



# Highly porous titanium cup in cementless total hip arthroplasty: registry results at eight years

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## Abstract

**Purpose** Highly porous cups were developed to improve osseointegration and reduce the rate of aseptic loosening. Highly porous titanium cups could mix the reliability of titanium metal with an enhanced porosity, improving the bony ingrowth. The aim of this report was to assess the survival rates and reasons for revision of a highly porous titanium cup, Fixa Ti-Por (Adler Ortho, Milan, Italy), fabricated using an additive manufacturing.

**Methods** The Registry of Prosthetic Orthopedic Implants (RIPO), the Emilia-Romagna region arthroplasty registry, was enquired about cementless cups, implanted since July 2007. Ti-Por cups were compared to all the other cementless sockets, acting as a control group. The survival rates and reasons for revision were evaluated and compared. Comparisons with the same articular couplings were also provided.

**Results** When all the articular couplings were included, Ti-Por performed better, achieving a statistically higher survival rate than the control group (98.7% vs 97.9%) and a statistically lower incidence of cup aseptic loosening. In case of ceramic on polyethylene couplings, Ti-Por achieved similar survival rate: cup aseptic loosening in Ti-Por group was 0.2%, whereas the control group rated 0.4%. In ceramic-on-ceramic implants, the survival rate was similar in the two groups, Ti-Por achieving a cup aseptic loosening rate of 0.1% (vs 0.14% in the control group).

**Conclusion** Highly porous titanium cups showed trustworthy results at eight years, reducing the rate of aseptic loosening. Longer follow-ups, ion analyses, and pre-clinical in vivo studies would be helpful to better define the reliability of these devices and their advantages.

**Keywords** Trabecular · Titanium · Aseptic loosening · Pore · Additive manufacturing · Ti-Por

## Introduction

Cementless acetabular cups were introduced to provide a direct, biologic fixation and osseointegration between the metal back and the bone, overcoming the need of cemented components [1]. First-generation cementless cup designs proved good: the survival rate at 15 years was 70.1–89.3% [1].

Apart from polyethylene osteolysis, only a few cases of aseptic loosening due to failed bony ingrowth and delamination of the porous coating were reported [1]. Highly porous cups in total hip arthroplasty (THA) were developed in order to furtherly improve the osseointegration, enhance the long-term durability, and reduce the rate of aseptic loosening and delamination to a minimum [2, 3]. Among porous cups, highly porous tantalum cups stood out, with many papers reporting dependable mid- and long-term results [4]. Tantalum devices can be surface coated or bulk implants and can be fabricated using elemental tantalum metal and vapor deposition techniques, enhancing the porosity (Trabecular Metal™, Zimmer, Warsaw, USA) [5, 6]. Thus, the strong points of tantalum cups are the high porosity (up to 80%, with 430–650 μm pore size) and the low elasticity modulus, very close to native bone [4–6]. However, tantalum cups did not show superior clinical and radiostereometric outcomes when compared to first-generation

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titanium cups (Trilogy, Zimmer, Warsaw, USA) [7, 8]. Recently, highly porous titanium cups have been developed to mix the reliability of titanium and the benefits of large pores. Fixa Ti-Por (Adler Ortho, Milan, Italy) is a bulk Ti6Al4V cup, developed in 2007 thanks to the electron beam melting (EBM) technology [9] (Fig. 1). EBM allows orthopedic manufacturing with full material properties and integrated trabecular surfaces, melting thin layers of metal powder in finely tuned 3D constructs [9, 10]. The process is performed by an electron beam gun in a vacuum chamber, maintaining high purity and high strength properties, with no risk of delamination [9, 10]. This additive manufacturing provided a bulk cup with a constant porosity (65%), each pore sizing 700  $\mu\text{m}$  (Table 1) [9]. Such a pore size, which is not achievable with a conventional manufacture, was demonstrated to provide a high fixation ability in the early weeks and a deep bone ingrowth in an in vivo study by Taniguchi et al. [11]. However, clinical outcomes on large case series are still lacking. Thus, the aim of this report was to assess the registry outcomes of the trabecular titanium cup Fixa Ti-Por.

## Methods

The Registry of Prosthetic Orthopedic Implants (RIPO) is the arthroplasty registry which includes 68 orthopaedic departments in the Emilia Romagna region (4,450,000 inhabitants) [12]. Primary hip, knee, and shoulder arthroplasty procedures and revision surgeries have been collected and traced since January 2000 [12]. Using specific forms, RIPO records data similarly to the main national registries [12]. Specifically, the clinical conditions of patients, the features of surgical procedures, and the type and fixation of implants are considered [12]. RIPO achieved a stable capture rate of 98% [12].

The RIPO database was enquired about cementless acetabular cups. In particular, Fixa Ti-Por was compared to all the other cementless cups, acting as a control group: survival rates and reasons for revision were assessed. In order to reduce

possible confounding factors, the results were provided for all the couplings and for specific bearing surfaces.

Cemented cups and metal-on-metal implants with head larger than 32 mm were excluded. To avoid overestimation related to loss to follow-up, the research was limited to resident patients, whose particular relationship with the region allows a reliable assessment of the outcomes. In fact, all the hospital admissions involving Emilia Romagna inhabitants, even when performed outside the region, are always billed back to the region itself, and thus captured by the registry.

Ethics approval was not necessary as the registry collects personal data as standard practice and conceals the identity of the patients.

## Statistical analysis

SPSS software (version 14.0.1, Chicago, IL, USA) was used for the statistical analyses. Demographics, pre-operative features, implant choice, and reasons for revision were presented as rates and percentages of the total cohort. Survivorship analysis was performed using Kaplan-Meier analysis: the endpoint was cup or insert revision (not stem revision). Ninety-five percent confidence intervals (CI) were also calculated. Wilcoxon tests assessed the statistically significant differences between the survival curves:  $p < 0.05$  was the threshold. The implants were followed until the last date of observation (date of death or 31st December 2015).

## Results

A total amount of 36,787 cementless cup THAs were eventually encompassed: the surgeries were performed between July 2007 (when Ti-Por was introduced on the market) and December 2015.

Ti-Por was implanted in 9864 patients, with a mean age of 68 years (range 13–95): the male involvement was 39% (female 61%). Overweight (between 25 and 30  $\text{kg}/\text{m}^2$ ) and obese (over 30  $\text{kg}/\text{m}^2$ ) patients accounted for 43% and 18%,

**Fig. 1** The 3D monolithic reticular structure of Fixa Ti-Por cup provides a porous surface with 700  $\mu\text{m}$  holes, improving the bone ingrowth. On the surface, multiple spikes are evident, with a height of 0.4 mm. The cup porosity is 65%



**Table 1** Features and mechanical tests performed on Ti-Por cups. Forty-two-millimeter cups are optional

Ti-Por features	Values/data
Available cup sizes	44–66, only even sizes
Design	Hemispherical
Fixation	Press-fit
Material	Ti6Al4V
Porosity	65%
Pore size	700 μm
Tensile stress resistance (according to ASTM F1147-05)	64.2 MPa
Shear stress resistance (according to ASTM F1144-05)	39 MPa
Shear stress fatigue resistance (according to ASTM F1160-05)	No damage
Abrasion resistance (according to ASTM F1978-00)	17.1 mg

respectively. The diagnosis leading to THA was primary osteoarthritis in 72% of the cases. Modular necks were implanted in 85% of the cases. Cemented stems were implanted in 2% of the patients. The articular couplings were ceramic-on-ceramic in 84%, ceramic-on-polyethylene in 12%, and metal-on-polyethylene in 4% (other bearings < 1%).

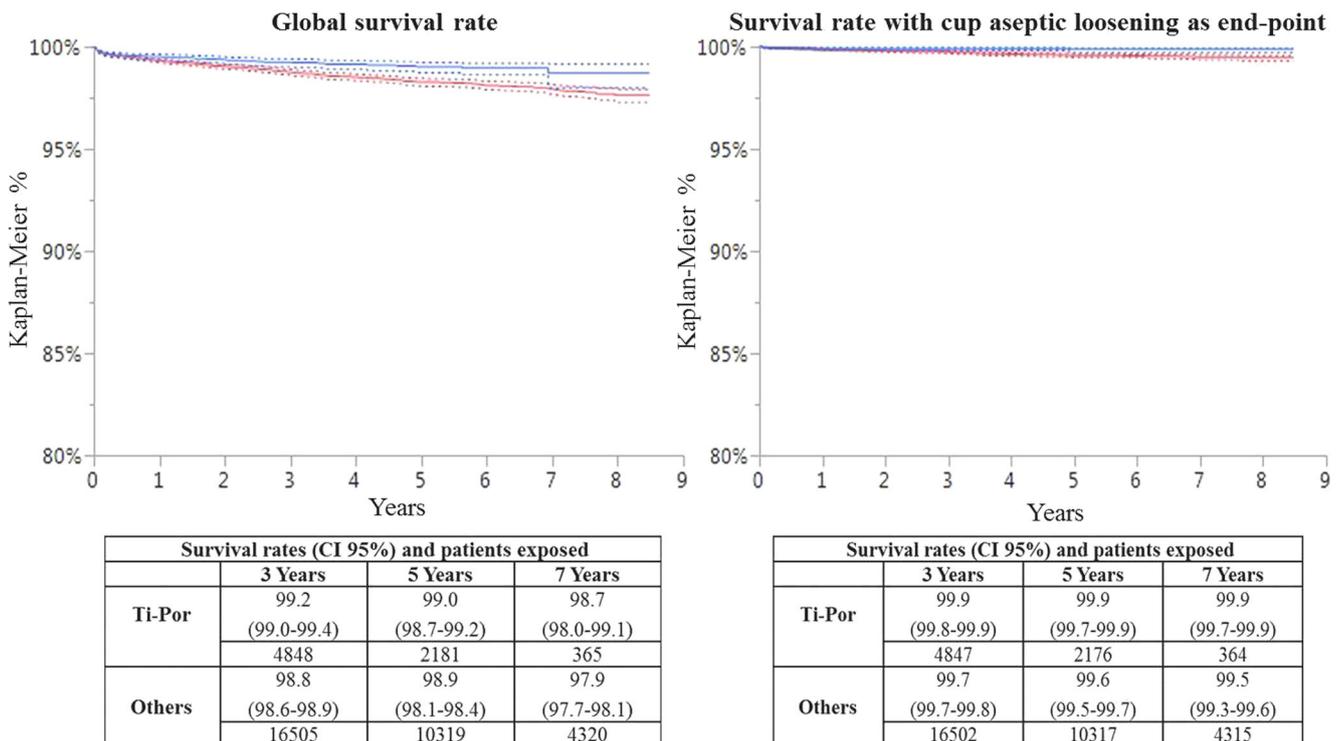
All the other cementless sockets were considered as a control group (26,923 cases). The mean age was 69 years (range

14–99), with male gender accounting for 40% (female 60%). Forty-four percent of patients were overweight and 19% were obese. The diagnosis leading to THA was primary osteoarthritis in the 70% of the cases. Modular neck implants were used in 20% of the cases. Cemented stems were adopted in 6% of the implants. The articular couplings were ceramic-on-ceramic in 50%, ceramic-on-polyethylene in 28%, and metal-on-polyethylene in 16% (other bearings 6%).

At a mean follow-up of 3.2 years (range 0–8.5), a cup revision surgery in Ti-Por group was performed in 75 patients (0.8%): in 18 cases (24%), only the liner was revised. At a mean follow-up of 4.1 years (range 0–9.6), the other sockets were revised in 390 patients (1.4%): in 94 patients (24%), only the liner was revised.

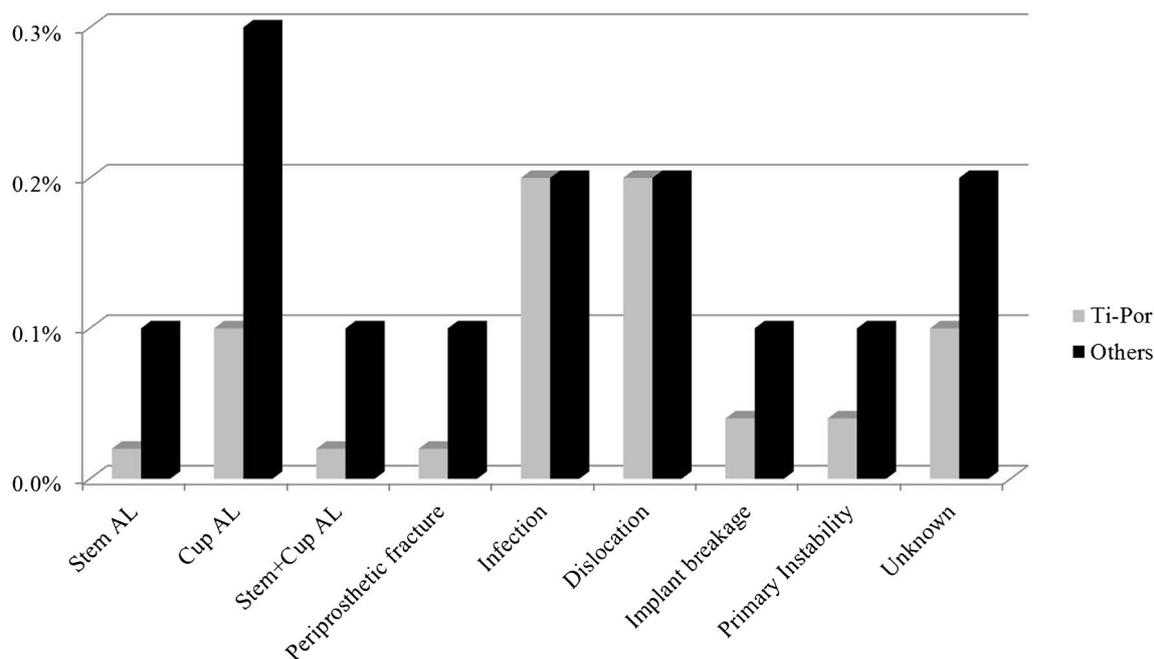
The overall survival rates for the Ti-Por cups and for the control group were reported in the figure (Fig. 2). A statistically significant difference was reported ( $p < 0.01$ ), and it was confirmed when aseptic loosening of the cup was the only end-point ( $p < 0.01$ ). Concerning the reasons for revision in the Ti-Por cohort and the control group, the rate of cup aseptic loosening was 0.1% (10 cases) for Ti-Por and 0.3% (90 hips) for the control group (Fig. 3).

In order to control the confounding factors related to articular couplings (for example, metallosis or osteolysis due to polyethylene), Ti-Por cups with cross-linked polyethylene and Biolox Delta head (CeramTec, Plochingen, Germany)



**Fig. 2** On the left, the Kaplan-Meier curve at 8 years showed a significant superior global survival rate for Fixa Ti-Por (blue line) when compared to the other cups (red line). When only cup aseptic loosening was the

end-point (curve on the right), Ti-Por confirmed the significant superiority ( $p = 0.0054$ )



**Fig. 3** The most important reasons for revisions for Ti-Por and other cups were reported as percentages (including all the articular couplings). The aseptic loosening (AL) rate for Ti-Por cups was very low when compared to other sockets

were compared to the other sockets with the same bearing surfaces. One thousand one hundred seven Ti-Por were selected; the control group included 4798 patients. The Ti-Por cohort and the control group were homogenous (respectively, mean age 76 years vs 72 years; male involvement 38% vs 40%; osteoarthritis as diagnosis leading to THA 76% vs 71%; overweight patients 34% vs 39%), apart for the modular neck involvement (60% vs 10%).

At a mean follow-up of two years (range 0–7.2), 11 cases (1%) were revised in Ti-Por group: in five cases (45%), only the liner was revised. At an average follow-up of 2.7 years (range 0–8.2), 69 cases (1.4%) of the control cohort were revised, with 13 liners (19%) undergoing isolated revisions.

The survival rates showed a little, non-significant superiority of Ti-Por (Fig. 4). The rate of aseptic loosening for Ti-Por cups was 0.2%, whereas the control groups totaled 0.4% (Table 2).

Ti-Por cups with Biolox Delta liners and heads were then compared to all the other cementless sockets with the same articular coupling. Eight thousand one hundred eighty-seven Ti-Por cups and 10,970 other sockets were evaluated. The two groups were homogenous in terms of mean age (respectively, 67 years and 66 years), male involvement (respectively, 40% and 45%), osteoarthritis as diagnosis leading to THA (respectively, 73% and 71%), and overweight patients (35% vs 39%). Once again, the modular neck implants were more frequently adopted in Ti-Por group (89% vs 25%).

At an average follow-up of 3.3 years (range 0–8.5), 57 Ti-Por cups were revised (0.7%), with isolated liner revision in nine cases (16%). At a mean follow-up of 3.6 years (range 0–

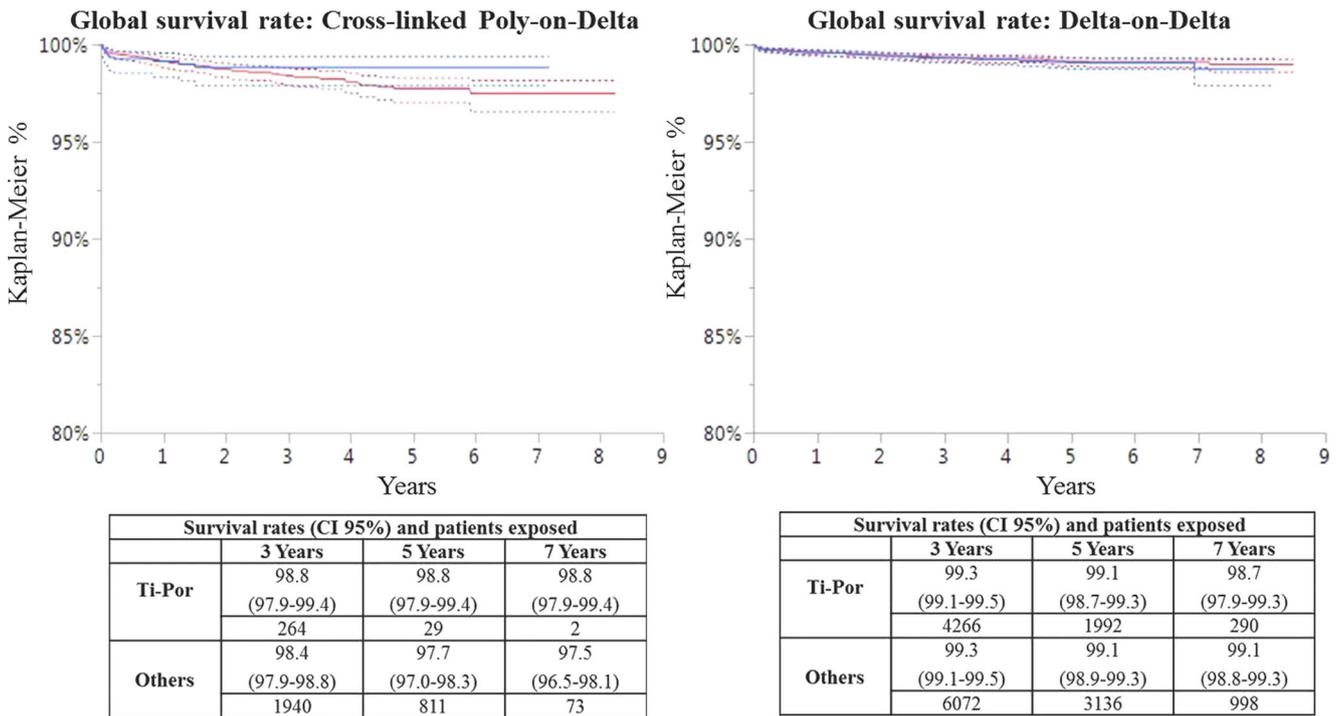
9), 75 sockets in the control group were revised (0.7%), including 17 isolated liner revisions (22%).

The survival rate of Ti-Por cups was slightly inferior to the control group (Fig. 4). The rate of cup aseptic loosening was 0.1% for Ti-Por, whereas the other sockets were revised due to aseptic loosening in 0.14% of the cases (Table 2).

## Discussion

Highly porous metals in cup manufacturing were introduced in order to reduce the aseptic loosening and improve the bony ingrowth [6, 11]. The rationale was explained in the studies by Bobyn et al. and Taniguchi et al.: the initial bony ingrowth was more efficient in case of large pore size implants and, for a mean porosity of 65%, the best fixation in the first weeks was achieved by 600- $\mu$ m pore size devices [6, 11].

Tantalum cups, matching the high biocompatibility of tantalum with highly porous constructs, showed excellent long-term outcomes but failed to demonstrate clear superiority over first-generation titanium sockets [4, 7, 8, 13, 14]. Thus, in order to mix the well-established titanium properties and the importance of pore size, highly porous titanium cups were designed, as Fixa Ti-Por and Delta TT cups (Lima Corporate, Villanova di San Daniele del Friuli, Italy) [9, 10] (Fig. 5). Additive manufacturing using EBM technology allowed the formation of bulk devices with highly porous surfaces and large pores (Fig. 1) [9, 10]. The good mechanical properties and the biological enhancement towards osteoblast proliferation and



**Fig. 4** The Kaplan-Meier curve at 8 years showed comparable global survival rates for Fixa Ti-Por (blue line) when compared to the other cups (red line): cross-linked polyethylene on BioloX Delta ball (on

the left) and BioloX Delta on BioloX Delta (on the right) were homogeneously considered, controlling the confounding factors related to articular couplings

differentiation were reported for Trabecular Titanium™; clinical results were encouraging for primary and revision arthroplasties [9, 15]. However, a registry comparison on a large case series is still lacking.

Enquiring the RIPO registry, Fixa Ti-Por (Orthopaedic Data Evaluation Panel rating: 7A\*) was investigated [16]. This device showed a remarkable survival rate at eight years:

a statistically significant difference was detected when compared to the other sockets ( $p < 0.01$ ) (Fig. 2). Specifically, the aseptic loosening of the cup was three times lower (0.1% in the Ti-Por cups, the other sockets achieving 0.3%) (Fig. 3). Similarly, Ti-Por performed better in terms of global aseptic loosening (0.02% vs 0.1%) and periprosthetic bone fractures (0.02% vs 0.1%) (Fig. 3).

**Table 2** Reasons for revision were provided for Ti-Por cups and other sockets, for ceramic-on-polyethylene and ceramic-on-ceramic couplings. The data were provided in absolute values and percentages

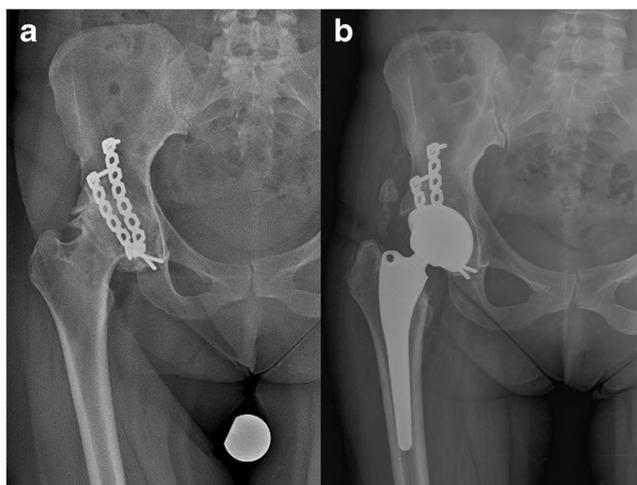
Reasons for revision	Cross-linked poly-on-Delta head				Delta liner-on-Delta head			
	Ti-Por		Others		Ti-Por		Others	
	N	%	N	%	N	%	N	%
Cup aseptic loosening	2	0.2	19	0.4	8	0.1	15	0.14
Stem aseptic loosening	1	0.1			1	0.01		
Aseptic loosening (both components)			5	0.1	1	0.01	2	0.02
Periprosthetic fracture	2	0.2	5	0.1				
Dislocation	4	0.4	14	0.3	12	0.15	12	0.11
Periprosthetic infection	1	0.1	4	0.08	14	0.17	9	0.08
Implant breakage			3	0.06	4	0.05	7	0.06
Pain (no loosening)			1	0.02			2	0.02
Primary instability			4	0.08	4	0.05		
Polyethylene wear			1	0.02				
Others/unknown	1	0.1	12	0.25	13	0.16	15	0.14
Total	11/1107 (1%)		69/4798 (1.44%)		57/8187 (0.7%)		69/10970 (0.68%)	

However, despite the analogous demographical parameters, the two groups were not homogenous regarding the bearing surfaces: specifically, the control groups demonstrated a lower rate of ceramic bearing surfaces [1, 3, 8]. Thus, as the bearing surfaces may influence the aseptic loosening of the cups (for example, due to polyethylene-induced osteolysis), the Ti-Por survival rate was compared to control groups with similar articular couplings.

In case of ceramic on polyethylene, the survival rate achieved by Ti-Por was superior to the other sockets, with no significant difference ( $p > 0.05$ ) (Fig. 4). However, the rate of cup aseptic loosening in the control group doubled Ti-Por; moreover, the other sockets showed higher rate of global aseptic loosening (Table 2). When the analysis was limited to ceramic-on-ceramic implants, Ti-Por achieved a slightly lower survivorship, with no significant difference ( $p > 0.05$ ) (Fig. 4). Once again, the rate of cup aseptic loosening was a little bit lower than the control group (Table 2).

Concerning revisions for septic reasons, Ti-Por did not show a safer profile than other sockets. Tantalum cups were occasionally reported to be protective against infections, with contradictive reports [17, 18]. If the porosity or the material alloy may play a role in bacterial adherence is in dispute and it may be an interesting issue for future researches [17, 18].

This report provided a very large case series about a specific highly porous titanium cup, assessing an immediate and realistic perspective about the clinical use of this device. The reported outcomes were still unpublished and provided new insights into a recent evolution of acetabular cups, produced using a particular additive manufacturing like EBM. However, the study had many limits related to the nature of registry studies. Clinical and radiographic evaluations and a radiostereometric analysis could not be provided. An ion



**Fig. 5** Pre-operative anteroposterior X-rays showed an osteoarthritic left hip in a 52-year-old male, who sustained an acetabular fracture 10 years before (a). Ti-Por achieved a good bony ingrowth at 5 years, with absence of radiolucency lines (b)

evaluation related to the possible titanium ion release would have been helpful to better set the safety of these implants.

In summary, the use of a highly porous titanium cup, as Fixa Ti-Por, seems effective when compared to currently adopted cups, with a notable reduction of revisions due to aseptic loosening. The good results were also confirmed when a possible confounding factor, the articular coupling, was controlled. The encouraging outcomes were in line with the previous literature, describing the results of a similar highly porous titanium cup fabricated using an additive manufacturing [9, 15]. Unfortunately, there is still a paucity of pre-clinical in vivo studies supporting the use of highly porous titanium cups. Similarly, large case series with radiographic assessments at long-term follow-ups are lacking, due to the recent and sporadic adoption of these devices. Thus, a definitive consensus on the use of these devices cannot be made. However, the report of initial results is very promising, deserving a more comprehensive long-term assessment on large case series.

## Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest.

**Ethical approval** Ethical approval was not necessary as the registry collects personal data as standard practice and conceals the identity of the patients.

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