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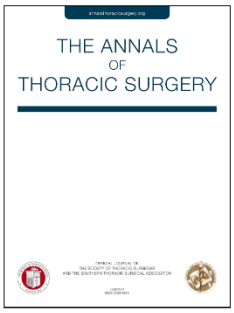

Perceval sutureless aortic valve implantation: mid-term outcomes

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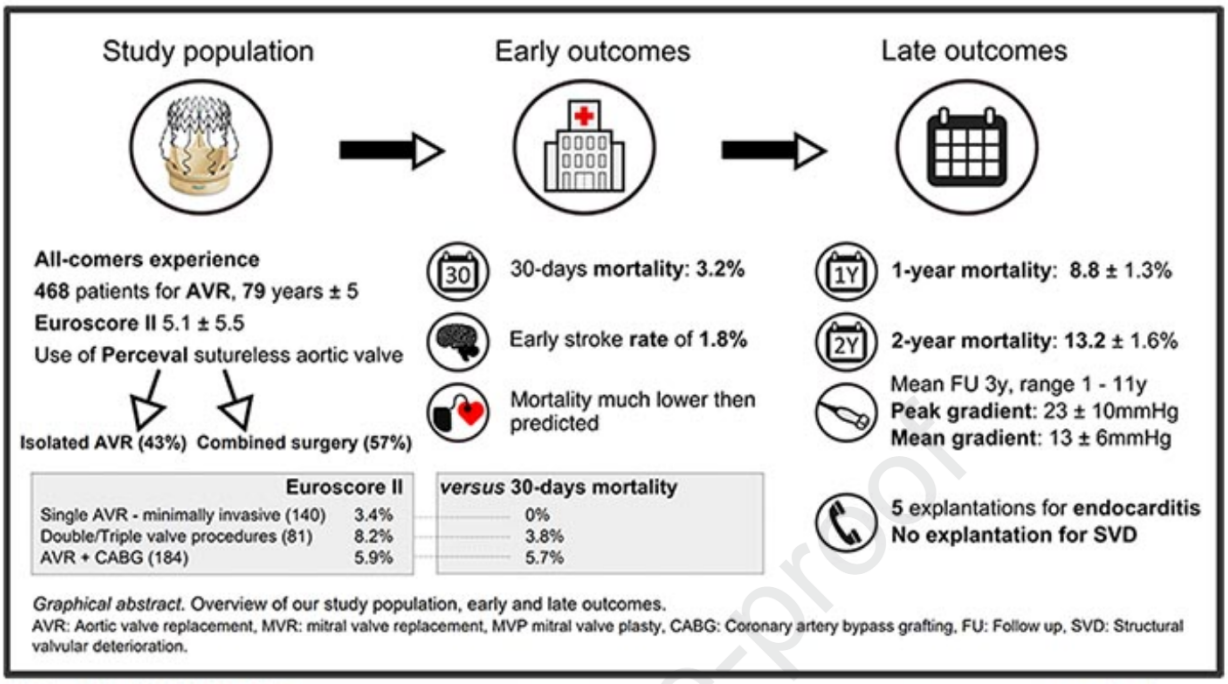

Graphical abstract. Overview of our study population, early and late outcomes.
AVR: Aortic valve replacement, MVR: mitral valve replacement, MVP mitral valve plasty, CABG: Coronary artery bypass grafting, FU: Follow up, SVD: Structural valvular deterioration.

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Perceval sutureless aortic valve implantation: mid-term outcomes

Running head: Midterm outcomes of Perceval

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Abstract

Background: Since our center participated in the 'First-in-Man' trial with Perceval in 2007, this series represents the longest available clinical follow-up (11 years) with sutureless technology in aortic valve replacement.

Methods: We collected all clinical and echocardiographic follow-up in 468 consecutive patients who received Perceval at our institution between 2007 and 2017. In 57% of cases, surgery was combined with CABG (39%), mitral valve surgery (17%), or other procedures (13%).

Results: Mean age was 79y, mean EuroSCORE II was 5.1 ± 5.5 (range 0.8 to 67) and mean STS score was 5.8 ± 5.5. Mean cross-clamp times for isolated and combined procedures were 39 and 79 minutes respectively. Observed all-cause 30-day mortality was 3.2% with an early stroke rate of 1.8%. Pacemaker implantation rate was 7.9% overall, but only 3.9% in patients without pre-existing conduction or rhythm disorders. All-cause mortality at 1 and 2 years was 8.8 ± 1.3% and 13.2 ± 1.6% respectively. At the latest echocardiographic follow-up (mean 3y, range 1 to 11y), peak and mean gradients were 23 ± 10mmHg and 13 ± 6mmHg. During follow-up, we explanted 5 valves for endocarditis, and none for structural valve degeneration (SVD).

Conclusions: After more than 11 years of continued clinical use of the Perceval sutureless valve, we observe low mortality and stroke rates, with good hemodynamic behaviour of the valve. None of our patients was reoperated for SVD. Because of the key benefits of this rapid-deployment valve, it has an added value in surgical aortic valve replacement.

Key words: Aortic valve replacement, sutureless valves, rapid-deployment valves.

In 2007, sutureless aortic valves were introduced into clinical practiceMost published papers focus on short-term follow-up, the longest being a mean follow-up of 1.5 years[1]. Our experience with sutureless valves started in September 2007, when we performed the "First-in-Man" trial for Perceval[2, 3]. This allowed us to gain rapid growing experience in the use of this prosthesis. We learned that the key advantages of this valve, being 1) the ease and speed of implantation; 2) the limited manipulation needed to position the valve and 3) the performance in small and calcified roots, were all strong drivers towards using this valve in various settings[2, 4, 5]. In 2013, we received full reimbursement for the valve in Belgium, which resulted in an important increase in daily use. We use it now either in combined procedures, multiple valve procedures, in elderly patients and patients with co-morbidities, and in minimally invasive procedures for isolated aortic valve replacement (AVR)[4, 5].

Even if transcatheter aortic valve replacement (TAVR) is now favored over surgical aortic valve replacement (SAVR), the Belgian government limited reimbursement of TAVR[6, 7]. This explains that – in Belgium - still an important number of patients undergo surgical valve replacement rather than TAVR. Practically all of these patients receive Perceval, which has become the most frequently used tissue valve in our practice. Throughout the years, we continuously monitored clinical and echocardiographic outcomes. The intermediate results from a small subgroup of this patient population were already published[1, 3]. Three patients from our initial cohort before 2009 represent the worldwide longest living patients with this sutureless technology.

Patients and Methods

Patients

All patients who received a sutureless Perceval aortic valve (LivaNova, Sallugia, Italy) between September 2007 (First-in-Man trial) and December 2017 were included in this

procedures was initially avoided but, with growing experience the prosthesis was used in a wide variety of indications. During the initial period of (2007-2010), 3 subsets of patients, in total 51 patients, were included in prospective clinical trials[1, 2]. The 5y follow-up in those cohorts was published previously[1]. Data *after* the 5y interval point in these patients were collected retrospectively. The majority of patients (n=417) reported here however were not involved in any prospective clinical trial, and therefore all data in these patients were collected retrospectively. Our centre is an academic training centre, so we use many kinds of aortic valve types. Throughout the years, Perceval was mainly used in elderly patients (>65-70y), in combined cases (with CABG and/or multiple valves, ablation, myectomy, etc…), in patients with high co-morbidity and elevated EuroSCORE II, in cases done via mini-sternotomy or mini-thoracotomy. The use of Perceval in patients below 60-65y old has been limited so far.

Surgical Procedure

Implantations were performed by any of the attending surgeons of our staff or by any of the trainees under supervision. The implantation technique was previously described[2, 4, 5]. Surgery was performed through a full sternotomy for all combined procedures. In isolated AVR, a minimal invasive approach (partial sternotomy or right anterior thoracotomy) was used predominantly Correct implantation of the prosthesis was confirmed with intra-operative transoesophageal echocardiography. In the postoperative regime, patients were discharged on low-dose aspirin only.

Follow-up

The majority of patients are followed on a yearly basis in our center. For patients from referring centers, follow-up was obtained by contacting the cardiologist and/or the general practitioner. All available echo reports were collected. Follow-up was closed in December

The definition used for structural valve degeneration (SVD) was based on the standardized definitions suggested by Dvir[8]. In summary, a mean gradient >40mmHg, an increase of mean gradient > 20mmHg associated with a decrease in effective orifice area (EOA) and/or a previously non-existing central regurgitation 2+/4, were defined as *severe SVD* (Stage 3 SVD). This definition is concordant to the majority of current literature and guidelines on SVD[9, 10]. Additionally, we also investigated the occurrence of *moderate stenosis or regurgitation* (Stage 2 SVD), with the advent of either a mean gradient between 20-40mmHg, an increase in mean gradient >10mmHg and/or a new central regurgitation 1+/4. Next to the echo data, we collected all available ECG's preoperatively, at discharge and at follow-up.

Statistical Analysis

Continuous and normally distributed data are expressed as mean ± standard deviation (SD). Data for early events (<30 days post-implantation) are described by numbers and/or percentages. Follow-up data are expressed in terms of actuarial event-free rates. Kaplan-Meier analyses were used for long-term survival and freedom from SVD or explantation of the valve. Echocardiographic data and values are expressed as mean and SD. For the visualization of the long-term evolution of peak and mean gradients, a polynomial curve was fitted through all collected values. Statistica (version 13.4, StatSoft Inc.) was used.

Results

Baseline Characteristics

During the study period (2007-2017), 468 consecutive patients underwent an aortic valve replacement using a Perceval bioprosthesis. Table 1 summarizes the most import baseline characteristics. There were 206 male patients (44%). The mean age was 79 ± 5y (range 63-92y), with 248 (53%) octogenarians. Most cases were primary, 19 cases (4%) were re-interventions. Most cases were elective, there were 91 urgent cases, 6 emergent and 1

Most 'urgencies' were related to the coronary artery disease. There were also 6 cases of active endocarditis. Nearly all cases were either aortic stenosis or mixed steno-insufficiency. Only in 8 cases (1.7%), Perceval was used to treat pure aortic insufficiency (AI). Mean EuroSCORE II was 5.1 ± 5.5 (range 0.8-67). The mean STS score was 5.8 ± 5.5 (calculated for patients with isolated AVR or AVR+CABG).

Intraoperative data are summarized in Table 2. Isolated AVR was done in 201 cases (45%), the remaining 267 were combined surgery. In the isolated AVR group, 140 procedures (70 %) were performed through a minimally invasive approach, either partial sternotomy in 126 patients or right anterior thoracotomy in 14 patients. There were 2 conversions (1.4%) to full sternotomy in the minimally invasive group.

Intra-operative Valve Placement

The distribution of implanted valve sizes was as follows: Small (6%); Medium (34%); Large (37%) and Extra-Large (22%). The success rate of placement of the sutureless valve was 99.6%. In 2 cases, the Perceval was replaced by a standard stented valve during the same surgery. One case was combined with mitral valve *replacement* and the nitinol frame of the Perceval could not deploy properly; the other case showed a central leakage >2/4 and was most likely due to *undersizing* (case performed via right anterior minithoracotomy). In 9 cases (1.9%), a second cross-clamp was needed to reposition the valve or (in one case) to choose a smaller size (case of frame *infolding* due to *oversizing*). None of our patients needed redo surgery within the initial hospitalization for a valve-related malfunction or for a severe paravalvular leakage. We never observed migration or displacement of the valve after correct initial placement.

Early Outcome

All-cause early mortality within 30 days was 3.2 % (n = 15), while mean EuroSCORE II was

AVR, early mortality was 0%. Table 3 summarizes early deaths in comparison to EuroSCORE II levels in different procedure types. Stroke, defined as focal or global neurological deficit lasting for >24h and confirmed by CT-scanning, occurred in 8 patients (1.8%). Reintervention for tamponade/bleeding was needed in 11 patients (2.3%) and 2 patients had new-onset permanent dialysis (0.4%). Fast-track recovery (meaning an early extubation and one night stay on a medium-care unit) without full intensive care (ICU) stay was possible in 55 cases; 119 patients stayed only 1 day at ICU.

ECG Analysis and Pacemaker Implantation

The overall rate of pacemaker implantation during the same hospitalization, was 7.9% (n = 37). Most pacemakers (>90%) are placed in the window of 5 to 7 days postoperatively. In the pre-operative ECG, conduction or rhythm disturbances were already present pre-operatively in 164 patients (35%): any degree of AV-block (n=51); left bundle branch block (LBBB, n=33); right bundle branch block (RBBB, n=36); atrial fibrillation or atrial flutter (n=44). In all patients with some degree of AV block (n=51), the need for pacemaker implant occurred in 5 patients (9.8%); in case of left bundle branch block (LBBB, n=33), 2 patients needed a pacemaker (6.0%). The pacemaker rate in patients *without* any pre-existing conduction or rhythm disorder was 3.9% (n=12).

Follow-up and Overall Survival

One patient was lost to follow-up, resulting in a completeness of follow-up of >99%. The mean clinical follow-up was 3.1 ± 2 years with a maximal follow-up of 11.2 years. All-cause mortality at 1 and 2 years were 8.8 ± 1.3% and 13.2 ± 1.6% respectively. The survival is shown in Fig. 1. In total, 97 patients dead during follow-up (after day 30) from various causes: unknown (n=37), malignancy (n=22), infectious (n=29), heart failure (n=26). One patient died with a clear diagnosis of severe SVD (refused reoperation). Regarding late

during the first 3y of the follow-up. Well over 80% of these elderly, intermediate-risk patients are in functional class I or II.

Reintervention

We explanted the Perceval valve in 5 patients, all because of acute endocarditis (occurring between 8 months and 3 years after the initial surgery). There were no explants for SVD, nor were there reoperations for valve thrombosis or valve migration. None of our patients needed TAVR valve-in-valve treatment.

Echocardiographic Findings and Freedom from Structural Valve Degeneration (SVD)

Peak and mean gradients at discharge were respectively 27.9 ± 10.1mmHg and 15.3 ± 5.8mmHg. Paravalvular leakage (PVL) was absent in 94% of cases, a trace PVL was reported in 5%. In four patients, a 1+/4 PVL was described on the discharge echo report. None of those PVL's resulted in hemolysis or reintervention.

At the latest echocardiographic follow-up (mean echocardiographic follow-up 3y, range 1 to 11y), peak and mean gradients were 23 ± 10mmHg and 13 ± 6mmHg respectively. Paravalvular leakage was only present in 3% of cases. One patient was diagnosed with severe SVD at 7y follow-up (increase in mean gradient >40mmHg), but the patient refused reoperation. This results in a freedom from SVD of 97% at 10y. In total, 10 patients met the Dvir-criteria for moderate SVD: an increase in mean gradients between 10-20mmHg was observed in 3 patients, in 5 cases an increase in central regurgitation >1/4, and 2 patients had both increased gradient and more central leakage[8]. Figure 2 illustrates a curve fitted through all collected peak and mean gradients over time. All patients who were discharged alive had discharge echo data available for evaluation (N=453). In order to construct Figure 2, only the most recent follow-up echo report was used. This way, data from 419 patients was available for analysis. In 104 patients, the most recent echo is at the 1-year interval, in 269

Bicuspid Native Aortic Valve

Despite the initial contra-indications of use of the Perceval in bicuspid native aortic valve and the use in multiple valve procedures, we did use Perceval in these conditions. All bicuspid valve cases (n=11) were successful, without any paravalvular regurgitation nor pacemaker implantation. These bicuspid valves were all Sievers type I, none were type 0 or type II. In these 11 patients, we reached a mean follow-up of 2.6y with the longest follow-up being 5y in one case. The most recent echo in this bicuspid patient cohort, shows a peak gradient of 22mmHg, a mean gradient of 10mmHg, an EOA of 1.6cm2, and no signs of paravalvular leakage.

Comment

We report our experience with the Perceval valve during 11 years, which is the longest follow-up using this sutureless technology. There is growing experience with rapid deployment valves, but long term data is still lacking[4, 5]. Our data from 2007 to 2017 show a good clinical and hemodynamic result both at short and long term, without explants for valve degeneration or need for valve-in-valve treatment so far, although we acknowledge the advanced age of our cohort and the (still) limited mean follow-up duration. The results do confirm the good clinical and hemodynamic outcomes that were demonstrated at the 5-year follow-up interval[1, 3].

In the daily mix of cases at our center, including emergencies, combined cases and elderly patients, it is not so evident to outperform EuroSCORE II or STS score. However, the early mortality observed in our population was 38% lower than what was predicted by EuroSCORE II (3.2% vs. 5.1 predicted risk). In 370 *elective* cases, the early mortality was only 0.8%, while 4.0 was predicted. Early stroke rate is similarly low, which is remarkable taking into account the advanced age and co-morbidities of our patient cohort. The reason behind these results

with stented valves, easily be reduced by 30 minutes or more, depending on the specific surgical situation. In isolated AVR (including minimally invasive cases), clamping times can easily go below 25 minutes. Second is the minimal manipulation needed to place this valve, even in diseased and challenging aortic roots. Third, Perceval makes minimally invasive surgery easier, safer and more applicable[5].

Regarding the long-term survival, we observed an overall mortality of only 9% at 1y and 13% at the 2y interval. In large studies such as PARTNER II and the SURTAVI trial, quite similar patients were included as our patient group, with STS risk scores between 4.5 to 5.8 on average[11-13]. The early mortality in those studies ranged from 3.9 to 5.0%, with early stroke up ranging from 2.8 to 4.3%, in both the surgical as the in the transcatheter study groups. These results led to the *non-inferiority* of TAVR vs. SAVR. Despite the fact that we have more complex surgery (multiple valves), the mortality and stroke rates in our Perceval cohort are lower.

With proper decalcification, sizing and valve positioning, paravalvular leakage is not an issue with this valve. Taking the characteristics of our patient group into account, the paravalvular leakage rate is comparable with standard surgical aortic valve replacement[14]. It is certainly lower in comparison to TAVR procedures[11-13]. None of our patients had to be reoperated for paravalvular leakage or hemolysis.

Concerning the pacemaker implantation rate, several factors need to be taken into account: advanced age, combined surgery, etc... But, most importantly, many of these patients have already pre-existing conduction disturbances. In patients without any of these pre-existing anomalies, the actual rate of implantation was only 3.9%. Patients *with* pre-existing conduction disturbances certainly have higher rates of pacemaker implants. In order to avoid pacemaker implants, the main tips are: 1) proper decalcification of the annulus, 2) correct sizing and certainly avoid oversizing, 3) proper placement of the guiding sutures being max

leakage or valve migration. We know now that neither of the complications occur, with proper sizing and positioning.

Although combined aortic and mitral valve surgery was previously an exclusion criterium, we did not experience more failures or PVL by using Perceval in multiple valve procedures, which corroborates with recent findings[15]. The use of Perceval in bicuspid valves is still a contra-indication in the European IFU (instructions-for-use), while in the US it is stated as a *precaution*. We limit the use of Perceval to Sievers type I cases, predominantly when there is a rather symmetrical distribution in native cusp size.

Sizing is critically important in this valve. We know now that oversizing (together with too low positioning) leads to more pacemaker implantations, possible stent-infolding and also to higher gradients (because of improper leaflet movement and fluttering at opening)[16]. Recently, LivaNova has changed the sizing instructions for the Perceval implantation. The new sizing recommendation clearly leads to the implantation of smaller valves, which also leads to lower gradients. Oversizing causes a pinwheel effect on the leaflets resulting in higher gradients. Recently, we shared our data on gradients and pacemaker rates in implants after this new sizing recommendation (2018 data), which showed a pacemaker rate of only 4.9% [17]. Currently, further research is ongoing to evaluate the effect of an existing preoperative AV-block, LBBB or RBBB on the postoperative rate of pacemaker implantation.

Analysis of gradients shows stability over time with a low incidence of severe SVD. In our total experience of 468 valves, we have no explantations for SVD so far. Perceval Plus, the next version of this valve, is currently being released clinically and has an even more advanced tissue treatment with the goal to prevent calcification and degeneration even better[17].

Limitations

predominant use of the valve occurred after 2013. Our results double the longest currently published mean follow-up, but is still limited[1]. The actual incidence of SVD therefore might still be underestimated. Also, follow-up echocardiographic data from most patients were collected retrospectively, from both our own center and from referring cardiologists, which means no specific study protocol was used. Only the first 51 patients included in the prospective studies underwent a specific study echo using a similar echo protocol. Only in 46 cases, the echocardiographic follow-up extends the 5-year interval. This study shows the result of a single valve and there is no comparison group.

In conclusion, patients with the Perceval sutureless aortic valve show low mortality and low stroke rates. Structural valve degeneration is limited at this moment of follow-up. Perceval can be used in many patients, both in minimally invasive surgery as in complex or combined procedures. In an era of rapidly increasing use of transcatheter therapies, these sutureless valves are an important tool for the surgeon to keep on providing safe surgery with low complication rates.

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Table 1. Baseline characteristics (N=468 patients).

Age, years	79 ± 5 (63 - 92)
Octogenarians (>80y)	248 (53%)
Male gender	206 (44%)
BSA (m², mean ± SD and range)	1.8 ± 0.2
Body mass index	27.4 ± 4.8
NYHA functional class	
I	26
II	164
III	231
IV	47
EuroSCORE II	5.1 ± 5.5 (0.8 – 67)
Redo surgery	19 (4%)
Risk factors	
Diabetes	116 (25%)
Recent myocardial infarct (<90d)	47 (10%)
Unstable angina	52 (11%)
Insulin-dependent diabetes	14 (3%)
Extracardiac arteriopathy	122 (26%)
Chronic lung disease	75 (16%)
Dialysis	28 (6%)
Urgency	
Elective	370 (79%)
Urgent	91 (19%)
Emergent	6 (1%)
Ejection fraction	
Normal (>49%)	318 (68%)
Moderate (31-49%)	76 (16%)
Poor (21-30%)	13 (3%)
Very poor (<21%)	3 (0.6%)
Pulmonary hypertension	
Moderate (31-55mmHg)	225 (48%)
Severe	58 (12%)
Active endocarditis	6 (1%)

Continuous patients are presented as mean ± SD (range). Categorical variables are presented as number (%). BSA: Body surface area. NYHA: New York Heart Association Functional Classification.

Table 2. Intra-operative data (N=468 patients).

Surgical approach	
Full sternotomy	328 (70%)
Minimal invasive approach	140
Conversion	2 (1.4%)
Isolated AVR	201 (45%)
Minimal invasive approach	140 (70%)
Partial sternotomy	126 (89%)
Right anterior thoracotomy	14 (11%)
Combined surgery CABG Mitral valve repair/replacement Tricuspid valve repair Other procedures	267 (57%) 184 (39%) 79 (17%) 27 (6%) 31 (7%)
Cardiopulmonary bypass time (min) All Isolated AVR Combined procedures	 94 ± 40 (23-289) 66 ± 22 118 ± 40
Cross clamp time (min) All Isolated AVR - Minimal access - Full sternotomy Combined procedures	 61 ± 30 (12-204) 39 ± 13 43 ± 10 36 ± 19 79 ± 32

Continuous patients are presented as mean ± SD (range). Categorical variables are presented as number (%). AVR: Aortic valve replacement. CABG: Coronary artery bypass grafting.

Table 3. Early mortality vs EuroSCORE II levels.

	N	EuroSCORE II	STS	30-day mortality
All patients	468	5.1	5.5	3.2
Isolated AVR – minimally invasive	140	3.4	4.7	0
Double/triple valve procedures	81	8.2	-	3.8
AVR + CABG	184	5.9	6.7	5.7

AVR: Aortic valve replacement. CABG: Coronary artery bypass grafting. STS: Society of Thoracic Surgeons score.

Table 4. Evolution in NYHA functional class.

NYHA Class	Preop (n=468)	1Y (n=349)	2Y (n=271)	3Y (n=159)
I	6%	59%	58%	56%
II	35%	22%	24%	30%
III	49%	9%	5%	4%
IV	10%	1%	0%	0%
Died	-	9%	13%	20%

Figure legends

Fig. 1

Kaplan-Meier curve showing freedom from overall death. All-cause mortality at 1 and 2 years were 8.8 ± 1.3% and 13.2 ± 1.6% respectively. Curve is shown with corresponding 95% confidence intervals. The curve was truncated from the moment there were less than 10 patients in follow-up.

Fig. 2

We collected all echocardiographic examinations. This figure shows a polynomial curve fitted through all collected peak and mean gradients over time, with the corresponding 95% confidence limits. One can observe 1) the slight drop in gradients during the first year, in comparison to the discharge gradients; and 2) the stability over time up to 11y postoperatively.