**
Igloo (Cotyle Igloo)	Biotechni	2	0	2	3	1	7	7	0	4	6	10	**42**
Trabecular Metal Revision Shell	Zimmer	0	0	0	0	1	2	4	3	9	11	10	**40**
Secur-Fit PSL Cup	Stryker Howmedica Osteonics	27	3	0	0	2	2	3	0	0	0	0	**37**
Espace B2C	Groupe Lepine	8	0	0	3	2	4	2	1	0	0	0	**20**
Duraloc 300	De Puy (Johnson&Johnson)	1	2	1	2	1	0	2	0	2	3	0	**14**
ABG II Cup	Stryker Howmedica Osteonics	1	0	1	6	1	0	0	1	0	3	0	**13**
Azur Acetabular Cup (Cotyle Azur)	Biotechni	1	2	4	1	1	1	0	2	0	0	1	**13**
L-Cup / Mallory-Head	Biomet	7	3	1	0	2	0	0	0	0	0	0	**13**
Atlas	Fournitures Hospitalieres	0	0	1	1	2	2	1	3	0	1	1	**12**
Swing Acetabular Cup (Cotyle Swing)	Biotechni	3	0	1	0	0	2	0	2	0	1	0	**9**
Trident PSL Acetabular Shell	Stryker Howmedica Osteonics	0	0	1	0	0	2	1	2	0	1	1	**8**
Allofit S Shell	Zimmer	0	0	0	0	0	2	1	2	2	0	1	**8**
Mallory-Head Acetabular Shell	Biomet	0	0	0	0	0	0	1	3	0	1	1	**6**
Pinnacle 300	De Puy (Johnson&Johnson)	0	0	0	0	0	0	0	3	1	1	0	**5**

6.1.4.4 15 most common femoral components implanted in partial revisions

Table 52 - 15 most common cemented femoral components implanted in partial revisions, 2001 -2015

Stem	Manufacturer	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
Omnifit Normalized Stem	Stryker Howmedica Osteonics	15	7	2	6	4	1	4	1	3	2	3	**48**
Omnifit Cemented Long Stem	Stryker Howmedica Osteonics	4	0	3	1	4	3	7	9	8	6	2	**47**
Metabloc Cemented Stem	Zimmer	0	0	1	6	2	2	3	0	9	6	8	**37**
Taperloc Femoral Stem	Biomet	10	0	0	1	3	1	1	2	1	4	0	**23**
Filler-3ND Titanium Cemented Femoral Stem	Biotechni	5	0	2	4	2	2	2	1	1	0	0	**19**
Exeter Stem	Stryker Howmedica Osteonics	4	2	0	5	0	2	1	0	2	1	2	**19**
MY Stem	Protetim	9	2	0	0	0	1	0	0	0	0	0	**12**
Virtec	Zimmer	0	0	0	0	6	0	4	0	1	0	0	**11**
Legend V40 Stem	Stryker Howmedica Osteonics	2	0	2	1	0	0	0	0	2	1	1	**9**
CPT Femoral Stem	Zimmer	0	0	0	1	0	0	0	1	1	0	2	**5**
PC Femoral Stem	Metrimed	4	1	0	0	0	0	0	0	0	0	0	**5**
Lubinus (R) SP II Stem	Waldemar Link	4	0	0	1	0	0	0	0	0	0	0	**5**
Autobloquante	Fournitures Hospitalieres	0	2	0	0	1	0	1	0	0	0	0	**4**
ArgoTEP Femoral Stem	Argomedical	3	0	0	0	0	0	0	0	0	0	0	**3**
Protasul Stem	Protek Sulzer Medica / Centerpulse	3	0	0	0	0	0	0	0	0	0	0	**3**

Table 53 - 15 most common cementless femoral components implanted in partial revisions, 2001 -2015

Stem	Manufacturer	'01-'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
Revitan	Zimmer	0	3	8	8	14	22	12	13	22	16	19	**137**
Restoration DLS Stem	Stryker Howmedica Osteonics	11	5	2	7	11	6	4	2	4	4	3	**59**
Omn	Stryker Howmedica Osteonics	19	7	5	6	3	3	0	3	0	0	0	**46**
Filler-3ND Ti	Biotechni	0	0	0	0	0	0	3	6	2	8	6	**25**
Kent Femoral Stem (DE REV	Biomet	14	4	1	1	2	0	1	0	0	0	0	**23**
TTHR	Biotechni	0	0	3	1	2	2	2	1	3	5	3	**22**
Filler-3ND Ti+HA	Biotechni	5	1	2	2	1	4	4	2	0	0	0	**21**
Metabloc Unc	Zimmer	0	1	0	0	1	4	1	1	0	2	5	**15**
Helios	Biomet	0	2	2	1	3	3	0	0	0	0	0	**11**
PAVI Standard	Groupe Lepine	0	0	0	2	2	2	0	3	0	1	1	**11**
Corail Standard Stem	De Puy (Johnson&Johnson)	0	1	1	0	1	1	2	1	3	0	0	**10**
VerSys Fiber	Zimmer	0	0	0	2	1	0	1	1	1	1	1	**8**
Restoration DPM	Stryker Howmedica Osteonics	5	0	1	1	0	0	0	0	0	0	0	**7**
Taperloc Femoral Stem	Biomet	1	1	1	0	1	1	0	0	0	0	2	**7**
Synergy	Smith & Nephew	0	0	0	0	1	1	0	1	2	0	0	**5**

6.1.5 Revision risk overview by implant type

Table 54 – Revisions rate by age group and endoprosthesis type

Endoprosthesis	< 49		50 - 59		60 - 69		70 - 79		> 80	
	Total Primary	% Revised	Total Primary	% Revised	Total Primary	% Revised	Total Primary	% Revised	Total Primary	% Revised
THR Cemented	1373	**8.1%**	5318	**5.1%**	15920	**3.5%**	15435	**1.7%**	2214	**0.9%**
THR Cementless	9005	**3.0%**	10745	**2.2%**	8967	**1.6%**	3072	**1.6%**	282	**2.5%**
THR Resurfacing	295	**9.2%**	95	**5.3%**	42	**7.1%**	9	**22.2%**	0	**0.0%**
THR Hybrid	125	**9.6%**	183	**4.9%**	207	**4.3%**	101	**2.0%**	11	**0.0%**
THR Reversed Hybrid	167	**10.8%**	443	**3.8%**	1415	**1.5%**	1380	**0.8%**	202	**2.0%**
HA Bipolar/Unipolar	703	**5.4%**	1326	**3.4%**	2020	**2.6%**	2172	**1.5%**	1106	**0.5%**
HA Moore/Thomps.	324	**5.6%**	1337	**9.0%**	4872	**5.6%**	13402	**2.8%**	11801	**0.7%**
TOTAL	11992	4.1%	19447	3.6%	33443	3.2%	35571	2.1%	15616	0.7%

For an outcome overview regarding the risk of revision between different endoprosthesis groups, Cox regression analysis was performed for THR: Cemented, Cementless, Resurfacing, Hybrid, Reversed Hybrid and HA: Bipolar/Unipolar Modular and Moore/Thompson. The following predictors were included in the analysis: gender and age group – age at the time of the intervention – (less than 49, 50-59, 60-69, 70-79 and over 80 years old).

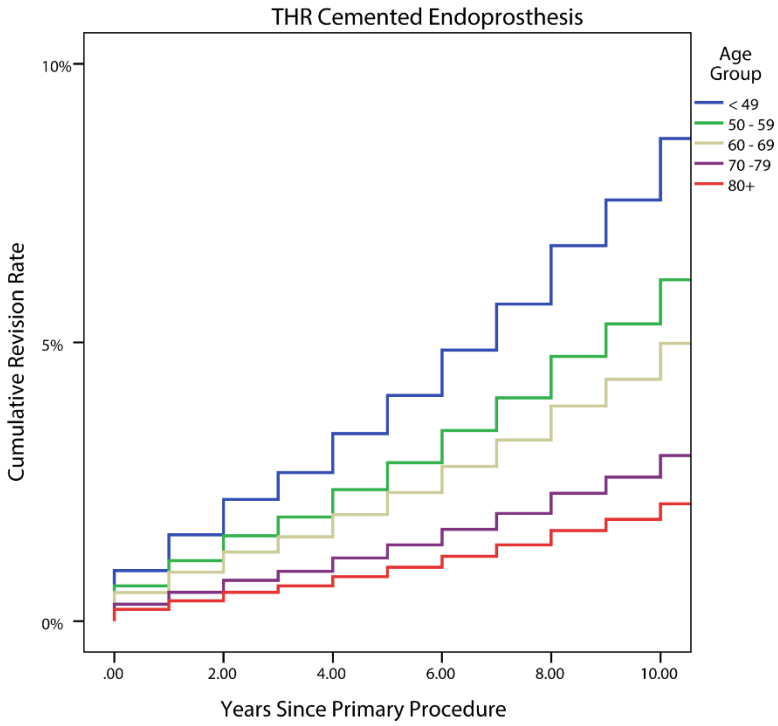
The regression models statistically valid included the following endoprosthesis categories:

- THR Cemented
- THR Cementless
- THR Hybrid
- THR Reversed Hybrid
- HA Bipolar/Unipolar
- HA Moore/Thompson type

The regression model based on the interventions using THR Resurfacing endoprosthesis was not marked as statistically valid, therefore the interpretation of the coefficients was irrelevant.

6.1.5.1 THR Cemented Endoprosthesis: Revision risk by age group and gender

Statistically significant results indicate that the risk of revision for the patients who suffered an intervention between 2001-2015 using THR Cemented endoprosthesis, has a constant decrease that comes with aging. Younger patients have a 4-times higher revision risk in comparison to patients aged over 80 The coefficients regarding the gender do not offer a significantly distinct perspective between the comparison groups.



HR: 2001 – 2015, adjusted by gender

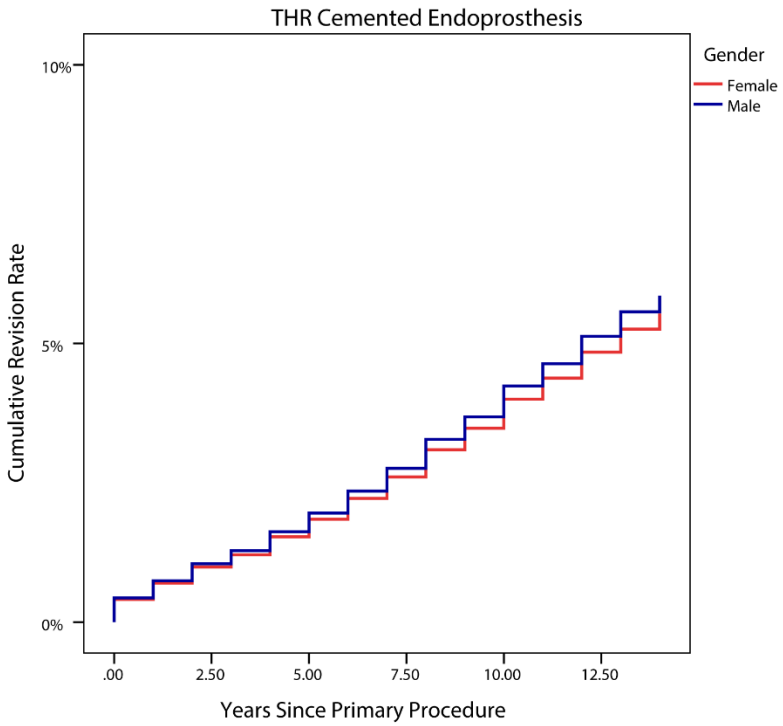
50-59 vs. <49 years old
HR = 0.698 (0.559, 0871), Sig.<0.001

60-69 vs. <49 years old
HR = 0.564 (0.460, 0.692), Sig.<0.001

70-79 vs. <49 years old
HR = 0.333 (0.266, 0.416), Sig.<0.001

>80 vs. <49 years old
HR = 0.235 (0.144, 0.383), Sig.<0.001

Figure 91 – Cumulative revision rate for THR Cemented Endoprosthesis by age group.



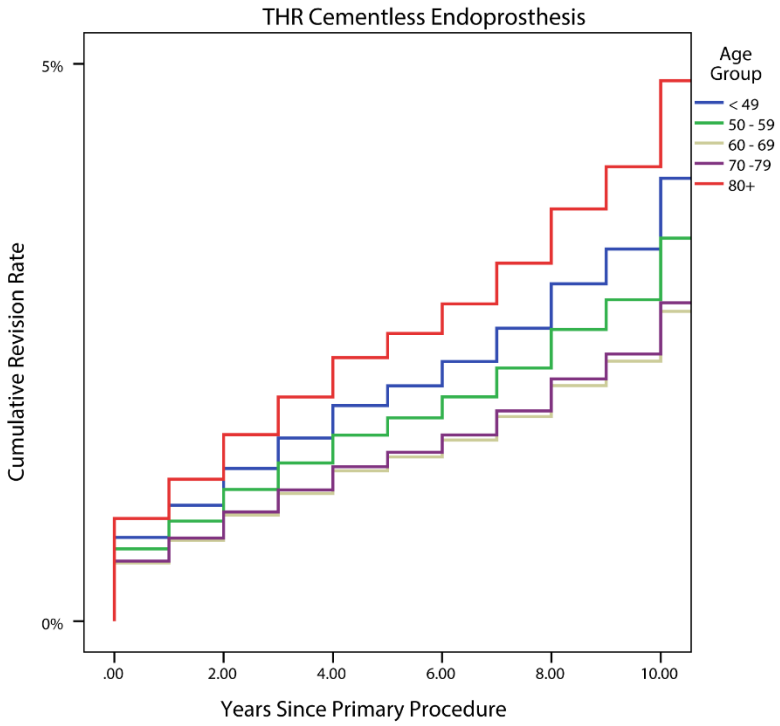
HR: 2001 – 2015, adjusted by age

Male vs. Female patients
HR = 1.06 (0.945, 1.189), Sig.= 0.397

Figure 92 – Cumulative revision rate for THR Cemented Endoprosthesis by age gender

6.1.5.2 THR Cementless Endoprosthesis: Revision risk by age group and gender

The modelled data for the interventions using THR Cementless endoprosthesis indicates an interesting turnover when analyzing the comparison between age groups. The biggest risk of revision is held by patients aged 80 and over, in contrast with THR Cemented, where the group holds the lowest risk of revision. There can be found similarities between the other age groups, whereas the lowest risk of revision is held by cases corresponding to 60-69 and 70-79 age groups. Male patients are less likely with 16.8% to have a revision of the THR Cementless endoprosthesis than female patients (HR = 0.832, Sig. 0.015).



HR: 2001 – 2015, adjusted by gender

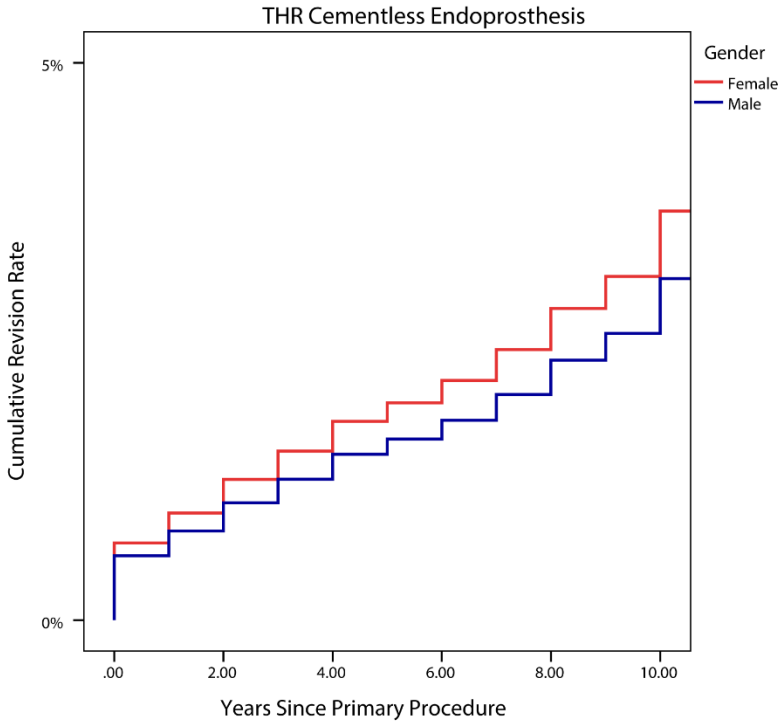
50-59 vs. <49 years old
HR = 0.862 (0.724, 1.027), Sig.= 0.097

60-69 vs. <49 years old
HR = 0.695 (0.566, 0.854), Sig.<0.001

70-79 vs. <49 years old
HR = 0.715 (0.523, 0.977), Sig.=0.035

>80 vs. <49 years old
HR =1.226 (0.578, 2.600), Sig.= 0.596

Figure 93 – Cumulative revision rate for THR Cementless Endoprosthesis by age group.



HR: 2001 – 2015, adjusted by age

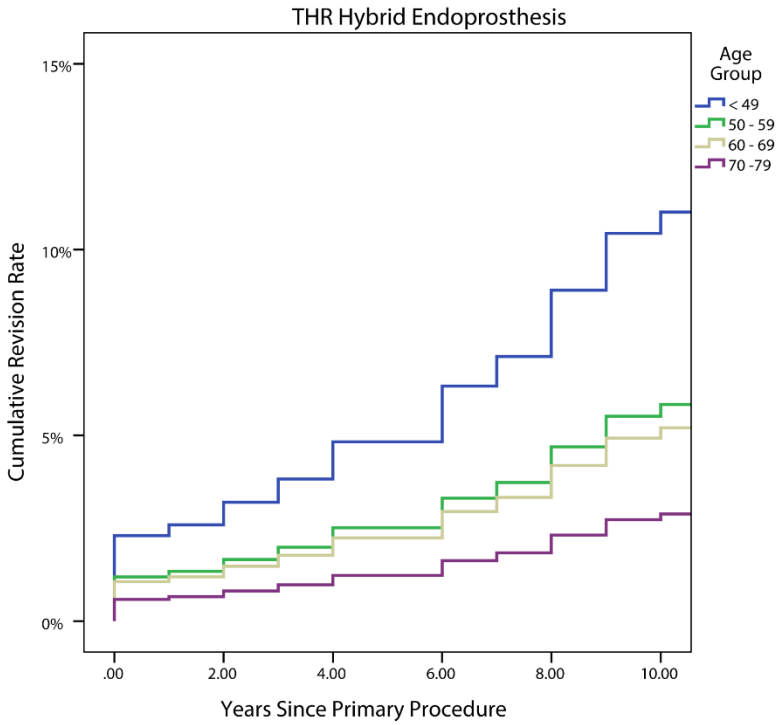
Male vs. Female patients
HR = 0.832 (0.717 - 0.965), Sig.= 0.015

Figure 94 – Cumulative revision rate for THR Cementless Endoprosthesis by gender

6.1.5.3 THR Hybrid Endoprosthesis: Revision risk by age group and gender

THR Hybrid endoprosthesis have the highest cumulative revision rate for the youngest age group (<49 years old). At the opposite pole, 70-79 years old patients at time of intervention have the lowest revision risk, 4 times lower than the reference group (HR =0.251, Sig.=0.071)

Male patients have a lower revision rate than female patients, but the risk difference between the two groups is not supported by statistical significance.



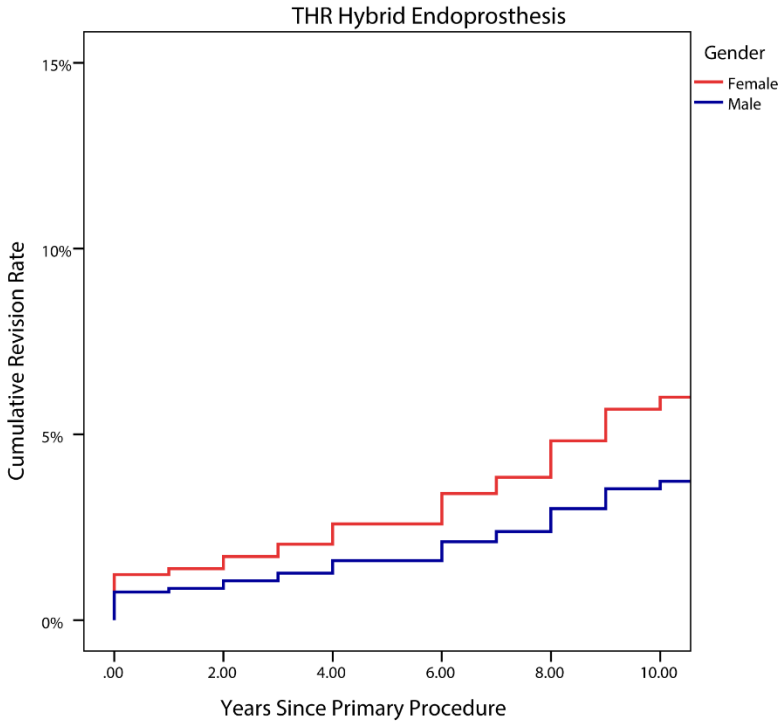
HR: 2001 – 2015, adjusted by gender

50-59 vs. <49 years old
HR = 0.515 (0.217, 1.233), Sig.= 0.133

60-69 vs. <49 years old
HR = 0.458 (0.192, 1.094), Sig.=0.079

70-79 vs. <49 years old
HR =0.251 (0.056, 1.127), Sig.=0.071

Figure 95 – Cumulative revision rate for THR Hybrid Endoprosthesis by age group.



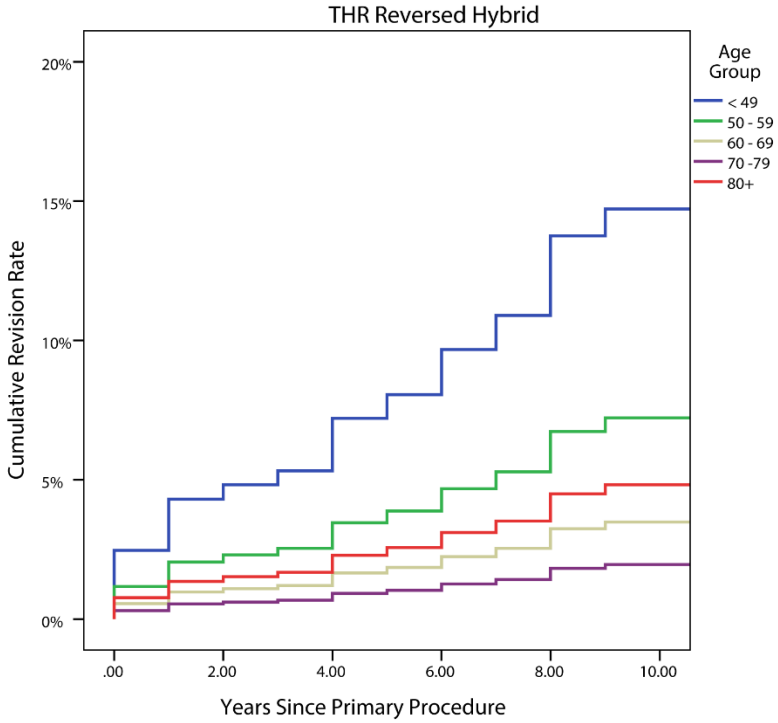
HR: 2001 – 2015, adjusted by age

Male vs. Female patients
HR = 0.616 (0.295, 1.285), Sig.= 0.196

Figure 96 – Cumulative revision rate for THR Hybrid Endoprosthesis by gender.

6.1.5.4 THR Reversed Hybrid Endoprosthesis: Revision risk by age group and gender

THR Reversed Hybrid endoprosthesis indicate concerning revision rates for young patients, with 15% at 10 years after the primary procedure. For the same time interval, 50-59 age group have a 7% cumulative revision rate with 53% less risk of having a revision. The lowest revision rate and also revision risk is associated to 70-79 age group, with only 2% revision rate in 10 years. There is no significant difference in the revision risk between male and female patiens with Reversed Hybrid THR.



HR: 2001 – 2015, adjusted by gender

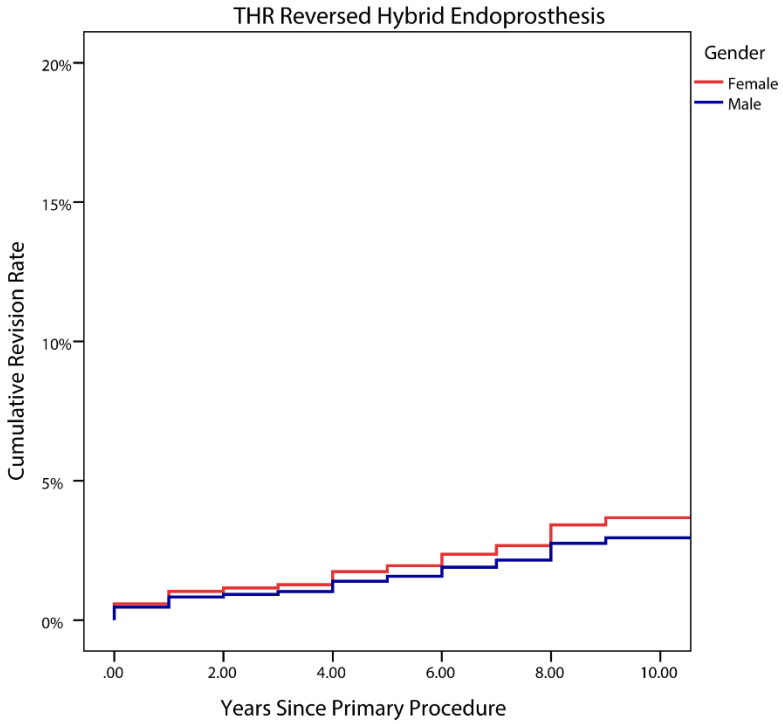
50-59 vs. <49 years old
HR = 0.471 (0.241, 0.923), Sig.= 0.028

60-69 vs. <49 years old
HR = 0.223 (0.115, 0.430), Sig.<0.001

70-79 vs. <49 years old
HR = 0.124 (0.057, 0.271), Sig.<0.001

>80 vs. <49 years old
HR = 0.31 (0.103, 0.936), Sig.= 0.038

Figure 97 – Cumulative revision rate for THR Reversed Hybrid Endoprosthesis by age group.



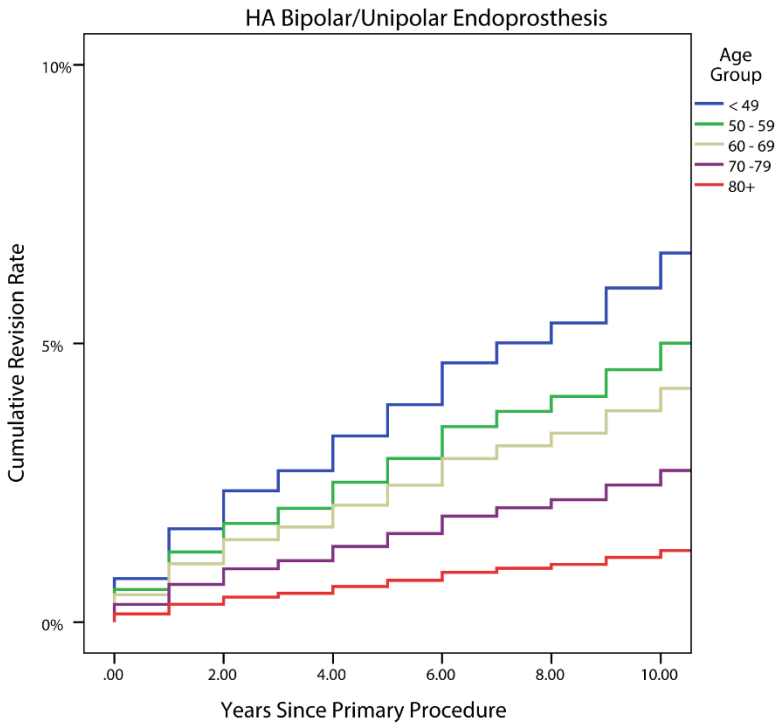
HR: 2001 – 2015, adjusted by age

Male vs. Female patients
HR = 0.803 (0.498, 1.293), Sig.= 0.367

Figure 98 – Cumulative revision rate for THR Reversed Hybrid Endoprosthesis by gender.

6.1.5.5 HA Bipolar/Unipolar Endoprosthesis: Revision risk by age group and gender

The revision risk trend for the Bipolar/Unipolar endoprosthesis when comparing the selected age groups is similar to THR Cemented trend, therefore the elderly age groups present a lower risk of revision. The biggest risk of revision is associated to the age group 40-49 which holds a predictor with 81% higher than the lowest associated revision risk (age group 80+, HR = 0.188, Sig.<0.001)



HR: 2001 – 2015, adjusted by gender

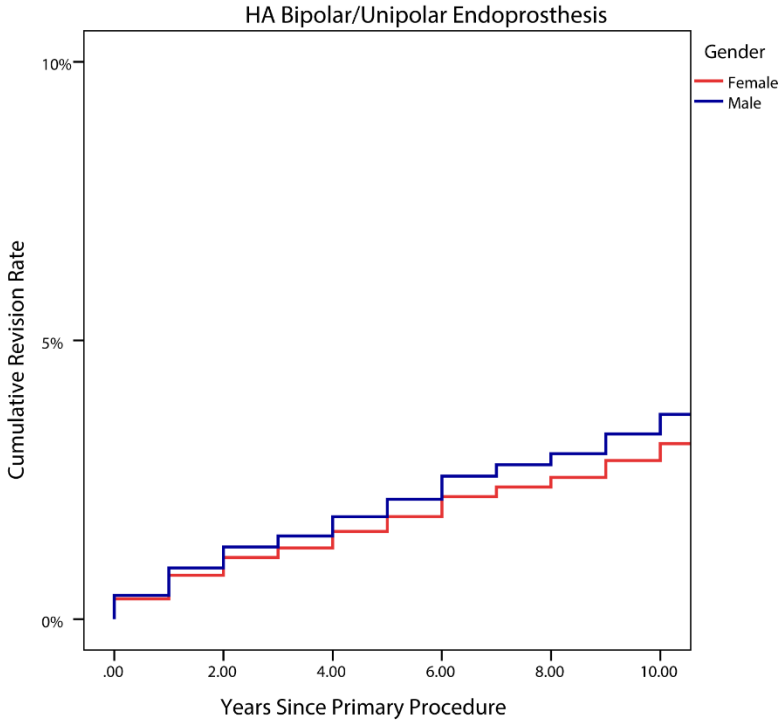
50-59 vs. <49 years old
HR = 0.749 (0.484, 1,160), Sig.= 0.196

60-69 vs. <49 years old
HR = 0.625 (0.406, 0.963), Sig.=0.033

70-79 vs. <49 years old
HR = 0.402 (0.247, 0.657), Sig.<0.001

>80 vs. <49 years old
HR = 0.188 (0.078, 0.454), Sig.<0.001

Figure 99 – Cumulative revision rate for HA Bipolar/Unipolar Endoprosthesis by age group.



HR: 2001 – 2015, adjusted by age

Male vs. Female patients
HR = 1.170 (0.854, 1.602), Sig.= 0.329

Figure 100 – Cumulative revision rate for HA Bipolar/Unipolar Endoprosthesis by gender.

6.1.5.6 HA Moore/Thompson Endoprosthesis Revision risk by age group and gender

Coefficients associated to age predictors are indicating a concerning situation. The highest risk of revision – with an enormous associated coefficient – belongs to the patients between 50-59 years old that have a risk over 9 times higher than the patients aged 80 and over (HR = 1.68; HR=0.18, Sig. <0.05).

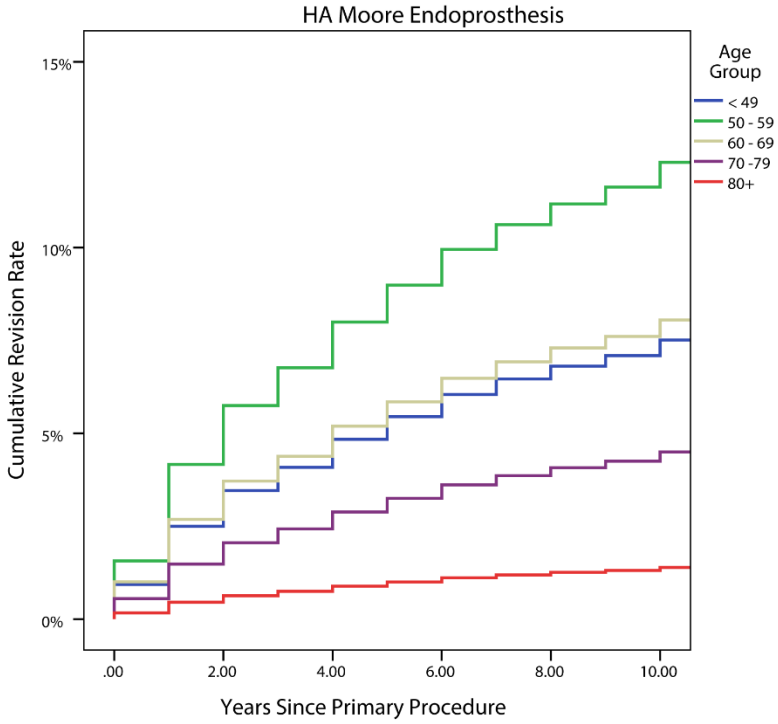


Figure 101 – Cumulative revision rate for HA Moore Endoprosthesis by age group.

HR: 2001 – 2015, adjusted by gender

50-59 vs. <49 years old
HR = 1.68 (1.023, 2.759), Sig.= 0.04

60-69 vs. <49 years old
HR = 1.075 (0.666, 1.736), Sig.=0.768

70-79 vs. <49 years old
HR = 0.59 (0.366, 0.951), Sig.=0.03

>80 vs. <49 years old
HR = 0.18 (0.107, 0.301), Sig.<0.001

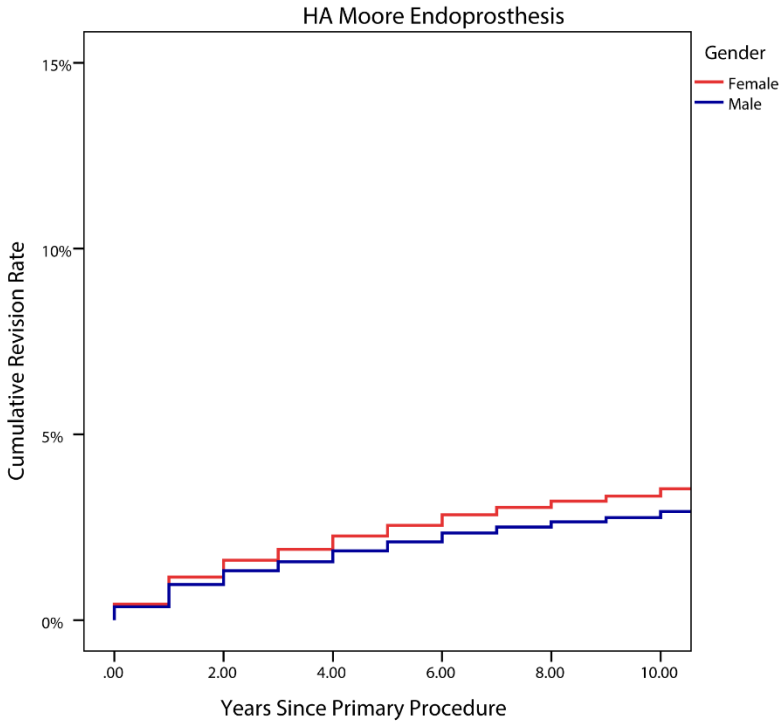


Figure 102 – Cumulative revision rate for HA Moore Endoprosthesis by gender.

HR: 2001 – 2015, adjusted by age

Male vs. Female patients
HR = 0.616 (0.707, 0.961), Sig.= 0.196

6.1.6 Percentage of revised endoprosthesis by age group and implant type between 2001 – 2015

Table 55 – Top 5 Diagnoses – Revision rate by Implant type, 2001 – 2015, Male

Age Group <49	N (Top 5 Diagnoses)	%Revised (Top 5 Diagnoses)	N Primary OA	%Revised Primary OA	N Femoral Neck Fracture	%Revised Femoral Neck Fracture	N Dysplasia (Sec. OA.)	%Revised Dysplasia (Sec. Cox)	N Posttraum. (Sec. OA)	%Revised Posttraum. (Sec. OA)	N As. Necrosis Fem. Head (Sec. OA)	%Revised As. Necrosis Fem. Head (Sec. OA)
THR_Cemented	673	6.39%	213	6.10%	30	0.00%	38	5.26%	58	13.79%	219	6.39%
THR_Cementless	5378	2.44%	1396	2.08%	120	1.67%	229	4.37%	276	2.90%	2779	2.30%
THR Hybrid	69	7.25%	13	15.38%	4	0.00%	6	0.00%	2	0.00%	33	6.06%
THR Reversed Hybrid	82	7.32%	23	0.00%	7	0.00%	9	11.11%	9	11.11%	23	8.70%
THR Resurfacing	203	8.37%	37	8.11%	0	0.00%	10	0.00%	8	0.00%	137	10.22%
HA Moore/Thompson	202	6.44%	1	0.00%	116	4.31%	0	0.00%	66	10.61%	10	10.00%
HA Bipolar/Unipolar	488	4.71%	29	3.45%	193	3.11%	0	0.00%	51	1.96%	167	7.19%
TOTAL	**7095**	**3.35%**	**1712**	**2.80%**	**470**	**2.77%**	**292**	**4.45%**	**470**	**5.32%**	**3368**	**3.24%**
50-59												
THR_Cemented	2369	4.52%	1312	4.27%	126	5.56%	115	0.87%	120	10.00%	464	4.53%
THR_Cementless	6190	2.05%	3094	2.00%	252	1.98%	209	1.91%	239	3.35%	1964	1.99%
THR Hybrid	86	4.65%	36	0.00%	3	0.00%	3	0.00%	10	10.00%	25	4.00%
THR Reversed Hybrid	250	3.60%	104	4.81%	35	0.00%	6	0.00%	22	9.09%	51	3.92%
THR Resurfacing	65	4.62%	15	0.00%	0	0.00%	4	0.00%	3	0.00%	39	5.13%
Moore	656	6.86%	5	0.00%	459	6.10%	0	0.00%	158	7.59%	4	50.00%
Bipolar/Unipolar	654	3.82%	28	3.57%	425	2.82%	1	0.00%	73	6.85%	79	8.86%
TOTAL	**10270**	**3.12%**	**4594**	**2.70%**	**1300**	**4.00%**	**338**	**1.48%**	**625**	**6.40%**	**2626**	**2.82%**
60-69												
THR_Cemented	6160	3.54%	4448	3.51%	394	3.55%	228	4.82%	225	6.67%	497	2.62%
THR_Cementless	4569	1.42%	3196	1.50%	243	2.06%	109	0.92%	106	2.83%	644	0.93%
THR Hybrid	90	1.11%	69	1.45%	3	0.00%	1	0.00%	1	0.00%	6	0.00%
THR Reversed Hybrid	645	1.55%	422	1.66%	61	0.00%	18	0.00%	19	5.26%	68	4.41%
THR Resurfacing	28	10.71%	17	11.76%	0	0.00%	2	0.00%	0	0.00%	9	11.11%
HA Moore/Thompson	1807	4.54%	13	0.00%	1387	4.11%	1	0.00%	350	6.29%	5	20.00%
HA Bipolar/Unipolar	752	2.66%	19	5.26%	563	1.95%	0	0.00%	105	3.81%	21	14.29%
TOTAL	**14051**	**2.84%**	**8184**	**2.63%**	**2651**	**3.28%**	**359**	**3.34%**	**806**	**5.58%**	**1250**	**2.16%**

Age Group 70-79	N (Top 5 Diagnoses)	%Revised (Top 5 Diagnoses)	N Primary OA	%Revised Primary OA	N Femoral Neck Fracture	%Revised Femoral Neck Fracture	N Dysplasia (Sec.OA)	%Revised Dysplasia (Sec. OA)	N Posttraum. (Sec. OA)	%Revised Posttraum. (Sec. OA)	N As. Necrosis Fem. Head (Sec. OA)	%Revised As. Necrosis Fem. Head (Sec. OA)
THR_Cemented	5360	2.16%	4012	2.22%	436	1.83%	143	2.10%	211	1.90%	242	2.48%
THR_Cementless	1379	2.25%	1053	1.80%	98	3.06%	13	7.69%	32	12.50%	89	1.12%
THR Hybrid	44	2.27%	33	3.03%	2	0.00%	1	0.00%	3	0.00%	3	0.00%
THR Reversed Hybrid	546	0.37%	396	0.25%	40	0.00%	18	0.00%	9	0.00%	29	0.00%
THR Resurfacing	6	0.00%	3	0.00%	0	0.00%	1	0.00%	0	0.00%	2	0.00%
HA Moore/Thompson	3493	2.12%	12	0.00%	2852	2.00%	1	0.00%	556	2.70%	6	0.00%
HA Bipolar/Unipolar	584	2.05%	18	5.56%	427	1.64%	2	0.00%	112	3.57%	6	0.00%
TOTAL	**11412**	**2.07%**	**5527**	**2.01%**	**3855**	**1.95%**	**179**	**2.23%**	**923**	**2.93%**	**377**	**1.86%**
80+												
THR_Cemented	692	1.16%	407	1.23%	156	0.00%	20	0.00%	28	3.57%	29	0.00%
THR_Cementless	112	2.68%	74	2.70%	20	5.00%	2	0.00%	6	0.00%	6	0.00%
THR Hybrid	5	0.00%	2	0.00%	1	0.00%	0	0.00%	2	0.00%	0	0.00%
THR Reversed Hybrid	74	2.70%	40	0.00%	17	5.88%	1	0.00%	4	0.00%	3	33.33%
THR Resurfacing	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
HA Moore/Thompson	2772	0.76%	12	0.00%	2430	0.66%	1	0.00%	289	1.38%	0	0.00%
HA Bipolar/Unipolar	274	0.73%	5	0.00%	223	0.90%	0	0.00%	38	0.00%	1	0.00%
TOTAL	**3929**	**0.92%**	**540**	**1.30%**	**2847**	**0.70%**	**24**	**0.00%**	**367**	**1.36%**	**39**	**2.56%**

Table 56 – Top 5 Diagnoses – Revision Rate by implant type, 2001 – 2015, Female

Age Group <49	N (Top 5 Diagnoses)	%Revised (Top 5 Diagnoses)	N Primary OA	%Revised Primary OA	N Femoral Neck Fracture	%Revised Femoral Neck Fracture	N Dysplasia (Sec. OA)	%Revised Dysplasia (Sec. OA)	N Posttraum. (Sec. OA)	%Revised Posttraum. (Sec. OA)	N As. Necrosis Fem. Head (Sec. OA)	%Revised As. Necrosis Fem. Head (Sec. OA)
THR_Cemented	699	9.73%	213	7.98%	39	0.00%	258	11.63%	26	19.23%	61	8.20%
THR_Cementless	3622	3.84%	978	3.37%	85	2.35%	1552	4.64%	103	2.91%	548	3.10%
THR Hybrid	55	12.73%	13	15.38%	1	0.00%	29	10.34%	1	0.00%	4	0.00%
THR Reversed Hybrid	85	14.12%	22	9.09%	1	0.00%	32	12.50%	5	60.00%	7	14.29%
THR Resurfacing	92	10.87%	16	12.50%	0	0.00%	24	20.83%	1	0.00%	47	6.38%
HA Moore/Thompson	121	4.13%	2	0.00%	76	5.26%	1	0.00%	35	2.86%	0	0.00%
HA Bipolar/Unipolar	215	6.98%	10	30.00%	113	7.08%	1	100.00%	34	2.94%	35	2.86%
TOTAL	**4889**	**5.24%**	**1254**	**4.70%**	**315**	**4.44%**	**1897**	**6.06%**	**205**	**6.34%**	**702**	**3.85%**
50-59												
THR_Cemented	2944	5.50%	1705	6.04%	185	2.70%	530	4.91%	122	10.66%	151	3.31%
THR_Cementless	4547	2.46%	2489	2.21%	268	1.87%	862	2.78%	127	3.15%	473	2.33%
THR Hybrid	97	5.15%	57	5.26%	5	0.00%	18	5.56%	5	20.00%	6	0.00%
THR Reversed Hybrid	193	4.15%	87	3.45%	16	6.25%	54	9.26%	5	0.00%	16	0.00%
THR Resurfacing	30	6.67%	7	0.00%	0	0.00%	3	33.33%	3	0.00%	16	6.25%
HA Moore/Thompson	680	11.03%	2	50.00%	470	10.00%	0	0.00%	178	11.80%	1	0.00%
HA Bipolar/Unipolar	672	2.98%	14	7.14%	479	1.88%	1	0.00%	103	5.83%	34	8.82%
TOTAL	**9163**	**4.19%**	**4361**	**3.81%**	**1423**	**4.71%**	**1468**	**3.88%**	**543**	**8.29%**	**697**	**2.87%**
60-69												
THR_Cemented	9746	3.55%	6901	3.36%	684	3.36%	795	4.15%	326	5.52%	338	3.85%
THR_Cementless	4392	1.75%	3186	1.51%	278	2.88%	308	2.92%	110	4.55%	255	1.96%
THR Hybrid	117	6.84%	86	6.98%	7	0.00%	6	0.00%	5	0.00%	3	0.00%
THR Reversed Hybrid	769	1.43%	519	1.73%	85	1.18%	53	0.00%	12	0.00%	36	0.00%
THR Resurfacing	14	0.00%	7	0.00%	0	0.00%	1	0.00%	1	0.00%	5	0.00%
HA Moore/Thompson	3059	6.24%	18	11.11%	2236	5.77%	1	100.00%	716	7.40%	4	0.00%
HA Bipolar/Unipolar	1267	2.60%	30	3.33%	920	2.50%	2	0.00%	253	2.77%	13	7.69%
TOTAL	**19364**	**3.44%**	**10747**	**2.77%**	**4210**	**4.37%**	**1166**	**3.69%**	**1423**	**5.83%**	**654**	**2.91%**

Age Group 70-79	N (Top 5 Diagnoses)	%Revised (Top 5 Diagnoses)	N Primary OA	%Revised Primary OA	N Femoral Neck Fracture	%Revised Femoral Neck Fracture	N Dysplasia (Sec. OA)	%Revised Dysplasia (Sec. OA)	N Posttraum. (Sec. OA)	%Revised Posttraum. (Sec. OA)	N As. Necrosis Fem. Head (Sec. OA)	%Revised As. Necrosis Fem. Head (Sec. OA)
THR_Cemented	10070	1.48%	7049	1.39%	1249	1.36%	438	1.83%	356	1.97%	289	0.35%
THR_Cementless	1693	1.00%	1273	1.18%	138	0.00%	73	0.00%	48	4.17%	68	0.00%
THR Hybrid	57	1.75%	39	0.00%	4	0.00%	3	0.00%	2	50.00%	2	0.00%
THR Reversed Hybrid	833	1.08%	582	0.52%	91	2.20%	38	2.63%	10	0.00%	28	3.57%
THR Resurfacing	3	66.67%	2	50.00%	0	0.00%	0	0.00%	0	0	1	100.00%
HA Moore/Thompson	9899	3.01%	59	6.78%	7945	2.95%	1	100.00%	1664	3.00%	6	16.67%
HA Bipolar/Unipolar	1587	1.32%	24	4.17%	1207	0.83%	1	100.00%	278	2.52%	6	0.00%
TOTAL	**24142**	**2.06%**	**9028**	**1.35%**	**10634**	**2.47%**	**554**	**1.99%**	**2358**	**2.84%**	**400**	**1.00%**
80+												
THR_Cemented	1518	0.79%	734	0.54%	527	0.95%	21	4.76%	75	0.00%	44	2.27%
THR_Cementless	168	2.38%	104	2.88%	39	0.00%	0	0.00%	9	11.11%	6	0.00%
THR_Hybrid	6	0.00%	2	0.00%	0	0.00%	0	0.00%	3	0.00%	0	0.00%
THR_Reversed_Hybrid	128	1.56%	69	1.45%	30	0.00%	4	0.00%	3	0.00%	3	0.00%
HA Moore/Thompson	9020	0.65%	49	0.00%	7874	0.69%	3	0.00%	936	0.32%	6	0.00%
HA Bipolar/Unipolar	832	0.48%	11	0.00%	665	0.30%	0	0.00%	132	2.27%	3	0.00%
TOTAL	**11672**	**0.69%**	**969**	**0.83%**	**9135**	**0.67%**	**28**	**3.57%**	**1158**	**0.60%**	**62**	**1.61%**

6.1.7 Revision outcome. Implant type comparison by diagnosis and gender

For a more accurate image about the revisions of the hip arthroplasties in Romania between 2001 – 2015, the revision analysis is extended to outcomes for specific age groups (taking in consideration patients' age at time of primary intervention) and, subsequently, top three diagnoses (as frequency) for each age group, as it follows:

Table 57 – Top three most frequent diagnoses by age groups, 2001 - 2015

Age Group	Top three diagnoses		
<49 years old	Primary osteoarthritis (OA)	Posttraumatic (Sec. OA)	Aseptic necrosis of femoral head (Sec. OA)
50 – 59 years old	Primary osteoarthritis (OA)	Femoral neck fracture	Aseptic necrosis of femoral head (Sec. OA)
60 – 69 years old	Primary osteoarthritis (OA)	Femoral neck fracture	Posttraumatic (Sec. OA)
70 – 79 years old	Primary osteoarthritis (OA)	Femoral neck fracture	Posttraumatic (Sec. OA)
80+ years old	All diagnoses		

The outcomes present the comparative 10 years **Cumulative Revision Rates** for each implant type (Total Hip Replacement: Cemented, Cementless, Hybrid, Reversed Hybrid, Resurfacing and Hemiarthroplasties: Moore/Thompson, Bipolar/Unipolar) of each subgroup (age – diagnosis; except for 80+ group – all diagnoses). For the accuracy of the analysis, the endoprosthesis with a frequency of less than 10 cases were censored for all subgroups.

Cox Regression Analysis was performed to indicate in the cases with significant effect on the survival, the revision hazard ratio/ risk ratio (HR) for the mutually adjusted covariates – gender and implant type. For the implant type all categories were compared to Cemented THR as reference group as it holds the highest overall implanting frequency.

- For <49 years age group, the lowest 10-years cumulative revision rate for both osteoarthritis and aseptic necrosis of femoral head belongs to Cementless THR. Cemented THR has significantly higher associated risks for revision with hazard rates of 1.756 (Sig. 0.014, OA) and 2.186 (Sig. 0.002, Aseptic Necrosis Femoral Head).

  In contrast, Hybrid THR is 4.8 times more likely to have a revision in Primary OA (Sig. 0.003), holding the highest 10 years cumulative revision rate. For posttraumatic and Aseptic Necrosis Femoral Head (sec. O.A.), THR Reversed Hybrid has a 10.5 times higher HR and 4.5 times higher HR, respectively when compared to Cementless THR (HR = 10.525, Sig.<0.001, 4.587, Sig.=0.010). Cemented THR holds the second highest HR (4.286 and sig <0.01) for Posttraumatic (Sec. OA).

- In 50 – 59 years old age group, Cemented THR and Reversed Hybrid THR have a higher HR in 10 years for each diagnosis and are more likely to have a revision for both OA and aseptic necrosis of femoral head in comparison to Cementless THR**. THR Resurfacing has a 2.2 times higher HR (Sig. 0.172)** than Cementless THR in cases of **aseptic necrosis of femoral head.** The unacceptable situation is maintained in the case of femoral neck fracture, Moore/Thompson HA having a hazard rate 4.05 times higher than Cementless THR (Sig. <0.001).

- For 60 – 69 years age group, THR Resurfacing has a 3.3 times higher HR and Cemented THR has a 1.549 increased HR when compared to Cementless THR (sig. 0.095 and sig <0.001 respectively) for Primary O.A. **Moore/Thompson HA is indicated to have the highest revision rate for both Femoral Neck Fracture and Post Traumatic Secondary O.A.** with 72.5% and 46.9% higher HR when compared to Cementless THR (sig 0.058 and sig. 0.303).

- 70 – 79 years old male patients with primary O.A. are 53.6% more likely (HR = 1.536, Sig.<0.001) to have a revision compared to female patients with the same diagnosis. The 70 – 79 OA subgroup **indicates a lower HR for THR Reversed Hybrid when compared to** Cementless THR (HR=0.378 Sig. 0.05). For posttraumatic Secondary OA, Cemented THR (HR=0.232 Sig. 0.004), Moore Type HA (HR=0.384 Sig. 0.026) and Bipolar HA (HR=0.340 Sig. 0.034) have a visibly lower HR when compared to Cementless THR which holds the highest cumulative revision rate in 10 years. In Femoral Neck Fractures, Moore Type implants have the highest cumulative revision rate and a 2.017 (sig. 0.227) increased risk to have a revision compared Cementless THR.

- For 80+ years age group regarding all diagnoses, Cementless THR has the highest HR rates, being outperformed by Bipolar HA (HR= 0.255 Sig. 0.014), Moore Type HA (HR = 0.340 Sig. 0.007) and THR Cemented (HR = 0.345 sig. 0.016) implants. THR Reversed Hybrid also performs only slightly better than Cementless THR (HR=0.895 Sig. 0.859).

6.1.7.1 Age Group <49 Years Old

6.1.7.1.1 Primary Osteoarthritis (OA)

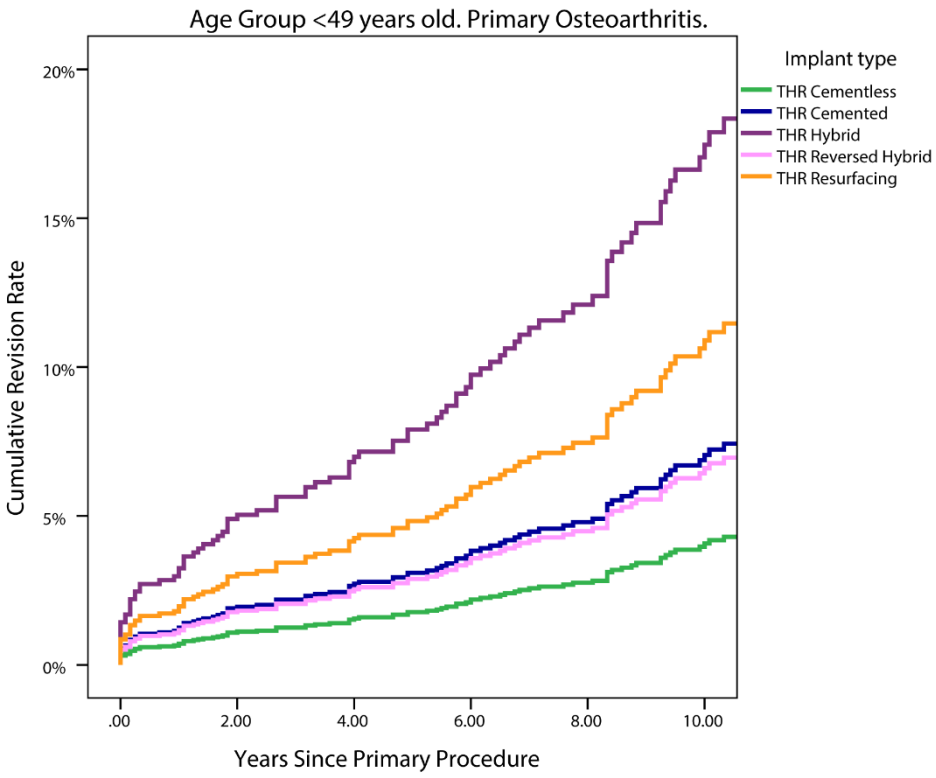


Figure 103 – Cumulative revision rate for age group <49 years old and diagnosis OA, by implant type.

HR: 2001 – 2015, adjusted by gender

THR Cemented vs. THR Cementless
HR = 1.744 (1.115, 2.727), Sig.=0.015

THR Hybrid vs. THR Cementless
HR = 4.847 (1.654, 12.582), Sig.= 0.003

THR Rev. Hybrid vs. THR Cementless
HR = 1.621 (0.396, 6.637), Sig.= 0.502

THR Resurfacing vs. THR Cementless
HR = 3.823(1.385, 10.556), Sig.= 0.010

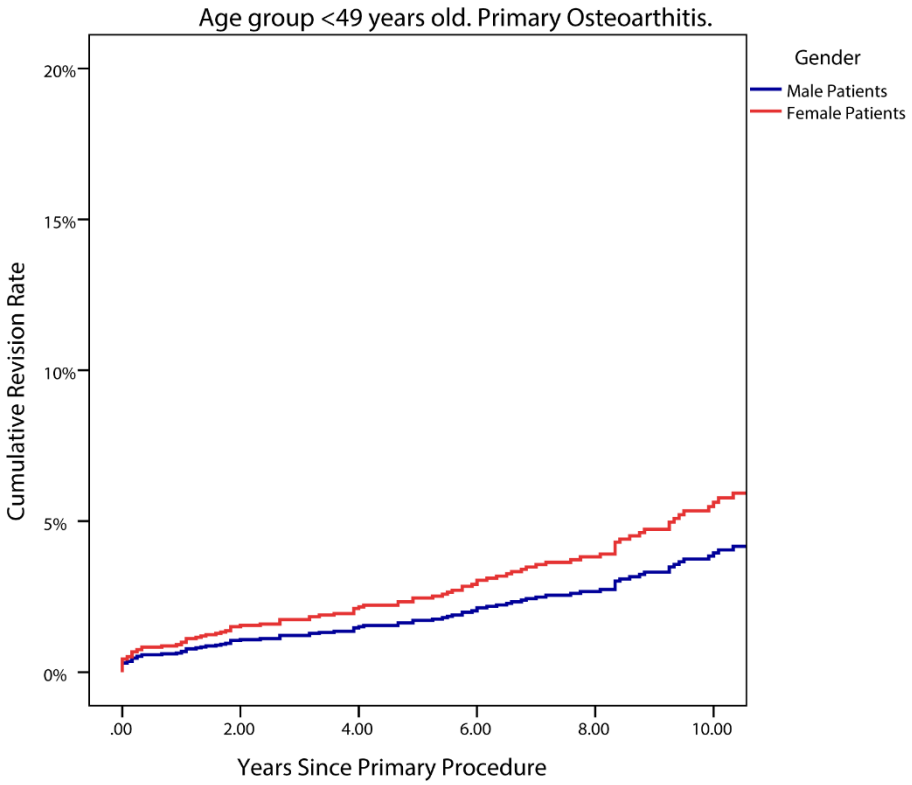


Figure 104 – Cumulative revision rate for age group <49 years old and diagnosis OA, by gender.

HR: 2001 – 2015, adjusted by implant type

Male vs. Female Patients
HR = 0.647 (0.439, 0.954), Sig.=0.028

6.1.7.1.2 Posttraumatic (Sec. OA)

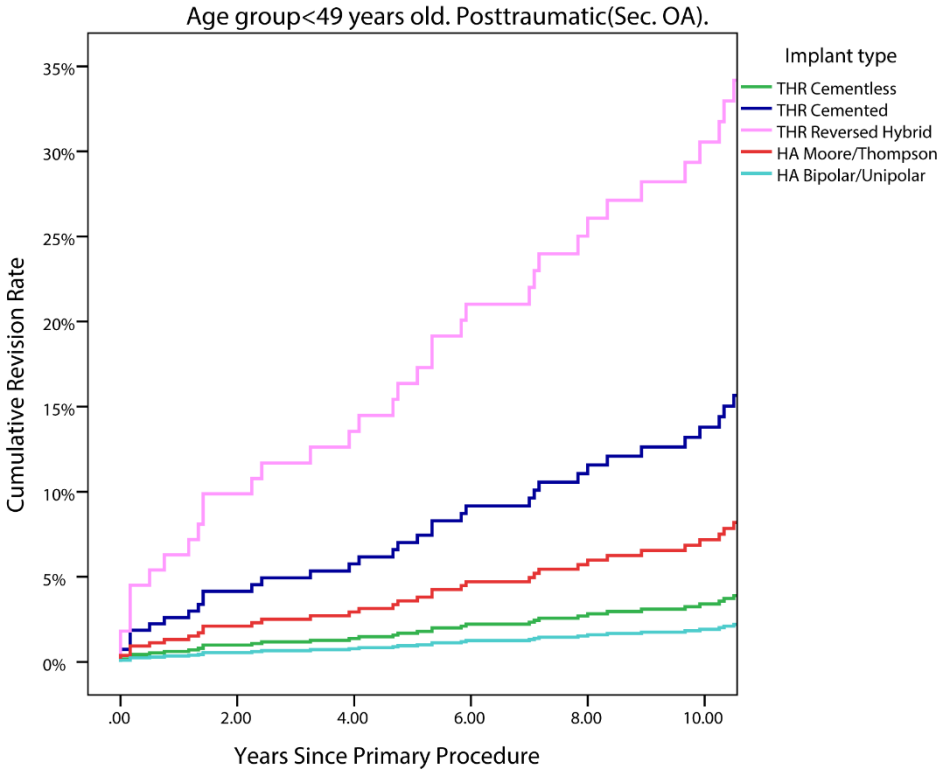


Figure 105 – Cumulative revision rate for age group <49 years old and diagnosis Posttraumatic (Sec. OA), by implant type.

HR: 2001 – 2015, adjusted by gender

THR Cemented vs. THR Cementless
HR = 4.286 (1.912, 9.607), Sig.<0.001

THR Rev. Hybrid vs. THR Cementless
HR = 10.525 (3.347, 32.560), Sig.<0.001

HA Moore/Thompson vs. THR Cementless
HR = 2.150 (0.859, 5.383), Sig.=0.102

HA Bipolar/Unipolar vs. THR Cementless
HR = 0.560 (0.123, 2.548), Sig.=0.453

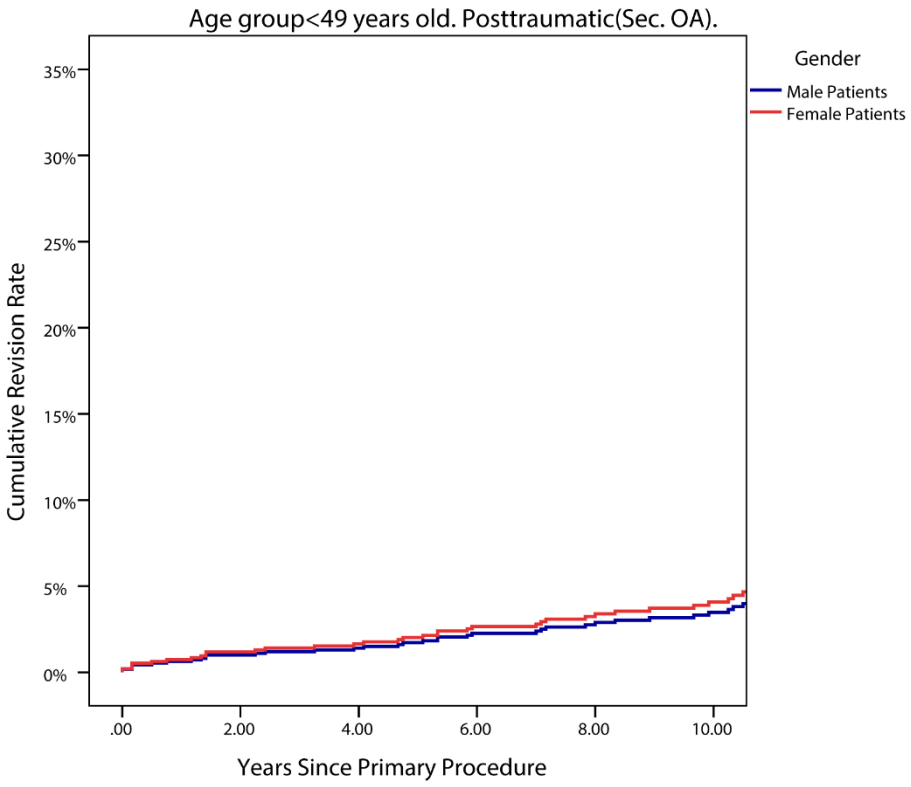


Figure 106 – Cumulative revision rate for age group <49 years old and diagnosis Posttraumatic (Sec. OA), by gender.

HR: 2001 – 2015, adjusted by implant type

Male vs. Female Patients
HR = 0.851 (0.434, 1.668), Sig.=0.638

6.1.7.1.3 Aseptic Necrosis of Femoral Head (Sec. OA)

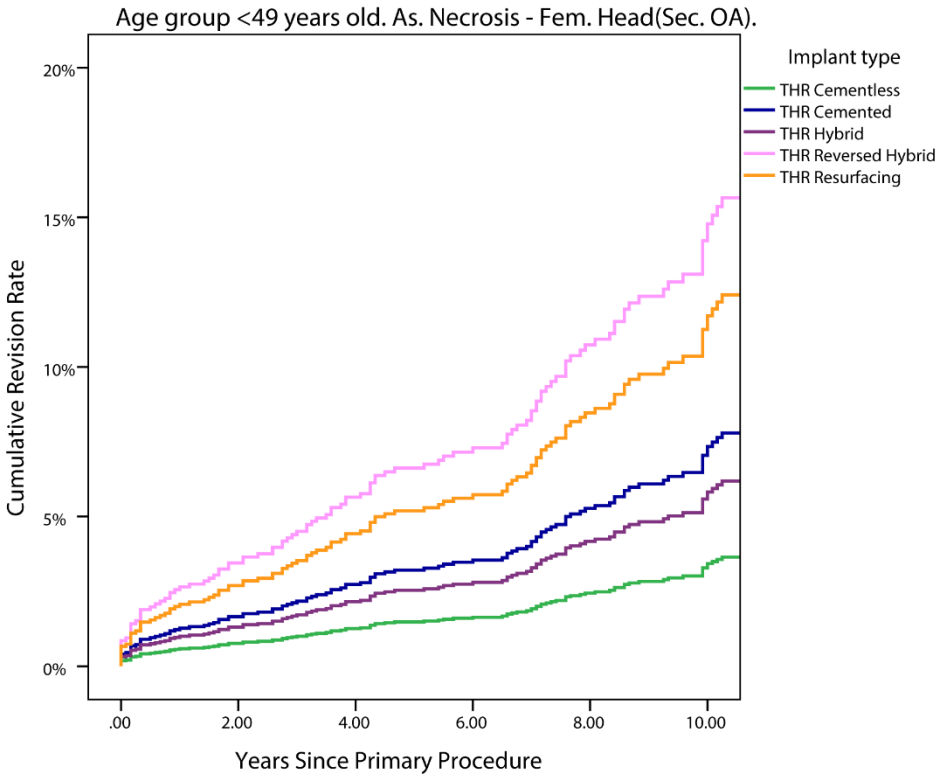


Figure 107 – Cumulative revision rate for age group <49 years old and diagnosis Aseptic Necrosis of Femoral Head (Sec. OA), by implant type.

HR: 2001 – 2015, adjusted by gender

THR Cemented vs. THR Cementless
HR = 2.186 (1.323, 3.611), Sig.=0.002

THR Hybrid vs. THR Cementless
HR = 1.720 (0.423, 7.004), Sig.=0.449

THR Rev. Hybrid vs. THR Cementless
HR = 4.587 (1.448, 14.529), Sig.=0.010

THR Resurfacing vs. THR Cementless
HR = 3.571 (2.109, 6.047), Sig.<0.001

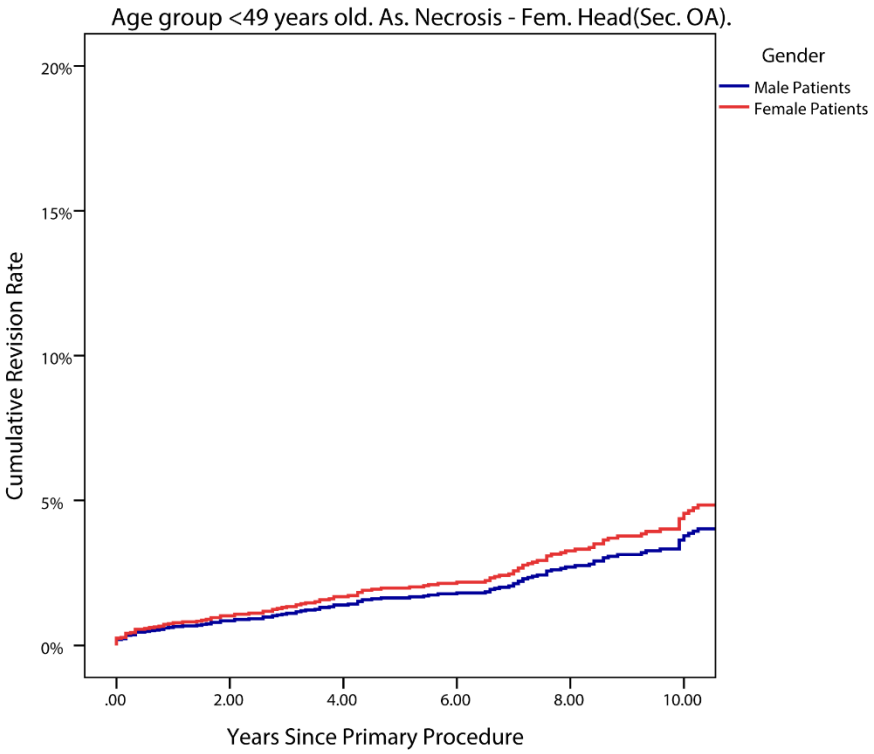


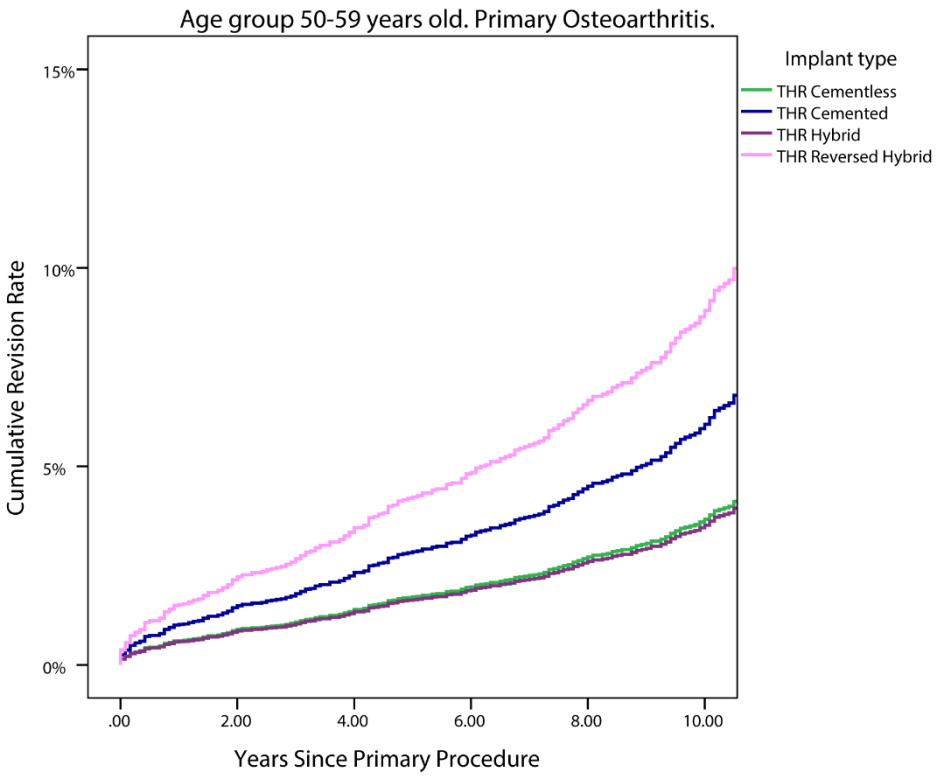
Figure 108 – Cumulative revision rate for age group <49 years old and diagnosis Aseptic Necrosis of Femoral Head (Sec. OA), by gender.

HR: 2001 – 2015, adjusted by implant type

Male vs. Female Patients
HR = 0.828 (0.535, 1.279), Sig.=0.395

6.1.7.2 Age Group 50 – 59 Years Old

6.1.7.2.1 Primary Osteoarthritis



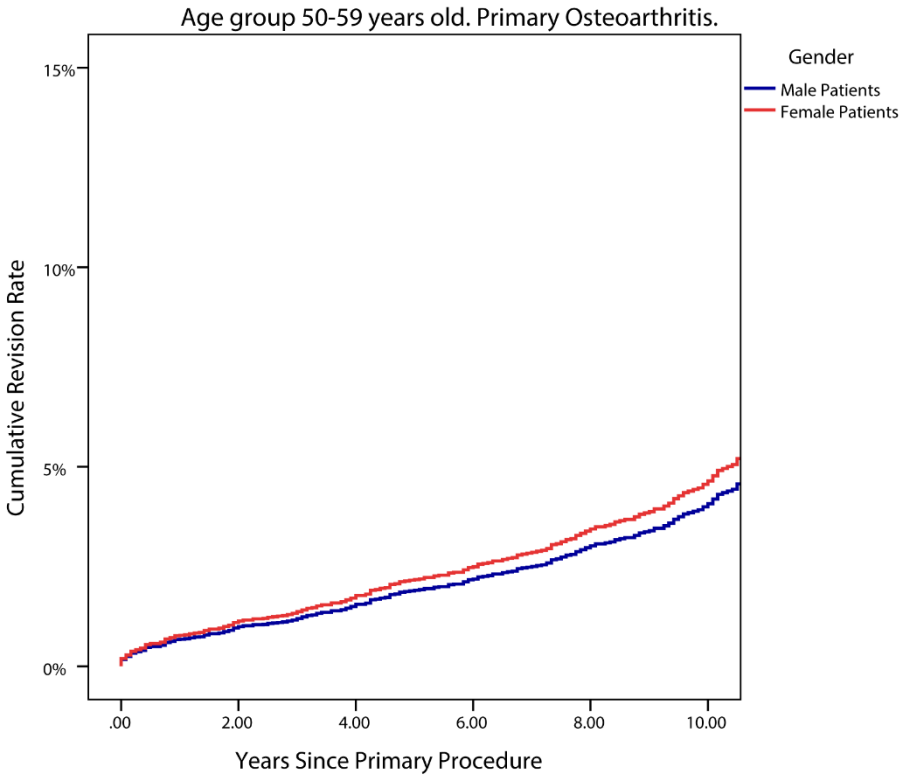
HR: 2001 – 2015, adjusted by gender

THR Cemented vs. THR Cementless
HR = 1.672 (1.309, 2.136), Sig.<0.001

THR Hybrid vs. THR Cementless
HR = 0.958 (0.304, 12.715), Sig.= 0.944

THR Rev. Hybrid vs. THR Cementless
HR = 2.502 (1.222, 5.124), Sig.= 0.012

Figure 109 – Cumulative revision rate for age group 50 – 59 years old and diagnosis OA, by implant type.



HR: 2001 – 2015,
adjusted by implant type

Male vs. Female Patients
HR = 0.875 (0.691, 1.107), Sig.=0.266

Figure 110 – Cumulative revision rate for age group 50 – 59 years old and diagnosis OA, by gender.

6.1.7.2.2 *Aseptic Necrosis of Femoral Neck (Sec. OA)*

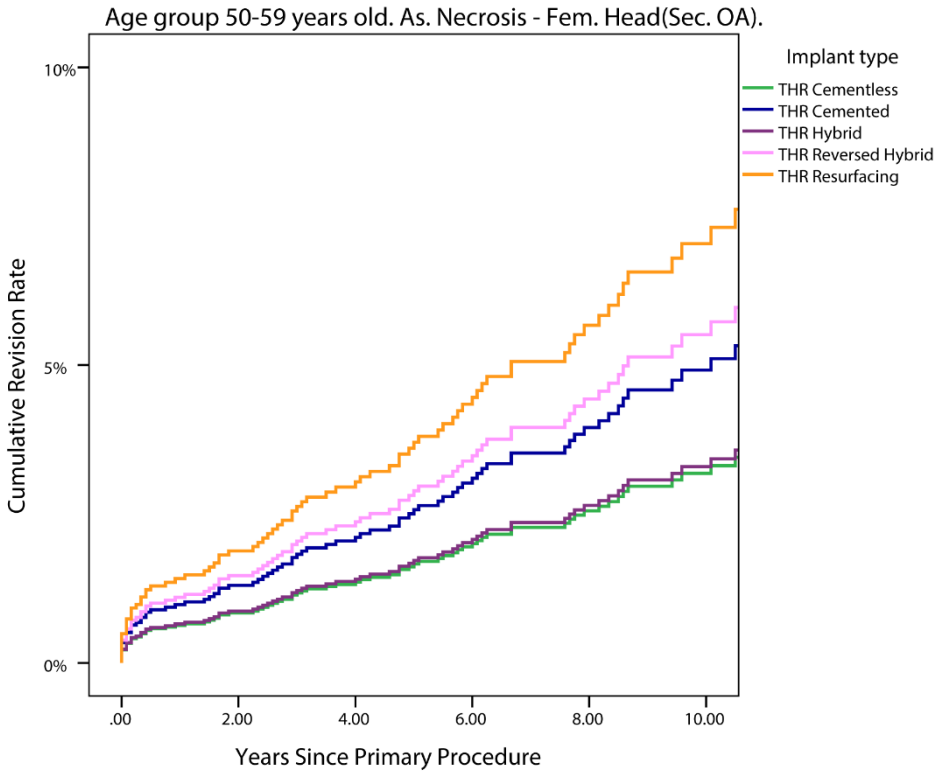


Figure 111 – Cumulative revision rate for age group 50 – 59 years old and diagnosis aseptic necrosis of femoral head(sec. OA), by implant type.

HR: 2001 – 2015, adjusted by gender

THR Cemented vs. THR Cementless
HR = 1.558 (0.964, 2.518), Sig.=0.070

THR Hybrid vs. THR Cementless
HR = 1.036 (0.143, 7.518), Sig.= 0.972

THR Rev. Hybrid vs. THR Cementless
HR = 1.752 (0.426, 7.207), Sig.= 0.437

THR Resurfacing vs. THR Cementless
HR = 2.256 (0.703, 7.243), Sig.= 0.172

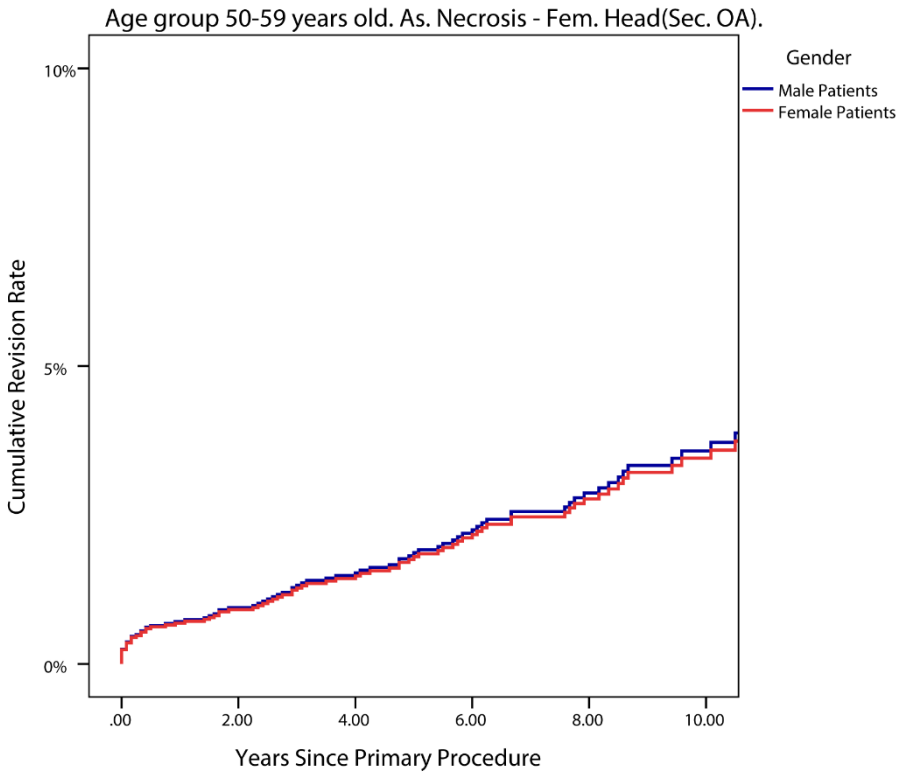


Figure 112 – Cumulative revision rate for age group 50 – 59 years old and diagnosis aseptic necrosis of femoral head (sec. OA), by gender.

HR: 2001 – 2015, adjusted by implant type

Male vs. Female Patients
HR = 1.037 (0.607, 1.769), Sig.=0.895

6.1.7.2.3 Femoral Neck Fracture

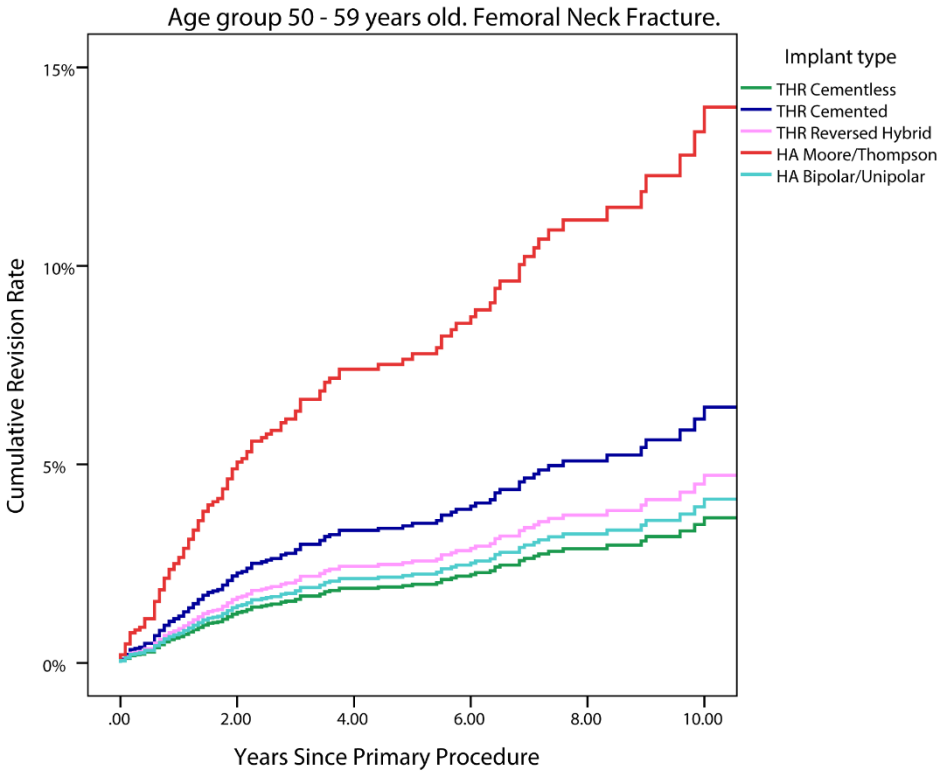


Figure 113 – Cumulative revision rate for age group 50 – 59 years old and diagnosis femoral neck fracture, by implant type.

HR: 2001 – 2015, adjusted by gender

THR Cemented vs. THR Cementless
HR = 1.788 (0.771, 4.149), Sig.=0.176

THR Rev. Hybrid vs. THR Cementless
HR = 1.300 (0.166, 10.178), Sig.= 0.803

THR Moore/Thompson vs. THR Cementless
HR = 4.050 (2.092, 7.839), Sig<0.001

THR Bipolar/Unipolar vs. THR Cementless
HR = 1.131 (0.532, 2.403), Sig.= 0.749

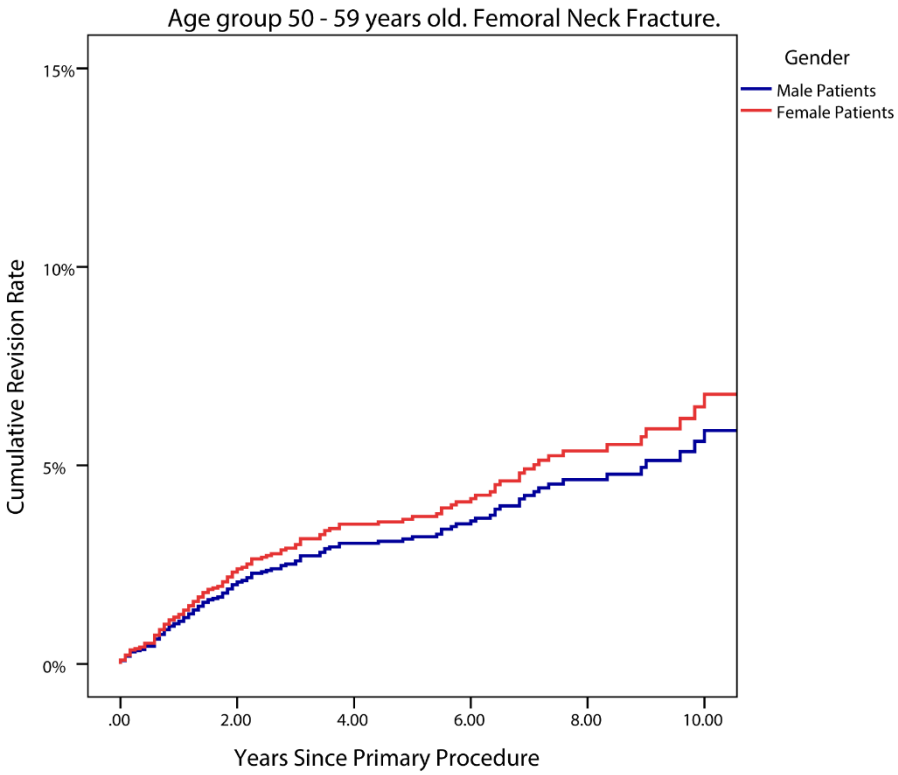


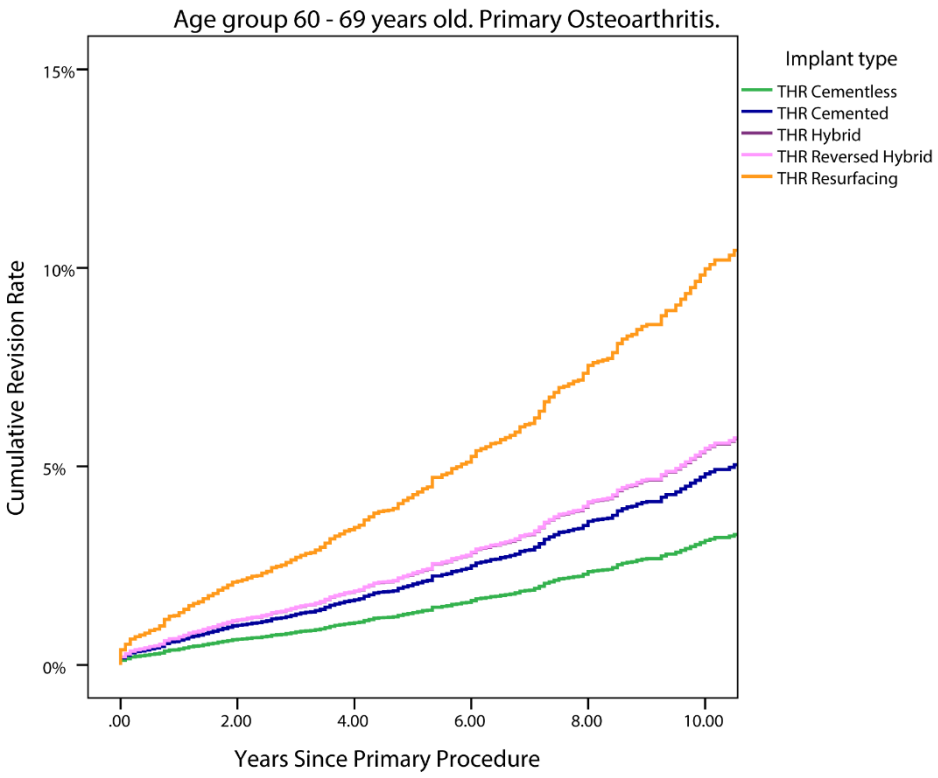
Figure 114 – Cumulative revision rate for age group 50 – 59 years old and diagnosis femoral neck fracture, by gender.

HR: 2001 – 2015, adjusted by implant type

Male vs. Female Patients
HR = 0.861 (0.599, 1.239), Sig.=0.420

6.1.7.3 Age Group 60 – 69 Years Old

6.1.7.3.1 Primary Osteoarthritis



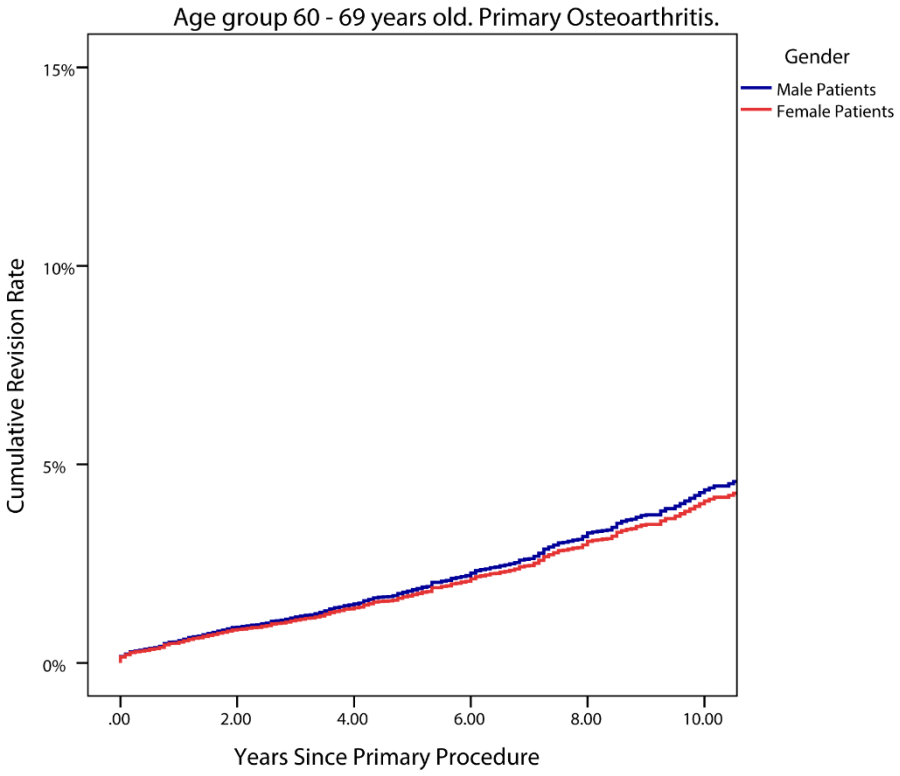
HR: 2001 – 2015, adjusted by gender

THR Cemented vs. THR Cementless
HR = 1.549 (1.235, 1.942), Sig.<0.001

THR Hybrid vs. THR Cementless
HR = 1.757 (0.815, 3.790), Sig.= 0.150

THR Resurfacing vs. THR Cementless
HR = 3.301 (0.813, 13.409), Sig.= 0.095

Figure 115 – Cumulative revision rate for age group 60 – 69 years old and diagnosis OA, by implant type.



HR: 2001 – 2015,
adjusted by implant type

Male vs. Female Patients
HR = 1.071 (0.897, 1.278), Sig.=0.449

Figure 116 – Cumulative revision rate for age group 60 – 69 years old and diagnosis femoral neck fracture, by gender.

6.1.7.3.2 *Femoral Neck Fracture*

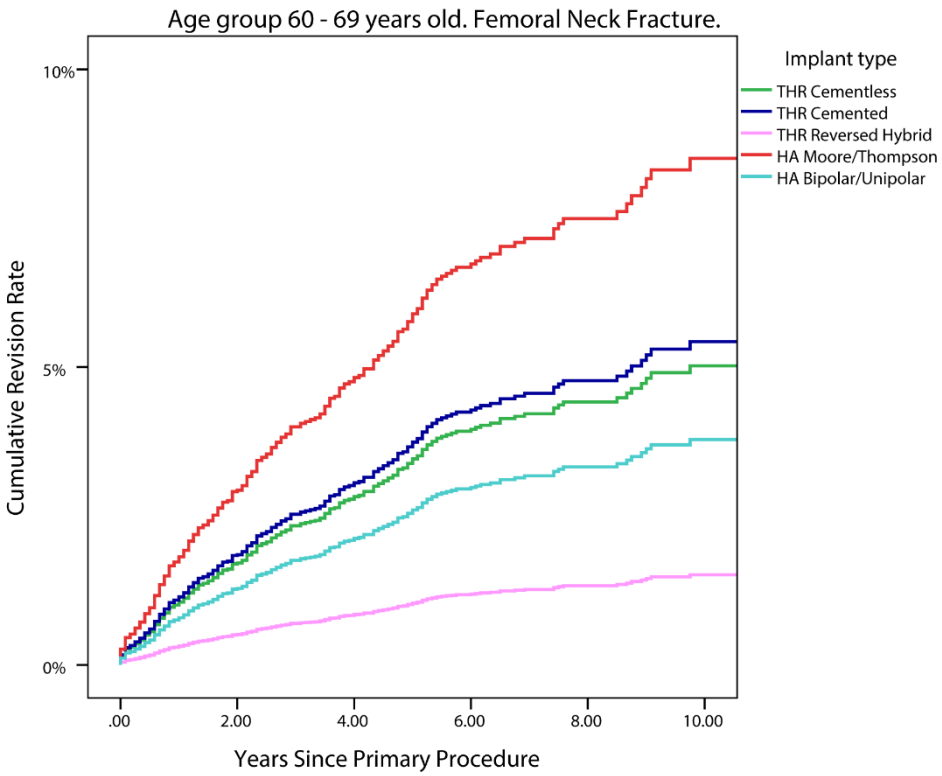


Figure 117 – Cumulative revision rate for age group 60 – 69 years old and diagnosis femoral neck fracture, by implant type.

HR: 2001 – 2015, adjusted by gender

THR Cemented vs. THR Cementless
HR = 1.083 (0.575, 2.041), Sig.=0.805

THR Rev. Hybrid vs. THR Cementless
HR = 0.296 (0.039, 2.264), Sig.= 0.241

THR Moore/Thompson vs. THR Cementless
HR = 1.725 (0.982, 3.032), Sig=0.058

THR Bipolar/Unipolar vs. THR Cementless
HR = 0.749 (0.395, 1.421), Sig.= 0.376

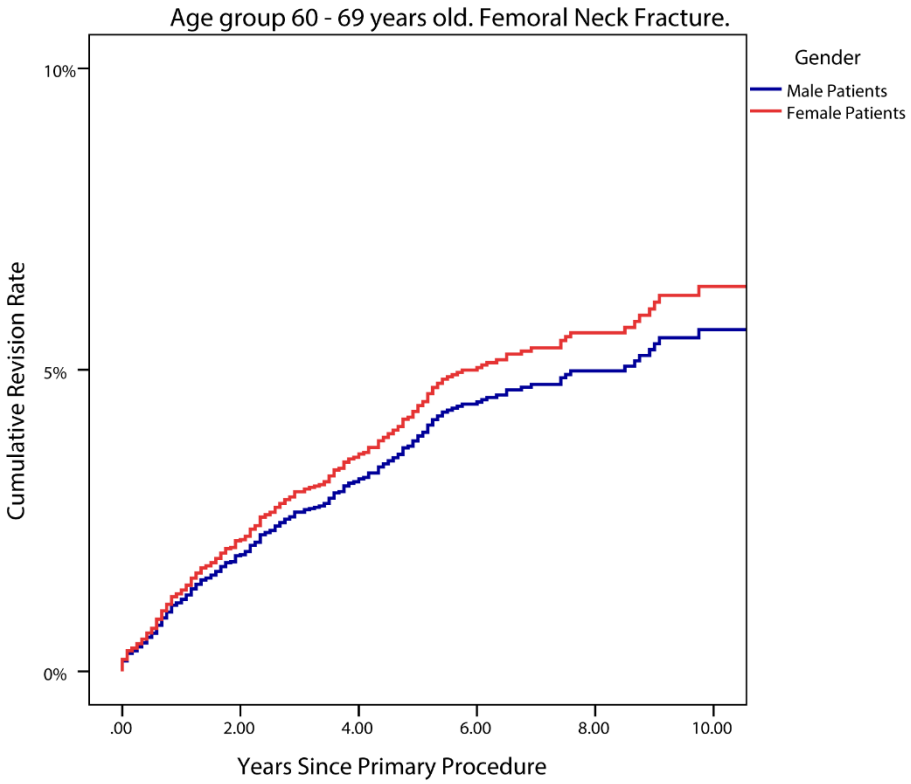


Figure 118 – Cumulative revision rate for age group 60 – 69 years old and diagnosis OA, by gender.

HR: 2001 – 2015, adjusted by implant type

Male vs. Female Patients
HR = 0.884 (0.685, 1.142), Sig.= 0.346

6.1.7.3.3 Posttraumatic (Sec. OA)

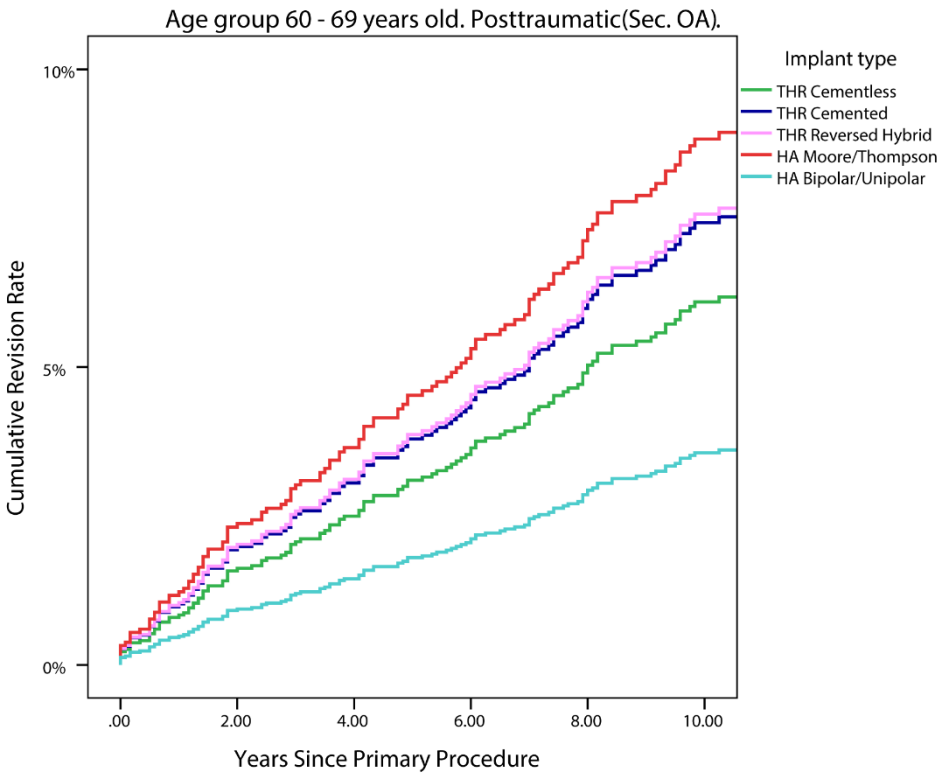


Figure 119 – Cumulative revision rate for age group 60 – 69 years old and diagnosis Posttraumatic (Sec. OA), by implant type.

HR: 2001 – 2015, adjusted by gender

THR Cemented vs. THR Cementless
HR = 1.227 (0.566, 2.660), Sig.=0.605

THR Rev. Hybrid vs. THR Cementless
HR = 1.251 (0.156, 10.026), Sig.=0.833

HA Moore/Thompson vs. THR Cementless
HR = 1.469 (0.706, 3.057), Sig.=0.303

HA Bipolar/Unipolar vs. THR Cementless
HR = 0.576 (0.231, 1.439), Sig.=0.238

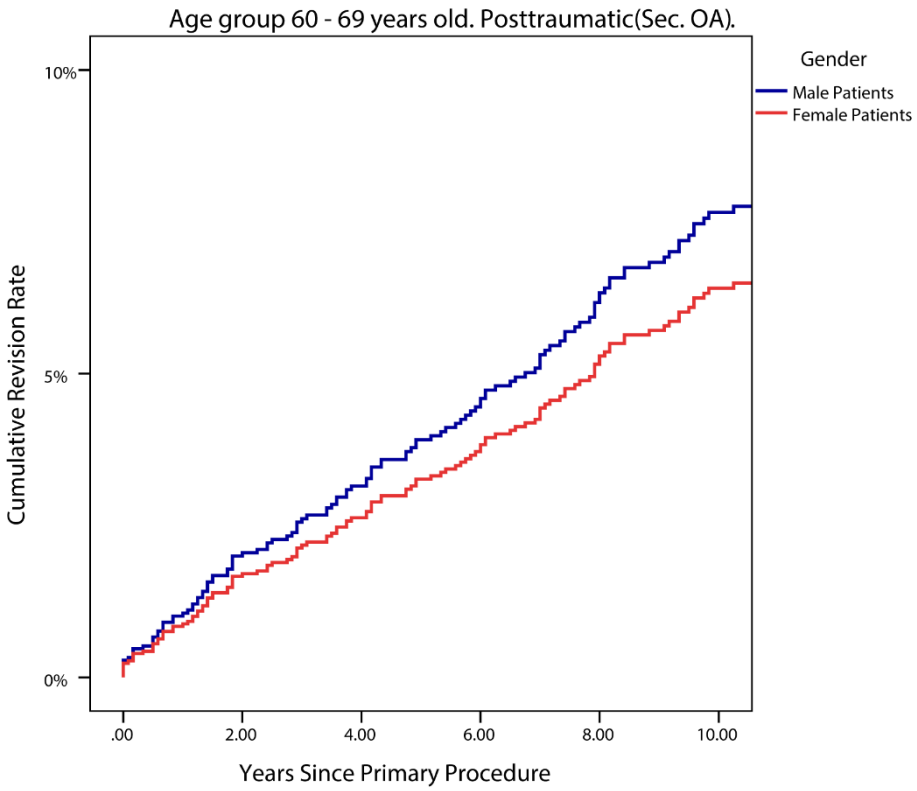


Figure 120 – Cumulative revision rate for age group 60 – 69 years old and diagnosis Posttraumatic (Sec. OA), by gender.

HR: 2001 – 2015, adjusted by implant type

Male vs. Female Patients
HR = 1.203 (0.834, 1.734), Sig.=0.322

6.1.7.4 Age Group 70 – 79 Years Old

6.1.7.4.1 Osteoarthritis

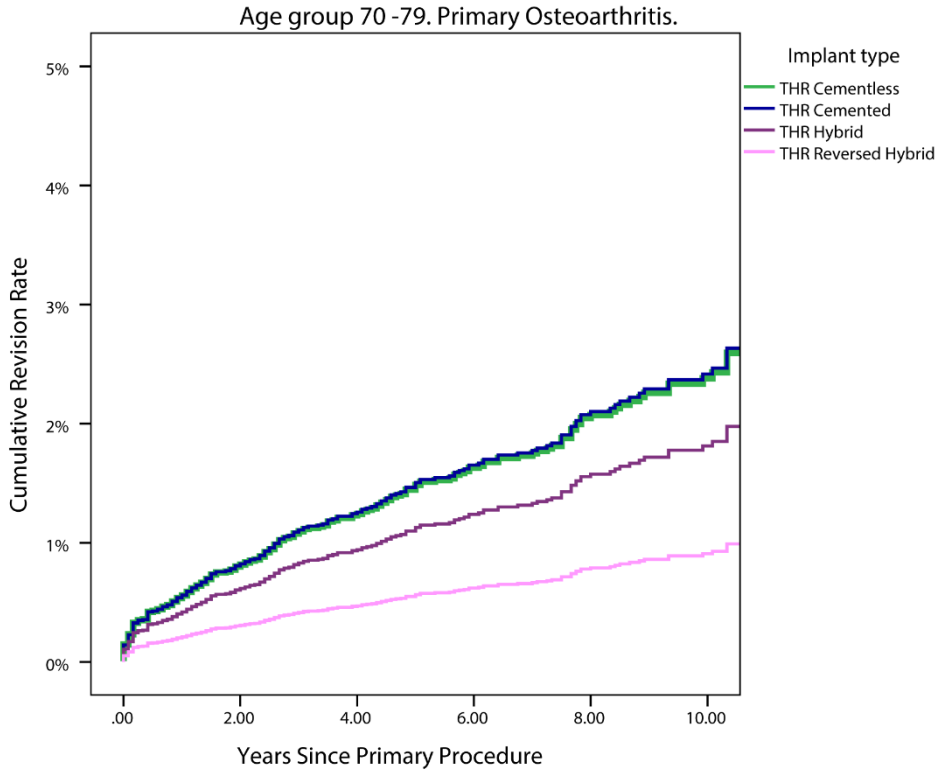


Figure 121 – Cumulative revision rate for age group 70 – 79 years old and diagnosis OA, by implant type.

HR: 2001 – 2015, adjusted by gender

THR Cemented vs. THR Cementless
HR = 1.012 (0.698, 1.469), Sig.=0.949

THR Hybrid vs. THR Cementless
HR = 0.757 (0.103, 5.538), Sig.= 0.784

THR Rev. Hybrid vs. THR Cementless
HR = 0.378 (0.134, 1.067), Sig.= 0.050

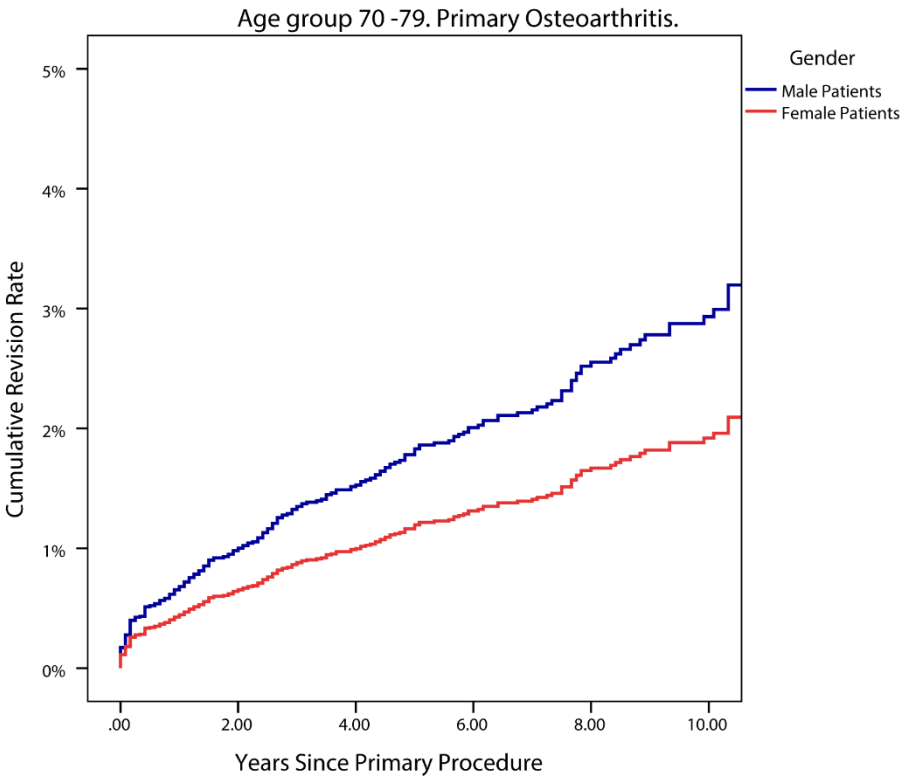


Figure 122 – Cumulative revision rate for age group 70 – 79 years old and diagnosis femoral neck fracture, by gender.

HR: 2001 – 2015, adjusted by implant type

Male vs. Female Patients
HR = 1.536 (1.182, 1.995), Sig.<0.001

6.1.7.4.2 Femoral Neck Fracture

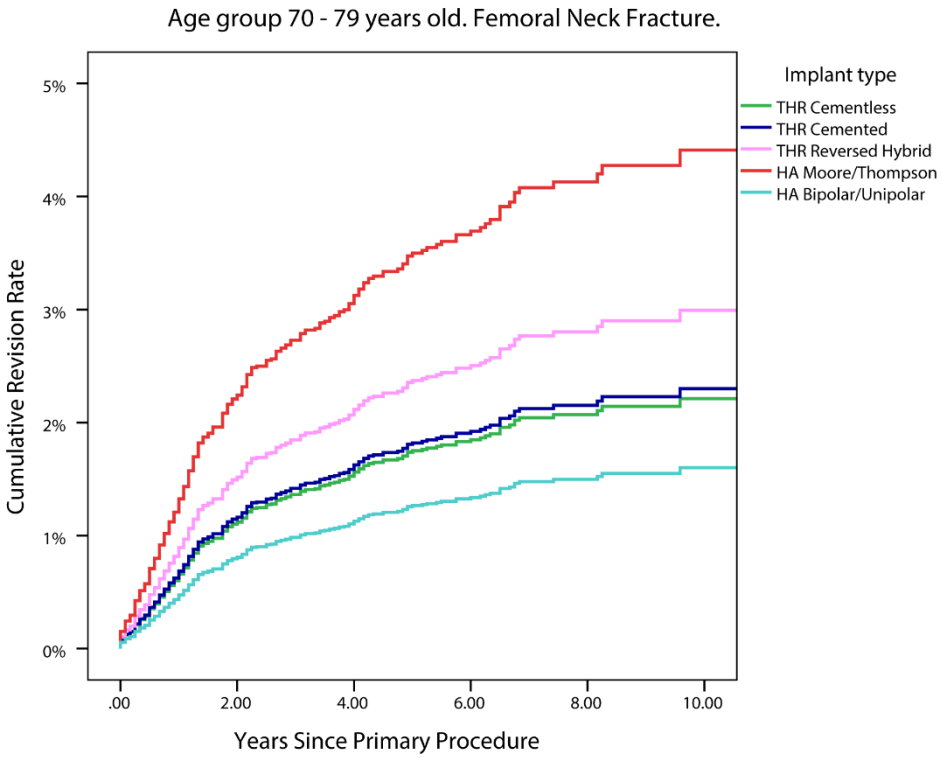


Figure 123 – Cumulative revision rate for age group 70 – 79 years old and diagnosis femoral neck fracture, by implant type.

HR: 2001 – 2015, adjusted by gender

THR Cemented vs. THR Cementless
HR = 1.040 (0.314, 3.477), Sig.=0.949

THR Rev. Hybrid vs. THR Cementless
HR = 1.359 (0.227, 8.136), Sig.= 0.737

THR Moore/Thompson vs. THR Cementless
HR = 2.017 (0.646, 6.294), Sig=0.227

THR Bipolar/Unipolar vs. THR Cementless
HR = 0.721 (0.211, 2.643), Sig.= 0.602

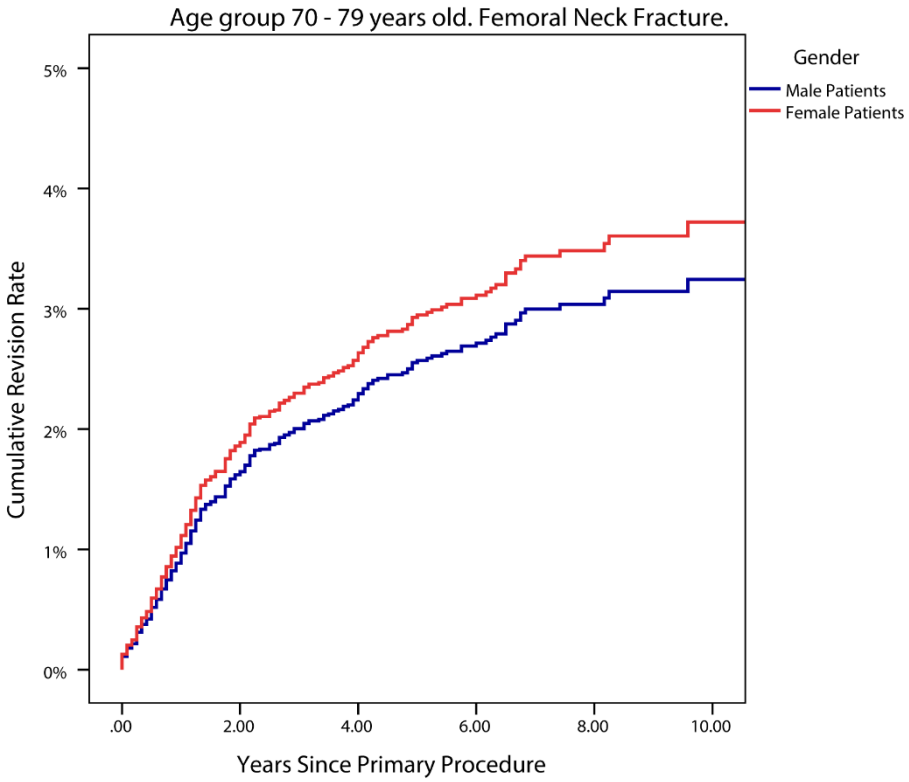


Figure 124 – Cumulative revision rate for age group 70 – 79 years old and diagnosis OA, by gender.

HR: 2001 – 2015, adjusted by implant type

Male vs. Female Patients
HR = 0.860 (0.673, 1.125), Sig.=0.288

6.1.7.4.3 Posttraumatic (Sec. OA)

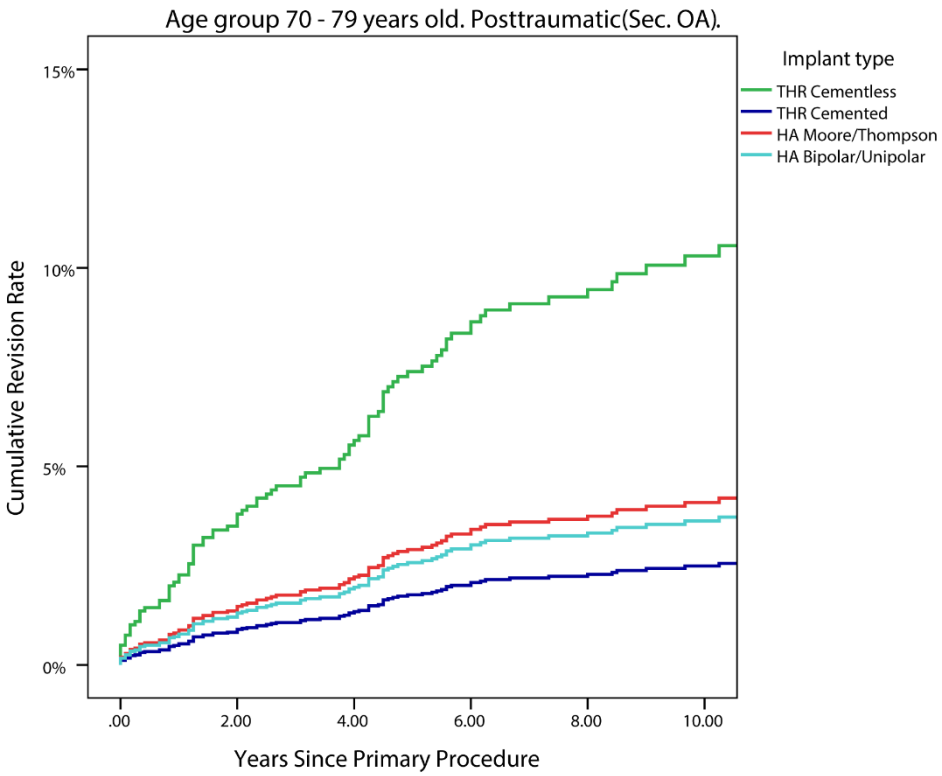


Figure 125 – Cumulative revision rate for age group 70 – 79 years old and diagnosis Posttraumatic (Sec. OA), by implant type.

HR: 2001 – 2015, adjusted by gender

THR Cemented vs. THR Cementless
HR = 0.232 (0.086, 0.627), Sig.=0.004

HA Moore/Thompson vs. THR Cementless
HR = 0.384 (0.166, 0.891), Sig.=0.026

HA Bipolar/Unipolar vs. THR Cementless
HR = 0.340 (0.125, 0.922), Sig.=0.034

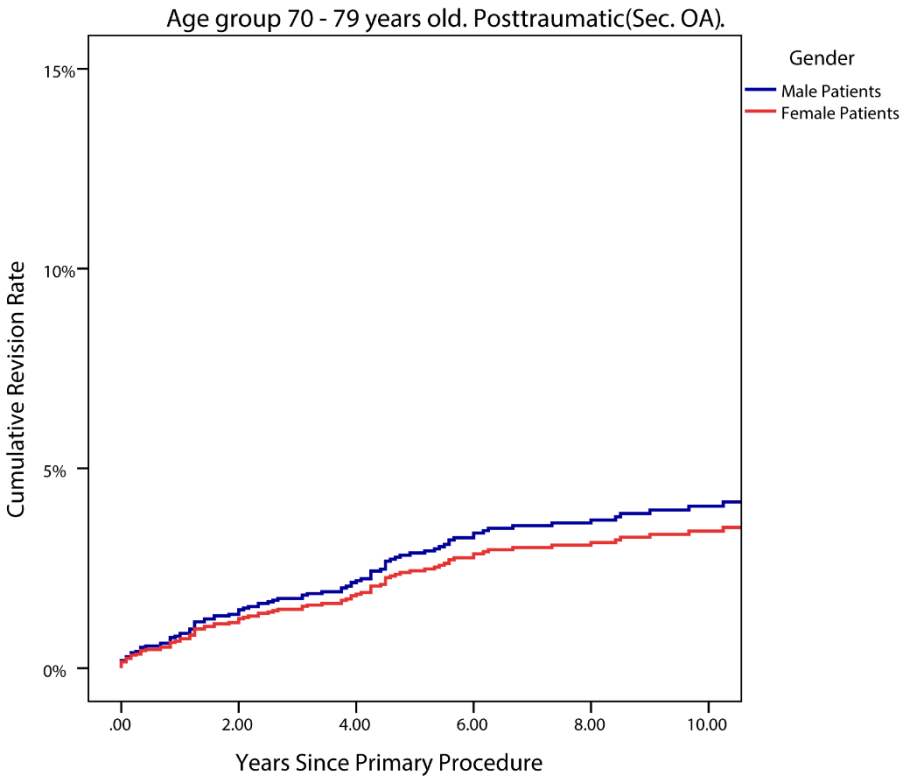


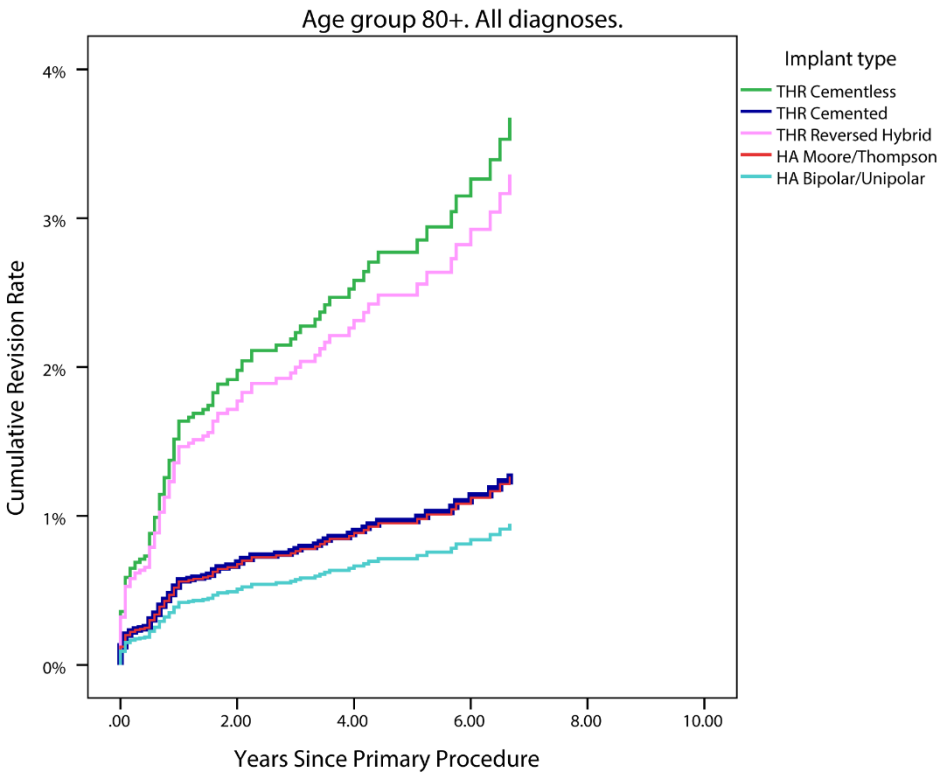
Figure 126 – Cumulative revision rate for age group 70 – 79 years old and diagnosis Posttraumatic (Sec. OA), by gender.

HR: 2001 – 2015, adjusted by implant type

Male vs. Female Patients
HR = 1.185 (0.753, 1.864), Sig.=0.464

6.1.7.5 Age Group 80 Years Old and Over.

6.1.7.5.1 All diagnoses



HR: 2001 – 2015, adjusted by gender

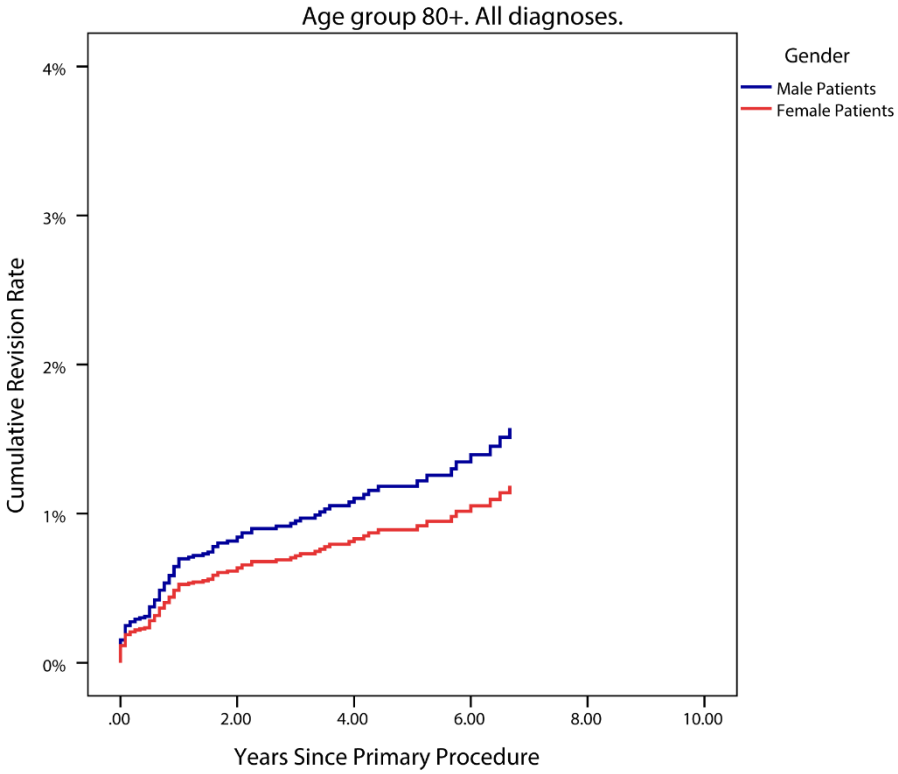
THR Cemented vs. THR Cementless
HR = 0.345 (0.145, 0.823), Sig.=0.016

THR Rev. Hybrid vs. THR Cementless
HR = 0.895 (0.262, 3.060), Sig.=0.859

HA Moore/Thompson vs. THR Cementless
HR = 0.340 (0.156, 0.740), Sig.=0.007

HA Bipolar/Unipolar vs. THR Cementless
HR = 0.255 (0.085, 0.760), Sig.=0.014

Figure 127 – Cumulative revision rate for age group 80+ for all diagnoses by implant type.



HR: 2001 – 2015, adjusted by implant type

Male vs. Female Patients
HR = 1.328 (0.890, 1.983), Sig.=0.165

Figure 128 – Cumulative revision rate for age group 80+ for all diagnoses by gender.

6.1.8 Discussion on hip revisions

From 2012 to 2015, compared to 2008-2011 we can observe a 11.2% increase in primary hip arthroplasty, and a 10.4% increase in revision hip arthroplasties. Still, in 2015 the number of revisions has decreased by 25%, compared to 2013.

The overall yearly revision burden varies between 4.9% and 6.7%, with a primary to revision ratio of 19:1. Revisions are split between 47% Total revisions, 28% Partial revisions and 21% Conversions.

About 91% of all acetabular components and 53.1% of all femoral components used in Revision procedures are Primary Components. Male patients are predominant under 59 years old, while Female patients are predominant over 60 years old. Overall, Female are predominant with 57% of all hip revision procedures.

When looking at the main reasons for revision, 62.36% refer to Acetabular Defects, 35.81% refer to Femoral Defects, 8.54% refer to early and late Infection, 9.7% refer to Luxation, 12.85% refer to Wear, and 6.38% refer to Periprosthetic Fractures.

Due to regional social and economic disparities, two counties (Bucharest 38.86%; Mures 21.95%) make up for 60.81% of all Revision procedures performed in Romania, while another 4 counties (Cluj Napoca 7.54%; Brasov 5.88%; Timis 4.41%; Iasi 3.78%) add up to 82.42% of all revisions.

Also, 53.96% of all revisions at national level, are performed in the above mentioned six counties (B-MS-CJ-BV-TM-IS) for patients that are non-county residents. This conclusion is supported by the fact that 73% of all patients undergo arthroplasty revision surgery outside their county of residence.

Between 2001-2015, the highest share of 76.4% from the total number were revisions performed without femoral or acetabular reconstruction. In addition, the rest of the revisions were performed with acetabular reconstruction (17.2%) and femoral reconstruction (6.4%). Most used reconstruction type in both femoral and acetabular reconstruction is the morselized graft procedure (48.8% of all reconstruction cases).

When comparing the Reasons for Revision in Total Revisions, we can observe that Acetabular Defects (74.86%) , Femoral Defects (58,4%), Wear (18.93%) and Infection rate (9.15%), Periprosthetic fracture (5.04%) and Luxation (4.46%) are predominant.

In Conversion type revisions, the main reasons for revision are: Acetabular defects (75.88%), Luxation (6.29%), Wear (6.57%), Periprosthetic Fracture (3.94% and Late infection (2.9%).

Partial revisions are mainly due to: Acetabular Defects (46.68%), Femoral Defects (23.04%), Luxation (19.95%), Wear (10.61%), Periprosthetic fractures (8.01%).

Revision risk for patients under 49 years old, is highest for THR Reversed Hybrid implants (10.8%). For patients 50-59 years old, Moore Type implants hold the highest revision risk (9%). For patients aged between 60-69 and 70-79 years old, the Resurfacing type implant holds the highest revision risk, with 7.1% and 22.2% respectively. The Cementless THR holds the highest revision risk for patients over 80 years old (2.5%).

For a more accurate image about the revisions of the hip arthroplasties in Romania between 2001 – 2015, the revision analysis was extended to outcomes for specific age groups (taking in consideration patients' age at time of primary intervention) and, subsequently, top three diagnoses (as frequency). Cox Regression Analysis was performed to indicate in the cases with significant effect on the survival, the revision hazard ratio/ risk ratio (HR) for the mutually adjusted covariates – gender and implant type (for details, please see section 6.1.7 Revisions Outcome. Implant type comparison by diagnosis and gender).

6.2 Complications

Definition: By ***short term complications***, we included all forms of reintervention within two years of the primary operation. Note that the report refers only to complications dealt with surgically. Infections treated with antibiotics, and non-surgically treated dislocations, are not captured in register reports. Patients undergoing repeated operations for the same complication are reported as one complication.

Definition: ***Adverse events*** are all forms of re-interventions that did not require the re-implantation of any new implant/component: soft tissue (e.g. lavage), cement spacers etc.

Complications Underreporting: Some units reported extremely few forms for complications. The RAR was perceived as a tracking tool for implantation, so any complication that did not require exchange of any component was not considered for reporting. Certain orthopaedic departments with a high number of interventions units should have had more than a few complications according to the above definition and over a period of 10 years appears improbable. An ongoing study matching the RAR data with **hospital records** in Foisor hospital as pilot, unfortunately, found a large amount of hidden information concerning the clinics' reporting of implant related complications/infections. Unfortunately, a solution for covering this nation-wide validation effort is still under discussion. This is highly undesirable considering the required data quality of the Register.

Interpretation of Data: The analysis of intervention complications is an outcome indicator that has never been and won't be computed per department. The indicator is solely used for better understanding the phenomena and correlate it with the implant-tracking statistics. Since the numbers for complications are generally low, miss-reporting can be mistaken for a better unit ranking. Independent of hospital category and result the clinics should analyses its own complications.

6.2.1 Soft tissues debridement

Since RAR started, 37 hospitals have reported a total number of 244 soft tissue forms between 2003-2015, representing less than 3.4% of all Revision Forms. There is an obvious reporting issue, since the estimated infections rate is well over 10-12%. Also, from the total number of soft tissue forms, more than 55% of them are Undetected Cultures (meaning the laboratory results were not available at the time the forms were reported).

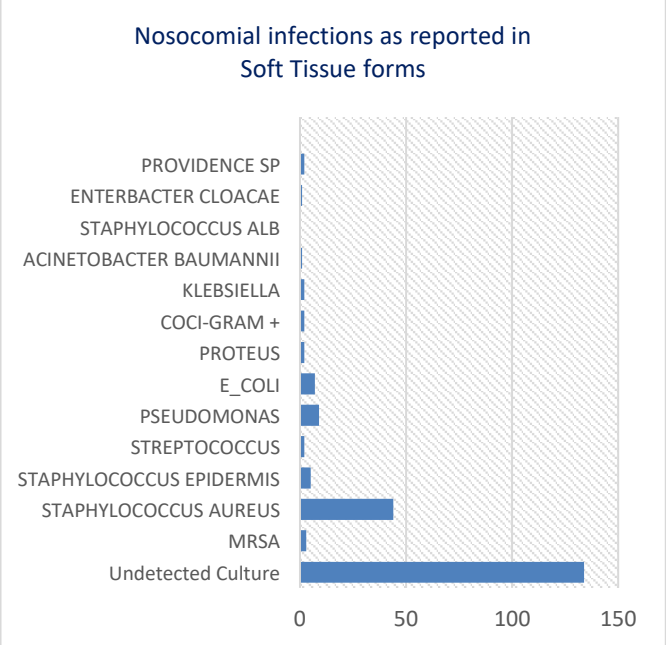


Figure 129 – Nosocomial infections as reported in Soft Tissue Forms, 2003 - 2015

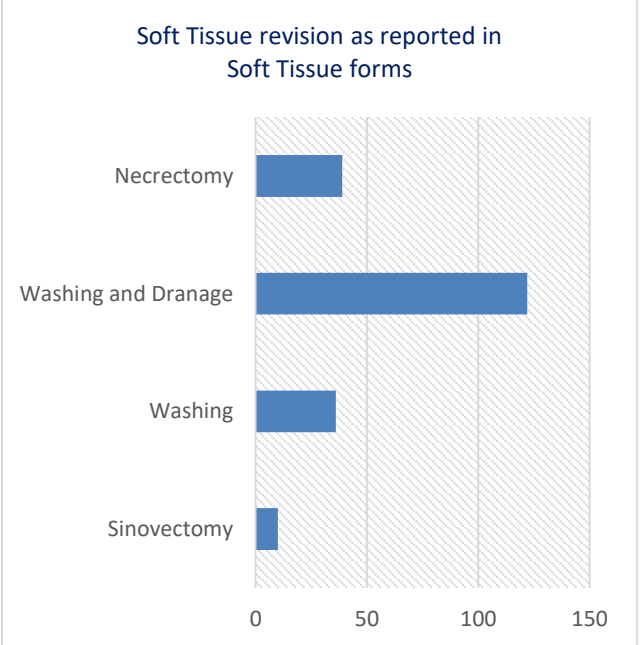


Figure 130 – Soft Tissue revision as reported in Soft Tissue Forms, 2003 - 2015

6.2.2 Reasons for revision by number of previous revisions

Table 58 – Reasons for revision frequencies in number of previous revision group, 2001 - 2015

Reason of revision	0 n = 6424	1 n=668	2 n=105	>2 n=32
Acetabular loosening	28.52%	24.40%	16.19%	18.75%
Femoral loosening	21.61%	18.86%	10.48%	12.50%
Acetabular erosion	17.42%	1.20%	0.00%	3.13%
Femoral osteolysis	15.64%	11.08%	5.71%	0.00%
Acetabular osteolysis	15.29%	11.08%	6.67%	6.25%
Wear	13.64%	7.63%	6.67%	12.50%
Luxation	9.03%	14.37%	24.76%	18.75%
Periprosthetic fracture	6.65%	4.94%	4.76%	3.13%
Late Infection	5.42%	16.62%	24.76%	28.13%
Acetabular protrusion	4.84%	4.04%	2.86%	0.00%
Para articular ossification	2.91%	1.35%	0.95%	0.00%
Broken Implants	1.68%	1.05%	2.86%	3.13%
Early Infection	1.39%	5.09%	3.81%	6.25%
Other*	20.50%	25.60%	30.48%	25.00%

From 2001 to 2015, of the first revision total number of procedures most frequent reasons for revision were Acetabular Loosening (28.52%) followed by Femoral Loosening (21.61%), Acetabular Erosion (17.42%), Femoral Osteolysis with (15.64%), Acetabular Osteolysis (15.29%), Wear (13.64%), Luxation (9.03%) and Periprosthetic Fractures (4.04%).

For the Second Revision, most frequent reasons for revision are: Acetabular Loosening (24.40%) followed by Femoral Loosening (18.86%), Late Infection (16.62%) and Luxation (14.37%).

Late Infection and Luxation are the most frequent reasons for revision for the third revisions (both with 24.76% frequency).

6.2.3 Reasons for revision by time to revision

Table 59 – Reasons for revision frequencies in known time to revision group, 2001 - 2015

Reason for revision	0-4 years	4-7 years	7-11 years	11+ years
Acetabular erosion	22.57%	17.10%	**7.38%**	2.08%
Luxation	19.32%	5.89%	**7.05%**	5.56%
Acetabular loosening	13.18%	24.86%	**35.74%**	36.81%
Femoral loosening	12.88%	18.10%	**26.39%**	24.31%
Late Infection	8.52%	14.22%	**8.04%**	7.63%
Periprostethic fracture	7.56%	2.01%	**4.59%**	4.17%
Femoral osteolysis	6.24%	9.63%	**11.31%**	8.33%
Acetabular osteolysis	5.22%	7.90%	**12.13%**	14.58%
Wear	4.46%	8.62%	**15.90%**	25.00%
Early Infection	3.75%	-	-	-
Acetabular protrusion	2.48%	4.02%	**5.25%**	2.78%
Para articular ossification	2.33%	2.01%	**1.80%**	1.39%
Broken Implants	0.41%	1.29%	**2.30%**	0.69%
Other	16.63%	7.33%	**5.74%**	4.17%

Acetabular Erosion is the main reason of arthroplasty early failure (almost 22.57% - 0-4 years), which is due to inadequate instructions and use on a large scale of the monopolar prostheses. Luxation is the second most frequent reason for revision in the first 4 years (19.32%), caused by the dislocation of mispositioned parts. The third major cause of early revision are acetabular and femoral loosening.

At 4-7 years, Acetabular Erosion (17.10%) is remains one of the top three reasons for revision, surpassed only by Acetabular Loosening (24.86%) and Femoral Loosening (18.10%).

At 7-11 years, the main reasons for revision are acetabular loosening (35.74%), femoral loosening (26.39%) and Wear (15.09%)

7 Indicators

7.1 Implant survival at 5 years by hospital

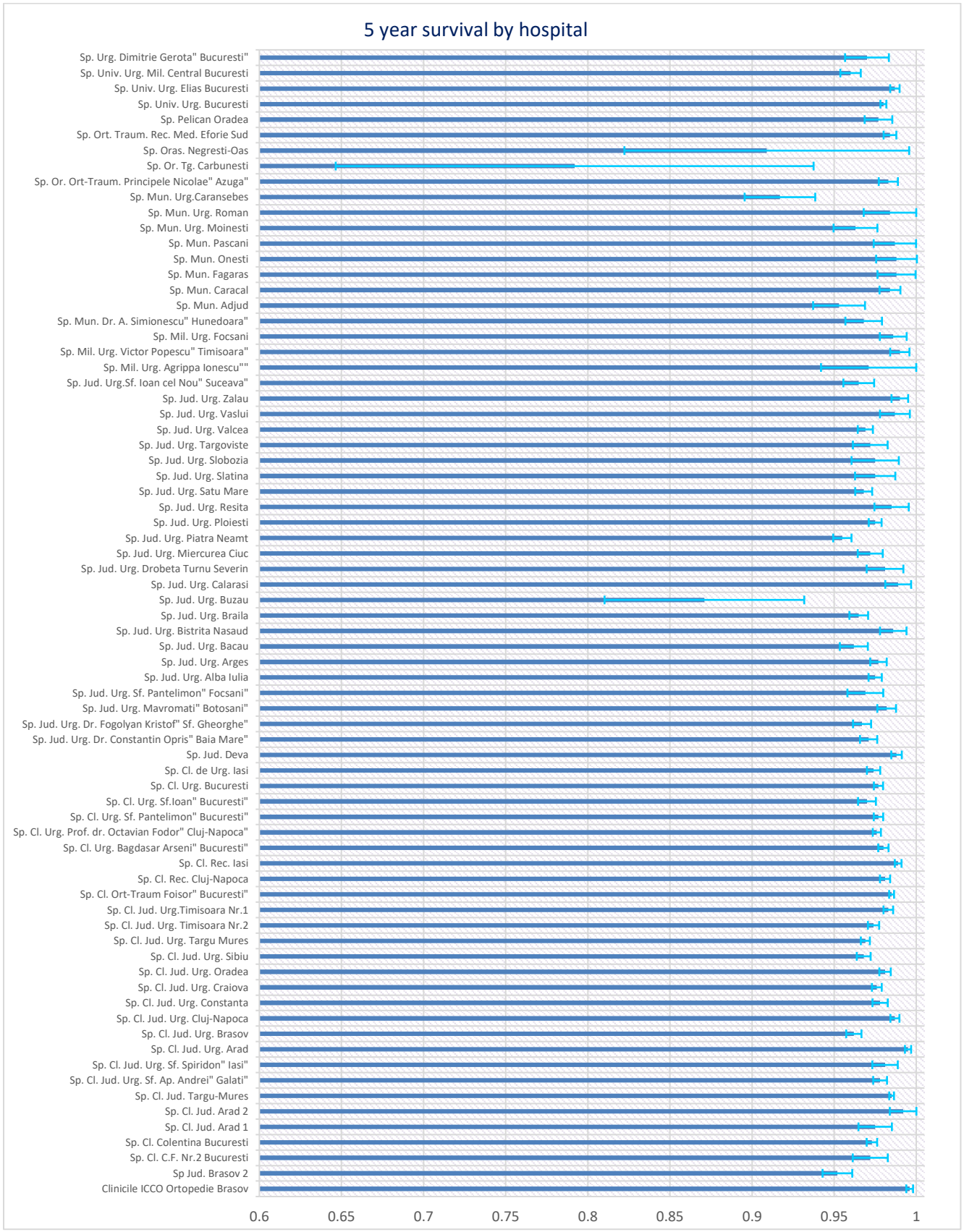


Figure 131 - Implant survival at 5 years by hospital. Kaplan-Meier survival estimator, 2001 - 2015

7.2 Implant survival at 10 years by hospital

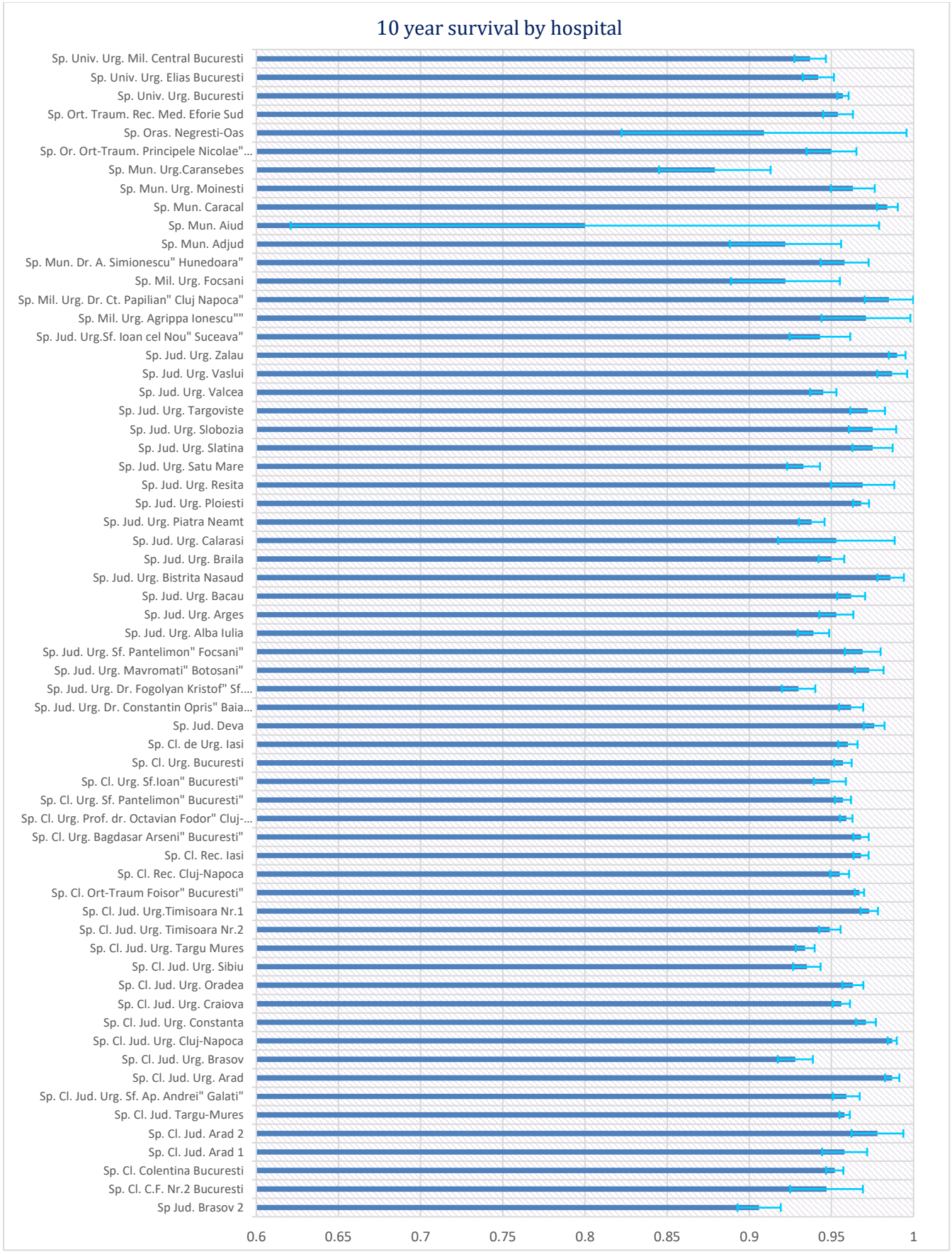


Figure 132 - Implant survival at 10 years by hospital. Kaplan-Meier survival estimator, 2001 - 2015

7.3 Implant type distribution by hospital

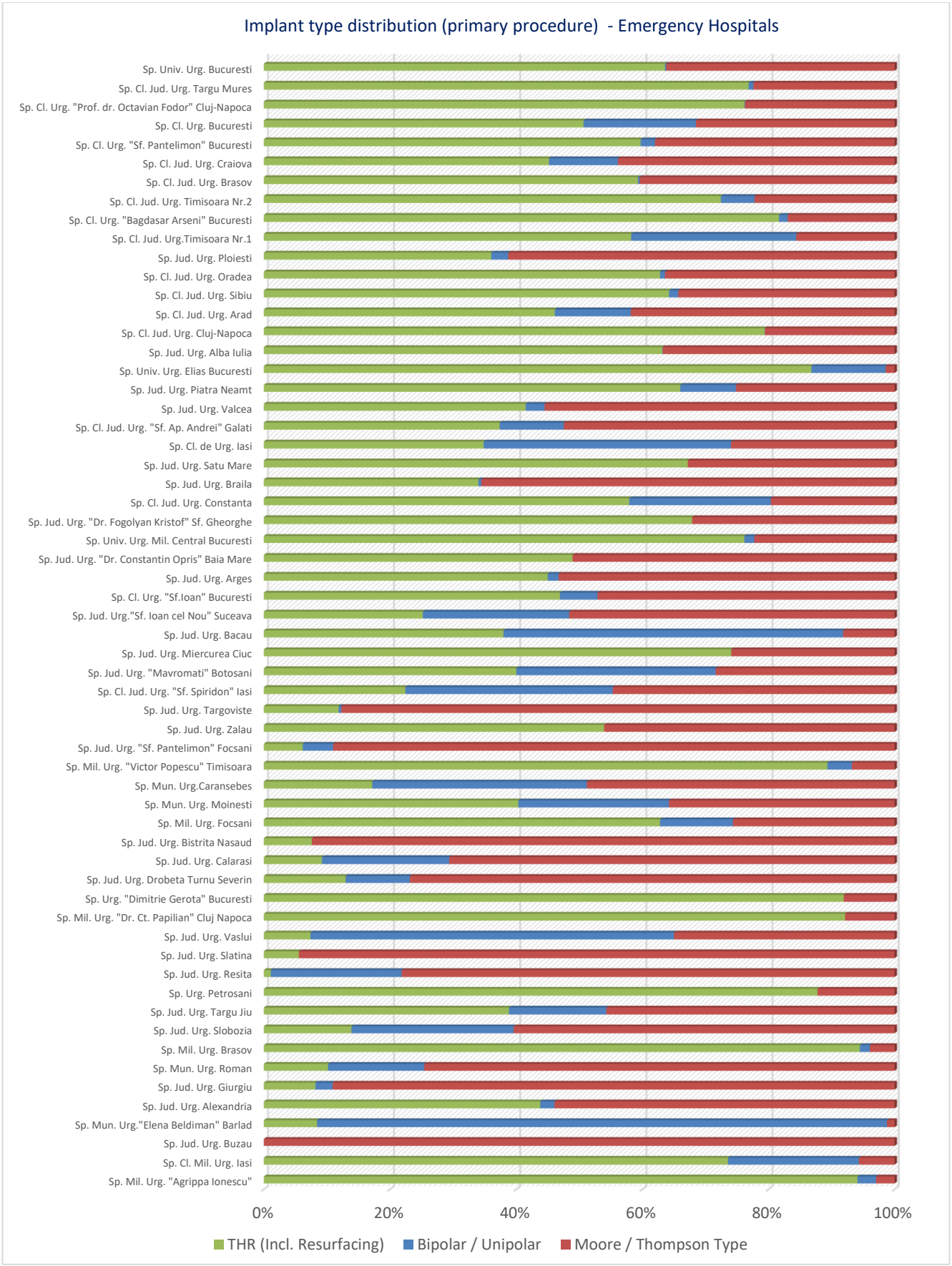


Figure 133 - Implant type distribution (primary procedure) - Emergency Hospitals, 2001 – 2015

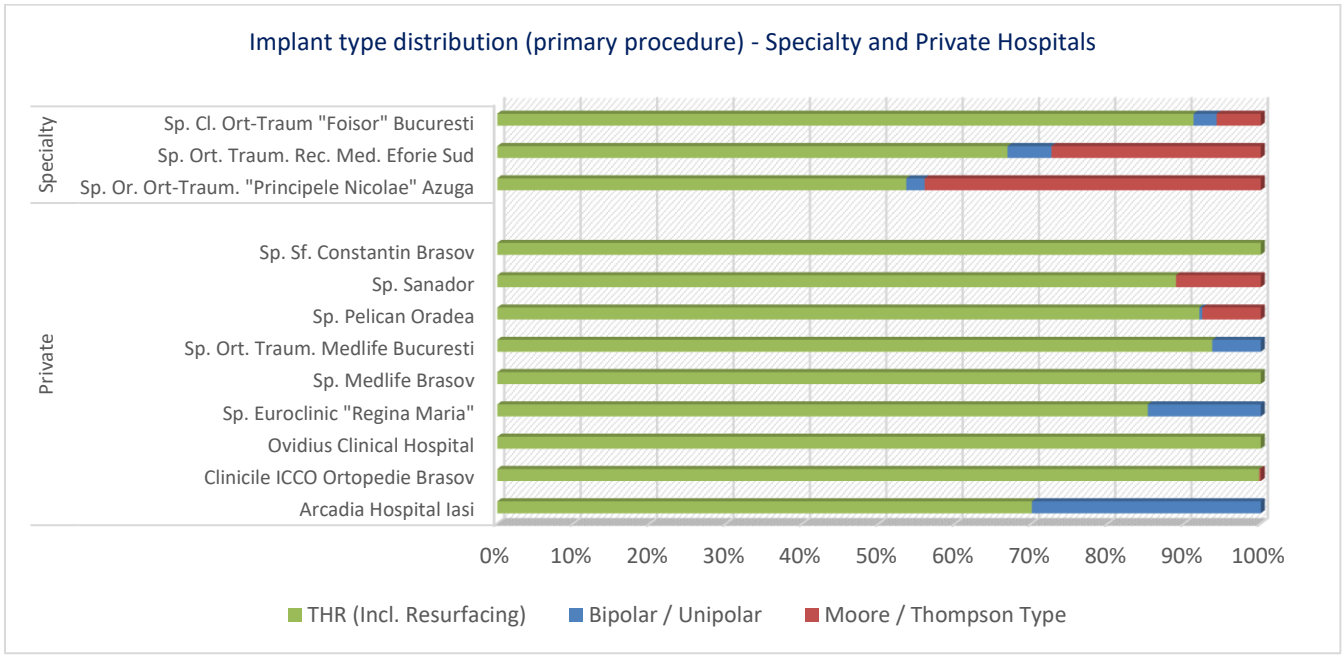


Figure 134 - Implant type distribution (primary procedure) - by Specialty and Private Hospitals, 2001 – 2015

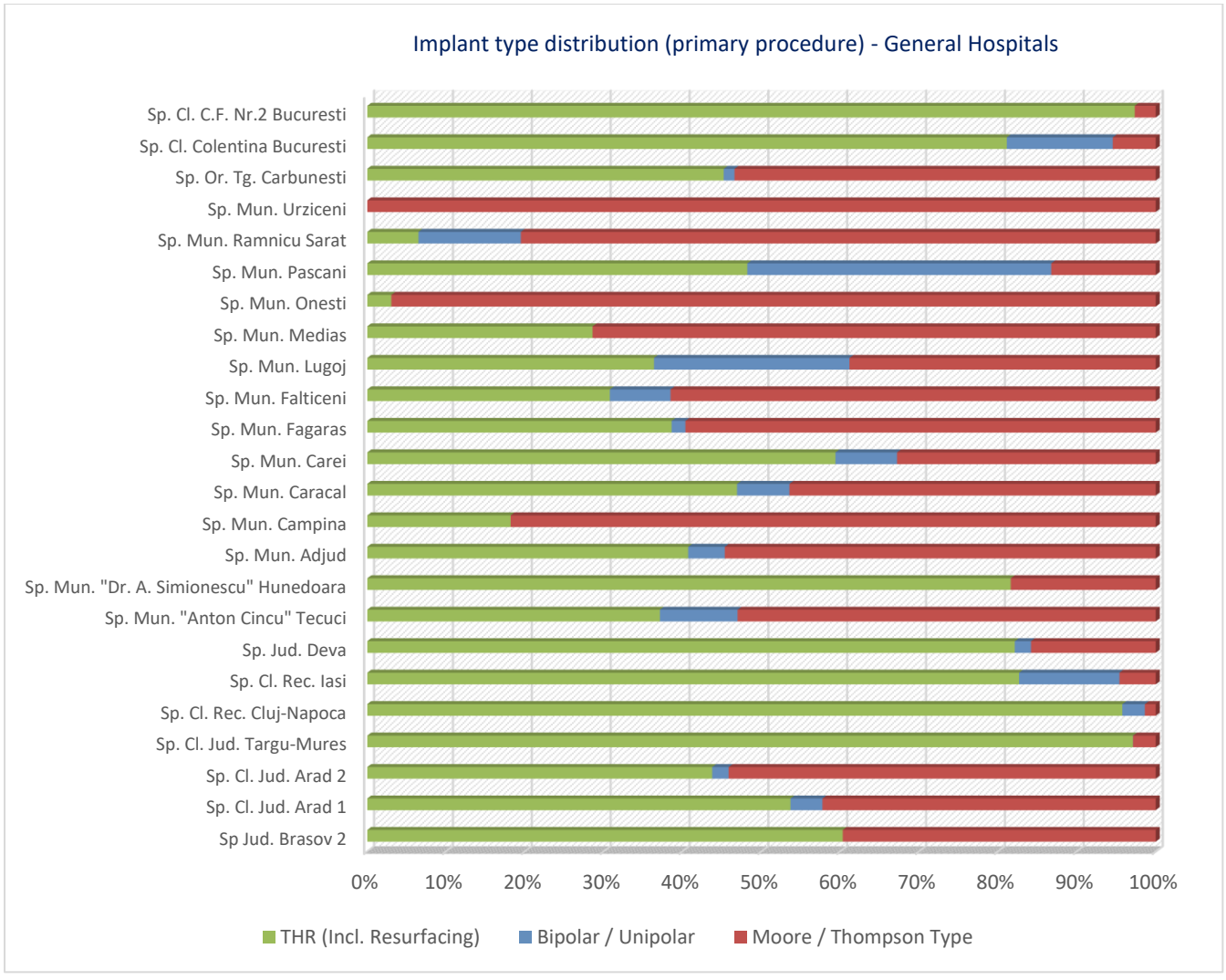


Figure 135 - Implant type distribution (primary procedure) - by General Hospitals, 2001 – 2015

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