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ESTIMATION OF TANTALUM NEEDS

FOR

ORTHOPAEDIC APPLICATIONS

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## INTRODUCTION

In this technical note, the main characteristics of porous Tantalum to be used as prosthesis are presented.

Taking into account that actually the main medical uses of porous Tantalum are for hip and knee replacement, based on the known statistics, an estimation of the annual hip and knee primary replacement in Europe has been made.

Finally, based on the related publications and statistics, it is assumed that the market share of this type of prostheses will be similar to other technologies, typically 20%. An estimation of the quantity of Ta for prostheses that will be used in Europe in 2050 has been made.

## TA AS ORTHOPAEDIC MATERIAL

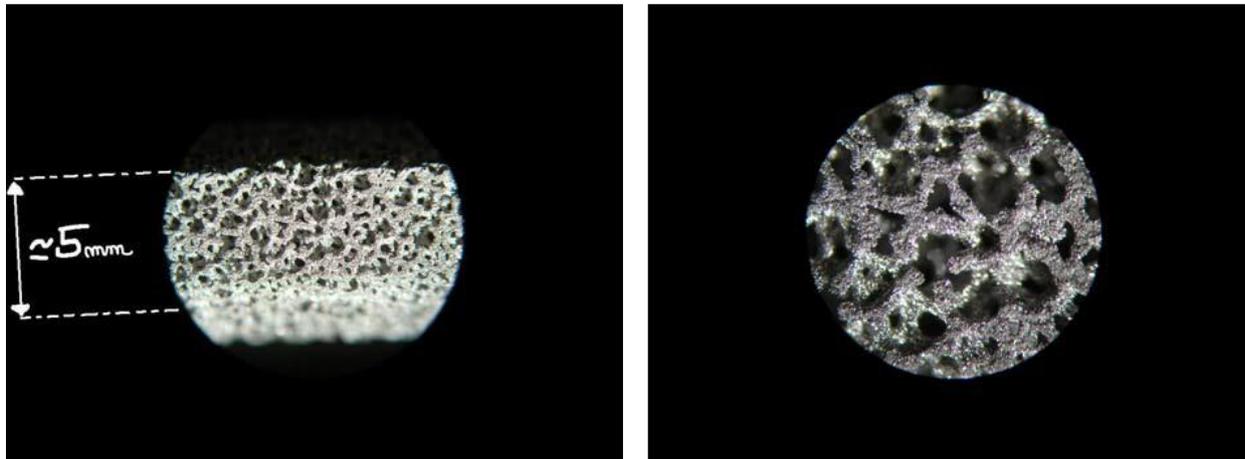
Prostheses are introduced into a corrosive environment in contact with biologic fluids. The main cause of implants failure is produced by tribologic causes (interacting surfaces into a determined medium). Titanium alloys prostheses have demonstrated a high resistance to the corrosion, nevertheless under sliding and friction with other materials Titanium suffers from big erosion; particles can be released and provoke a premature prosthesis failure. In this context, prostheses made of porous Tantalum have demonstrated very good performances, crucial to extend the life service of the prostheses.

Porous Tantalum is currently available for use in several orthopaedic applications, mainly hip and knee arthroplasty, but also for spine surgery, dental implants and bone graft substitute.

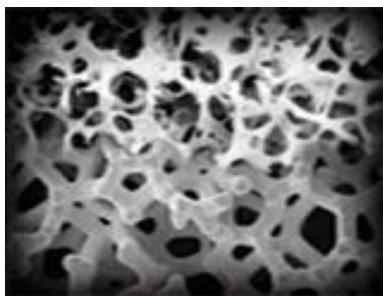
The open-cell structure (75/80% of porosity, with porous size of 550  $\mu\text{m}$  [3]) is produced via carbon vapour deposition/infiltration of commercially pure tantalum onto a vitreous carbon scaffolding with a composition of Ta 99 % and vitreous carbon 1 % [1].

Other researchers are working with coatings of Tantalum Nitride [5], but this type of prosthesis is under development yet.

Porous Tantalum (also known as metal trabecular or metal trabecular bone) presents a characteristic appearance similar to cancellous bone and its outstanding characteristic for orthopaedic uses is its similarity to human bone, from both structural and physical properties.

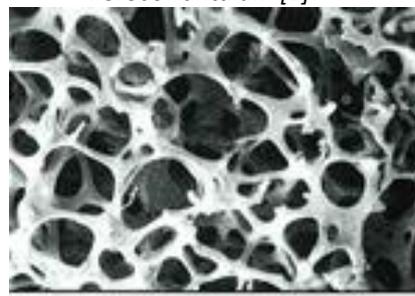


*Porous Tantalum [1]*



*Porous Tantalum*

<http://www.clinicadrdelacerda.com/tantalo-trabecular>



*Human trabecular bone*



*Osseointegration*

<http://www.traumatologosociados.com/noticias/noticia.asp?i=5&p=1>

Ta was used in hip surgery for the first time in 1997. This material has some very good characteristics to be used in orthopaedic surgery; mainly [2] [3] [4]:

- Excellent biocompatibility
- High volumetric porosity material (nearly 80%), which improves the osseointegration
- High friction coefficient with the human bone, which implies an excellent primary fixation.
- Modulus of Elasticity (3 GPa) quite similar to the subchondral bone's one (2 GPa), which in addition facilitates the growth of new bone over the prosthesis, better distributes stress, diminishing the bone resorption.
- High resistance to fatigue
- High resistance to the corrosion.

Porous Tantalum is safe to use in vivo (as evidenced by its historical and current use in pacemaker electrodes, cranioplasty plates and as radiopaque markers) and performs as a wonderful structure for the growth of new bone. The bioactivity and biocompatibility of porous tantalum come from its ability to form a self-passivating surface oxide layer. This surface layer leads to the formation of a bone-like coating in vivo and affords excellent bone

and fibrous in-growth properties allowing for rapid and substantial bone and soft tissue attachment.

*“In some clinical studies, it has been observed than in only 15 days after the surgery, the porous Tantalum was covered of new formed bone, decreasing the porosity of the implant” [1].*

*“A prospective follow up was performed on 23 hip replacements in 23 patients. The mean follow-up of the series was 12 years. All the implants were osseointegrated at the end of follow-up. Tantalum acetabular monoblocks have an excellent survival with follow-ups longer than ten years in primary hip surgery” [3].*

*“The porous tantalum components provide immediate metaphyseal stabilization of the implant, allowing early weight-bearing. The high porosity of these cones results in satisfactory primary fixation on recipient bone” [4].*



Sistema Acetabular Zimmer® Continuum®  
Hip Surgery



Tibial Trabecular Metal Monoblock  
Zimmer®  
Knee Surgery



Tantalum cone for Knee  
arthroplasty  
[4]

## ESTIMATION OF NUMBER OF ANNUAL PROTHESIS IN EUROPE

### NATIONAL JOINT REGISTRY (NJR) FOR ENGLAND, WALES, NORTHERN IRELAND AND THE ISLE OF MAN

The National Joint Registry for England and Wales started collecting data in April 2003. The ‘cut off’ period for outcomes analysis for this report was December 2015, which gives a potential **follow-up of almost 13 years for hip and knee replacements.**

The registry now contains over 2 million procedure level records (including ankle and shoulders) and during the financial year 2015/16 nearly 225,000 were added, which demonstrates the size and growth of this very large dataset.

Registries attempt to collect all possible records of procedures but clearly this is not achievable when dealing with such a high volume of activity. Compliance (the number of cases submitted compared to the number carried out) has grown over the lifetime of the

registry, so missing data is more common in the first five years compared to the last eight years. They have monitored compliance by comparing submissions to routinely collected National Health Service NHS data (Hospital Episode Statistics) but as this does not include privately funded work carried out in the independent sector, they have monitored compliance by comparing submissions to the number of implants sold (up to 2 years ago). Both these methods are inexact and they have carried out a detailed national audit of data quality and compliance by comparing NJR submissions with locally collected hospital data for the year 2014/15 to explore this further. This audit is not yet complete and will be reported at a later date but **preliminary analysis suggests that over 95% of primary operations and over 90% of revision operations have been captured.**

## HIP REPLACEMENTS

In the following table, it can be seen the number of primary hip replacements in each calendar year [6]:

Percentage of hip replacements by fixation and bearing surface for each year of primary operation:												
2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
n=	n=	n=	n=	n=	n=	n=	n=	n=	n=	n=	n=	n=
14,433	28,029	40,202	47,573	60,570	66,922	67,903	70,395	73,443	77,639	79,669	85,972	83,886

## POPULATION

In the following table, it can be seen the population of England, Wales, Northern Ireland and Isle of Man for the years in which each has been included into the Register.

In July 2015, the NJR welcomed the Isle of Man.

	England	Wales	Northern Ireland	Isle of man	Total
<b>2001</b>	<b>49,138,831</b>	<b>2,903,085</b>	<b>1,685,300</b>		<b>53,727,216</b>
2003	49,925,500	2,937,700	1,704,900		54,568,100
2004	50,194,600	2,957,400	1,714,000		54,866,000
2005	50,606,000	2,969,300	1,727,700		55,303,000
2006	50,965,200	2,985,700	1,743,100		55,694,000
2007	51,381,100	3,006,300	1,761,700		56,149,100
2008	51,815,900	3,025,900	1,779,200		56,621,000
2009	52,196,400	3,038,900	1,793,300		57,028,600
2010	52,642,500	3,050,000	1,804,800		57,497,300
<b>2011</b>	<b>53,012,456</b>	<b>3,063,456</b>	<b>1,810,900</b>		<b>57,886,812</b>
2012	53,493,733	3,074,067	1,823,600		58,391,400
2013	53,865,800	3,082,400	1,829,700		58,777,900
2014	54,316,600	3,092,000	1,840,500		59,249,100
2015	54,786,300	3,099,100	1,851,600	87,780	59,824,780

Sources: Office for National Statistics (GB), “United Nations Statistics Division”. “Isle of Man Census Report 2011”, Economic Affairs Division Isle of Man Government Treasury, Northern Ireland Statistics and Research Agency: “Census 2011: Population and Household Results for Northern Ireland”.

## HIP INCIDENCE

Incidence can be defined as the percentage of population with some hip prosthesis.

In the following table the incidence, together with the annual growing rates, both relative to the number of prosthesis (defined as [number of prosthesis in year I minus number of prosthesis in year (i-1)]/number of prosthesis in year (i-1), and to the incidence defined in the same way.

	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Incidence (%) HIP	0.026	0.051	0.073	0.085	0.108	0.118	0.119	0.122	0.127	0.133	0.136	0.145	0.140
Annual Growing number of prosthesis (%)		94.2%	43.4%	18.3%	27.3%	10.5%	1.5%	3.7%	4.3%	5.7%	2.6%	7.9%	-2.4%
Annual Growing incidence (%)		93.1%	42.3%	17.5%	26.3%	9.6%	0.7%	2.8%	3.6%	4.8%	1.9%	7.1%	-3.4%

It can be seen that in the beginning of the Register, the incidence regarding hip prosthesis increased quickly, probably because each year, more hospitals participated in the NJR programme. For this reason, it is not probably to expect such a strong growth in the number of prosthesis or incidence, else a 2.8% in incidence or 3.6% in number of prosthesis, as is the mean for the 6 last years (2010-2015).

	MEAN 2003-2015	MEAN 2010-2015	2015
Incidence (%)	0.11%	0.13%	0.14
Annual Growing number of prostheses (%)	18%	3.6%	
Annual Growing incidence (%)	17%	2.8%	

Other information from the European Commission webpage (<https://ec.europa.eu/programmes/horizon2020/en/news/medical-engineering-new-non-metal-%E2%80%9Cbone-preserving%E2%80%9D-hip-replacement>), said that “Around 800.000 hip procedures are carried out every year”. This represents an incidence of almost 0.16%, for the EU population in 2014. **So, figures are around these percentages.**

And the article says also: “With the number of hip operations rising by around 15% annually”. Regarding this number, it can be the actual growing number of prostheses, because of the ageing population and the increased welfare of our society, but this percentage cannot be maintained through the time until 2050, because in this case, the incidence in 2050 will be bigger than 16%, which is unthinkable. Reinforcing this hypothesis,

in the graph incidence of hip and knee replacement over time can be seen that actually the slope of the curve is much steadier.

## KNEE REPLACEMENTS

In the following table, it can be seen the number of primary hip replacements in each calendar year [6]:

	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
All types	13,529	27,737	41,923	49,544	66,713	74,115	76,062	78,752	82,349	86,158	85,753	94,814	94,023

*Yearly Primary knee replacements in England, Wales, Northern Ireland and the Isle of Man (this last on, only from 2015)*

## KNEE INCIDENCE

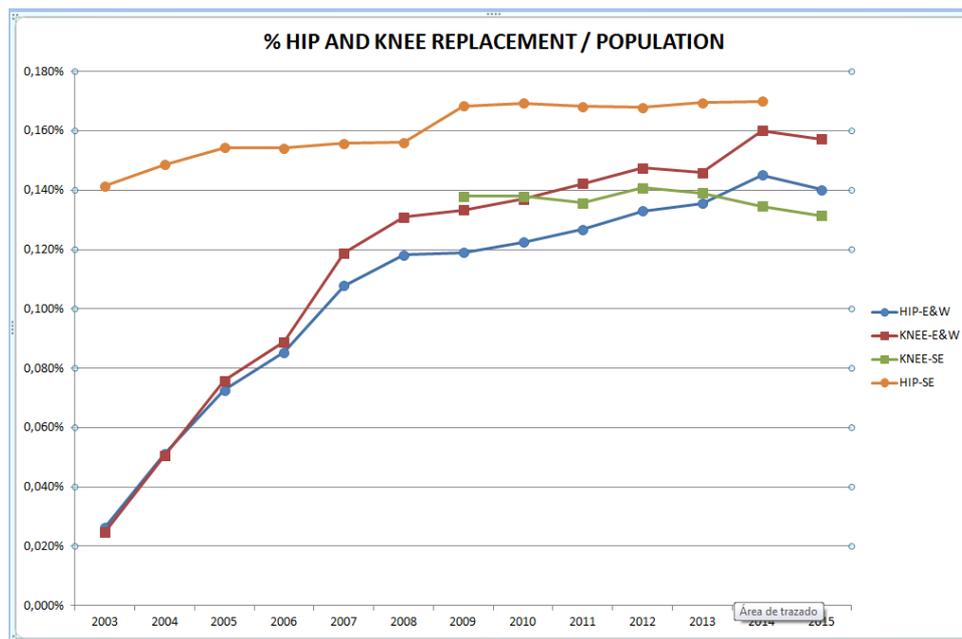
Incidence can be defined as the percentage of population with some knee prosthesis.

In the following table, the incidence together with the annual growing both are presented, relative to the number of prosthesis and to the incidence.

	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Incidence (%) HIP	0.02	0.05	0.08	0.09	0.12	0.13	0.13	0.14	0.14	0.15	0.15	0.16	0.16
Annual Growing number of prosthesis (%)		105%	51%	18%	35%	11%	3%	4%	5%	5%	0%	11%	-1%
Annual Growing incidence (%)		104%	50%	17%	34%	10%	2%	3%	4%	4%	-1%	10%	-2%

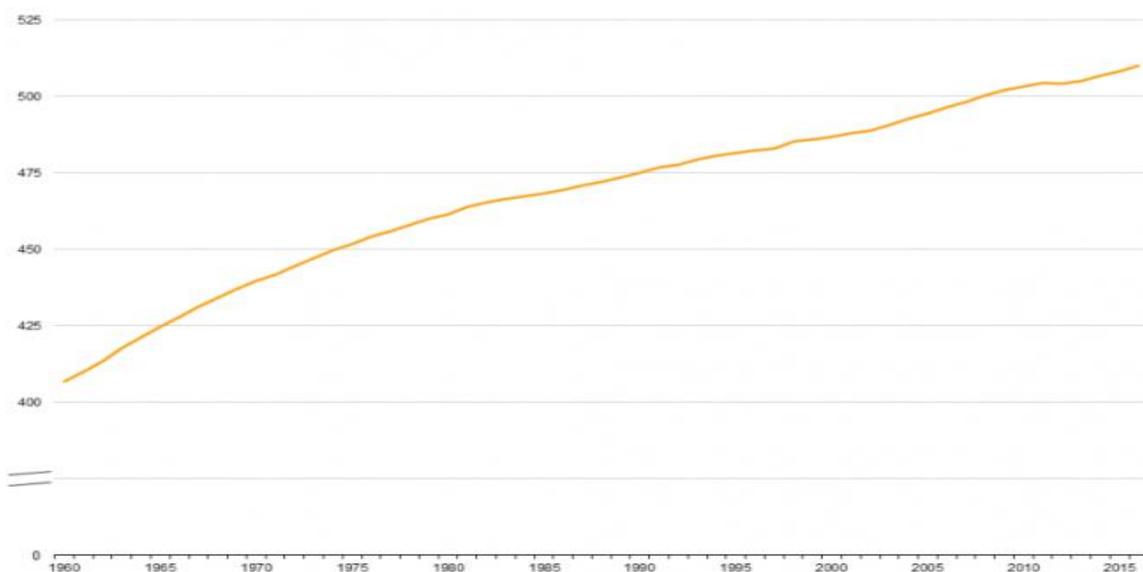
It can be seen that in the beginning of the Register, the incidence regarding hip prosthesis increased quickly, probably because each year, more hospitals participated in the NJR programme. For this reason, it is not probably to expect such a strong growth in the number of prosthesis or incidence, else a 2.8% in incidence or 3.7% in number of prosthesis, as is the mean for the 6 last years (2010-2015).

	MEAN 2003-2015	MEAN 2010-2015	2015
Incidence (%)	0.12%	0.15%	0.16
Annual Growing number of prostheses (%)	20.4%	3.7%	
Annual Growing incidence (%)	19.5%	2.8%	



## EU POPULATION

The following graph represents the EU 28 population' evolution from 1960 to 2015. It can be observed that the mean growth is near to 0.42% yearly.



(\*) Excluding French overseas departments up to and including 1997. Breaks in series: 2001, 2010-12 and 2014-16.  
Source: Eurostat (online data code: demo\_gind)

*EU population' evolution from 1960 to 2015. Source: Eurostat*

With this tendency, we can estimate **the EU population will be 590 million people by 2050.**

## QUANTITY OF TANTALUM IN TRABECULAR METAL PROSTHESES

We have had some contacts with the leader in medical implants (Zimmer), but we have not achieved the exact information about what quantity of Ta there are in hip and knee prostheses, because, the company refers to a large quantity of different references (size, pieces, etc).

### QUANTITY OF TANTALUM IN A KNEE PROSTHESIS



*Monoblock Tibial Component (ZIMMER-BIOMET)*

We have estimated Ta quantity geometrically.

Trabecular Metal composition contains almost 98% of Ta, according to the received information from an Orthopaedic Surgeon (source: Zimmer).

#### Materials

##### *Trabecular Metal*

##### Chemical Composition (% weight)

O: 0.02 max    N: 0.2 max

H: 0.05 max    Fe: 0.5 max

W: 0.2 max    Nb: 1 max

Si: 0.04 max    Ni: 0.05 max

Ta: csp 100%

The Trabecular Metal (TM) used in the monoblock tibial component, has a porosity of 80% [9].

The thickness of Monoblock Tibial components are 10, 12, 14 and 17 mm [9]. Visually, the thickness of the Trabecular Metal is 3 mm.

Taken a middle diameter, visually, the area of the component is similar to a disc of 4 cm of diameter  $\rightarrow 12.6 \text{ cm}^2$ .

Volume of TM =  $12.6 \text{ cm}^2 * 0.3 \text{ cm} = 3.78 \text{ cm}^3$

Tantalum volumic mass =  $16.6 \text{ g/cm}^3$

Weight (solid) =  $16.6 * 3.78 = 62.75 \text{ g}$

Weight (porous material) =  $12.55 \text{ g}$

**Weight (Ta in knee prosthesis) = 12.3 g.**

### QUANTITY OF TANTALUM IN A HIP PROSTHESIS



*Acetabular System Zimmer Continuum*

We have estimated Ta quantity geometrically.

In the case of hip prostheses, the cotilum is covered by TM, upon a substrate of Tivanium® alloy [10].

Visually, the thickness of TM seems 1 mm, but in some bibliography is said “The thickness of the Trabecular Metal is 2-3 mm to facilitate the osseointegration [3]”.

Taking a middle component: diameter 52 mm

Area =  $42.45 \text{ cm}^2$  (semi-sphere)

Volume =  $4.25/8.5/12.7 \text{ cm}^3$ , corresponding to trabecular metal thickness of 1/2/3 mm

Weight (solid) = 70.55/141.1/210.82 g

Weight (porous material) = 14.11/28.22/42.16 g

**Weight (Ta in hip prosthesis) = 13.8/27.6/41.3 g.**

## TRABECULAR METAL PROSTHESES MARKET SHARE

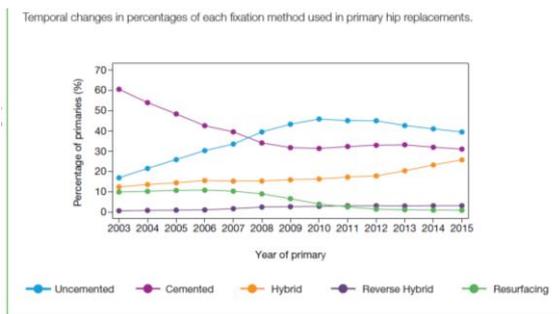
Actually, the market share for trabecular metal prostheses is quite low. In the following table, the market share (2015) of different types of knee prostheses in Sweden can be seen.

NexGen TM (trabecular metal) has only 1.2% of the market (2015) in Sweden (knees) for total knee arthroplasty (TKA), being the standard treatment, which in 2015 accounted for 94% of the knee surgeries in Sweden [8].

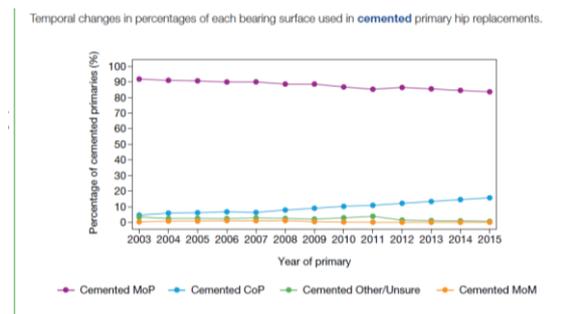
But because of its good performance, reflected in its low risk of revision [8], the trabecular metal appears as a promising material for prosthesis.

Implants for primary TKA			OA / TKA	n	p-value	RR	95% CI
	Number	Percent					
NexGen MBT	5,572	45.9	PFC-Sigma MBT	17 780		ref.	
PFC-MBT	2,501	20.6	AGC	7,294	0.00	1.57	1.32-1.86
Triathlon	1,334	11.0	Duracon	3,911	0.00	1.38	1.12-1.70
Vanguard	1,079	8.9	F/S MIII	2,434	0.00	2.11	1.71-2.61
PFC-APT	914	7.5	Genesis II	545	0.82	1.11	0.46-2.69
Legion/GenII Prim	169	1.4	NexGen APT	4,089	0.08	1.23	0.98-1.54
Genesis II	157	1.3	NexGen MBT	37,041	0.05	0.87	0.75-1.00
NexGen TM	150	1.2	NexGen TM	1,106	0.09	0.67	0.42-1.06
Attune	26	0.2	PFC-Sigma APT	11,972	0.96	1.00	0.84-1.18
PFC-RP	6	0.1	PFC-RP	1,019	0.00	2.41	1.87-3.12
Link Gemini	6	0.1	Profix	1,855	0.02	1.44	1.07-1.93
NexGen APT	5	0.1	Triathlon	7,883	0.44	0.92	0.73-1.14
Others*	229	1.9	Vanguard	9,092	0.02	1.27	1.05-1.54
<b>Totalt:</b>	<b>12,134</b>	<b>100</b>	Others	1,811	0.00	1.65	1.24-2.18
<i>Type of implants for TKA (knee) in 2015. Sweden. [8]</i>			<i>Risk of revision (RR) with 95% confidence interval vs type of prostheses. TKA. [8]</i>				
			Gender (male is ref.)		0.07	1.08	0.99-1.18
			Age (per year)		<0.01	0.96	0.95-0.96
			Year of op. (per year)		0.75	1.00	0.98-1.02

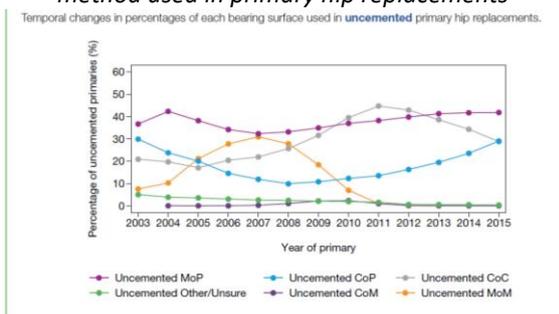
In the following graphs, the evolution of market share for different type of fixation used in hip surgery are shown. The most important types of fixation in the market are cemented, uncemented and hybrid [6]:



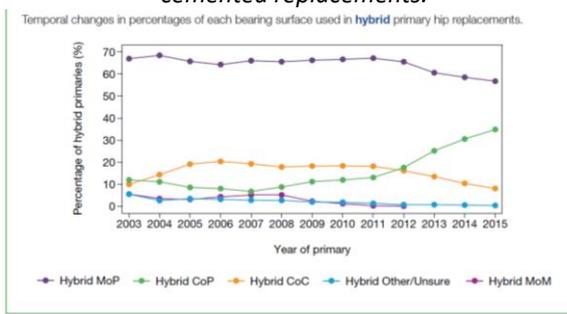
Temporal changes in percentages of each fixation method used in primary hip replacements



Temporal changes (%) of each bearing surface used in cemented replacements.



Temporal changes (%) of each bearing surface used in uncemented replacements.



Temporal changes (%) of each bearing surface used in hybrid replacements.

MoP (metal on polyethylene); CoP (ceramic on polyethylene); CoC (ceramic on ceramic); MoM (metal on metal)

Trends of implant usage are interesting in that the decline in cemented implants between 2003 and 2009 has stabilized to around a third of cases. Conversely, although the use of uncemented implants has decreased since 2010, they still remain the most widely used compared to other implants. Hybrid implants continue to steadily increase in popularity and now account for a quarter of cases.

With regard to bearing surfaces, metal-on-polyethylene (MoP) is still the most widely used, with ceramic-on-polyethylene following close behind, while the use of ceramic-on-ceramic is declining.

It can be seen that MoP, which is the case for trabecular metal prostheses, is the most popular for all types of fixation.

Uncemented	40%	MoP/unc.	40%	16%
Cemented	30%	MoP/cem.	85%	26%
Hybrid	25%	MoP/hyb.	57%	14%

Even with all this information, it is quite difficult to estimate the market share of trabecular metal prostheses by 2050, because other outstanding materials can appear in the market, etc., but taking into account that the Metal-on-Polyethylene prosthesis have a market share of 56% proximately, that CoP tendency is growing and that its main competitor is Titanium, we can estimate a **market share of 20% for trabecular metal prostheses.**

## TA ESTIMATION NEEDED BY 2050 FOR SURGICAL APPLICATION

**Weight (Ta in hip prosthesis) = 13.8/27.6/41.3 g**, corresponding to thickness of 1/2/3 mm

**Weight (Ta in knee prosthesis) = 12.3 g.**

It can be estimated **the EU population will be 590 million people by 2050.**

It can be estimated **a market share of 20% for trabecular metal prostheses.**

We can estimate an incidence by 2050 of 0.41% for knee replacement and 0.36 % for hip replacement over population.

Knee:  $590 \cdot 0.41 \cdot 0.2 \cdot 12.3 = 5.95$  t

Hip:  $590 \cdot 0.36 \cdot 0.2 \cdot 27.6 = 11.72$  t (for trabecular metal thickness = 2 mm)

**Estimated total need of Ta for surgical applications: 18 t approximately**

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