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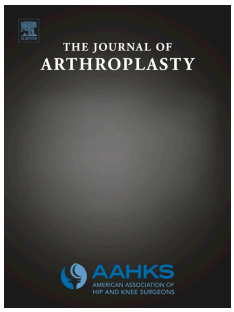

Cruciate-Retaining Versus Posterior-Stabilized Primary Total Arthroplasty. Clinical Outcome Comparison with a Minimum Follow-Up of 10 Years

Ricardo Serna-Berna, MD, Alejandro Lizaur-Utrilla, PhD, MD, Maria F. Vizcaya-Moreno, PhD, MD, Francisco A. Miralles Muñoz, MD, Blanca Gonzalez-Navarro, MD, Fernando A. Lopez-Prats, PhD, MD

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CRUCIATE-RETAINING VERSUS POSTERIOR-STABILIZED PRIMARY TOTAL ARTHROPLASTY. CLINICAL OUTCOME COMPARISON WITH A MINIMUM FOLLOW-UP OF 10 YEARS.

Ricardo Serna-Berna, MD[1]
Alejandro Lizaur-Utrilla, PhD, MD[1,3]
Maria F. Vizcaya-Moreno, PhD, MD[2]
Francisco A. Miralles Muñoz, MD[1]
Blanca Gonzalez-Navarro, MD[1]
Fernando A. Lopez-Prats, PhD, MD[3]

[1] Orthopaedic Surgery, Elda University Hospital, Ctra Sax s/n, 03600 Elda, Alicante, Spain
[2] Clinical Research Group, Faculty of Health Sciences, University of Alicante, Ctra San Vicente Raspeig s/n, 03690 San Vicente Raspeig, Alicante, Spain
[3] Traumatology and Orthopaedia, Miguel Hernandez University, Avda Universidad s/n, 03202 San Juan, Alicante, Spain

Author for correspondence:
Dr. Alejandro Lizaur-Utrilla
Dpt. Orthopaedic Surgery, Elda University Hospital
Ctra Elda-Sax s/n, 03600 Elda, Alicante, Spain
Phone: +31 966 969 055
Fax: +31 966 975 024
e-mail: lizaur1@telefonica.net

CRUCIATE-RETAINING VERSUS POSTERIOR-STABILIZED PRIMARY TOTAL ARTHROPLASTY. CLINICAL OUTCOME COMPARISON WITH A MINIMUM FOLLOW-UP OF 10 YEARS.

ABSTRACT

Background: Controversy continues regarding whether the posterior cruciate ligament should be retained or removed during total knee arthroplasty (TKA) procedure. The objective was to compare the clinical outcomes with a minimum follow-up of 10 years between patients who received contemporary cruciate retaining (CR) or posterior stabilized (PS) primary TKA.

Methods: Case-control study of 268 patients underwent CR TKA versus 211 to PS design, with the same arthroplasty system, and a minimum follow-up of 10 years. Clinical assessment was performed by Knee Society scores, Western Ontario and MacMasters Universities and Short-Form 12 questionnaires, range of motion, and patient satisfaction.

Results: Successful outcomes were found for both designs. No significant differences in functional scores, range of motion, patient-related scores or patient satisfaction. Between the 5-year and last postoperative follow-up, there were a significant decrease of all clinical scores in both groups. In addition, complication rate and implant survival were similar between groups.

Conclusion: The superiority of one design over the other was not found. Both designs can be used expecting long-term successful outcomes and high survival. The choice of the design depended on the status of the posterior cruciate ligament and surgeon preference.

Keywords: Total knee arthroplasty; Cruciate-retaining; Posterior stabilized; Functional outcome; Patient satisfaction.

INTRODUCTION

Total knee arthroplasty (TKA) has provided high rate of successful outcomes in patients with end-stage knee osteoarthritis [1]. Several designs have been developed to improve the durability and function of this procedure. However, the most widely used designs for primary arthroplasty have been, and continue to be today, cruciate–retaining (CR) and posterior-stabilized (PS) [2]. Currently, controversy still continues regarding whether the posterior cruciate ligament (PCL) should be retained or removed during the procedure [3]. Advantages and disadvantages for both CR and PS designs have been reported in numerous biomechanical and kinematic studies [4-7]. However, the impact of the kinematic differences on the clinical outcomes has been controversial, and the superiority of one design over the other has not been unequivocally demonstrated in vivo [8].

There were a large number of publications examining the clinical differences between CR and CS designs, but most of them had small size and a follow-up as short as 5 years and the findings on clinical outcomes were controversial [9-12]. As far as we know, only 3 studies have reported comparative clinical outcomes with a minimum follow-up of 10 years [13-15]. One of these [13] was a randomized study of 62 patients at 2 years and then reviewed at 10 years where the authors reported similar ROM and functional outcomes. The 2 other were retrospective comparative studies with follow-up of 10 years, one of which reported better ROM and function in the PS group [14], and the other better ROM in PS group but similar functional scores [15]. Thus, evidences on long-term functional outcomes are limited and controversial. Several systematic reviews comparing both designs have reported no significant clinical differences with the available evidences [3,8], and the authors suggested that longer follow-up investigations were needed.

The main purpose of this study was to compare the clinical outcomes with a minimum follow-up of 10 years between patients who received contemporary CR or PS primary total knee arthroplasty. We hypothesized that long-term outcomes are similar.

PATIENTS AND METHODS

This long-term retrospective case-control study was approved by our institutional review board and informed consent was required to perform a new patient evaluation.

A search to identify patients underwent CR and PS primary TKA between 2001 and 2006 was performed on the departmental arthroplasty database using diagnostic and surgical codes. The inclusion criterion was primary TKA. The exclusion criteria were diagnosis of posttraumatic or inflammatory arthritis, if bone grafting was required, varus/valgus deformity greater than 15º, or prior knee osteotomy.

Six hundred and ten patients meeting the criteria were identified. Of them, 82 (13.4%) patients were excluded for death within 10 postoperative years unrelated to the TKA (38 CR and 44 PS), 31 could not be contacted or they were unable to return for re-evaluation (17 CR and 14 PS), and 18 refused to participate in a new evaluation (12 CR and 6 PS). Among the remaining 479 patients, 268 received CR and 211 PS artrhoplasty. In that time, the indication of one or the other TKA design depended on intraoperative PCL status, and the first years also on preference of the surgeon. Baseline characteristics at the time of the TKA in both groups are shown in Table 1. There were no significant differences in preoperative data between groups.

Operative protocol

The operations were performed by several experienced surgeons, according to the standardized practice in our center. All procedures were performed in operating room

with laminar flow, under spinal anaesthesia. A standard anterior midline skin incision and medial parapatellar arthrotomy was used in all patients. Standard operative techniques were used for all patients with the respective instrument systems.

The same modular TKA systems were used in all patients (Trekking, Samo, Italy). The two designs (CR and PS) were identical except for the cam-post mechanism. CR design had hybrid fixation (cementless femoral component) and PS design cemented fixation of both components. Tibial preparation was performed first, and intramedullary alignments were used for femur and tibia in all patients. Care was taken during bone resections to balance flexion and extension gaps. All patellae were routinely resurfaced with an all-polyethylene cemented design. After intraoperative assessment, all patients with sufficient PCL received CR TKA. Among patients receiving PS TKA, 26 had sufficient PCL and the remaining 185 had insufficient PCL.

According to the standard protocol, all patients received antibiotic prophylaxis with first generation cephalosporin for 24 hours (started 1 hour prior to skin incision) and thromboembolic prophylaxis with low-molecular-weight heparin for 30 days. Standardized at our centre, continuous passive knee motion started on the first postoperative day and from the third day active motion under the supervision of the therapist and full weight-bearing were allowed.

Evaluations

At our institution, the arthroplasty register prospectively collects clinical and radiographic data on all patients treated with arthroplasty with a minimum follow-up of 5 years. Standardized assessment was performed preoperatively and postoperatively at 1, 3, 6 months, and then yearly until at least 5 years. For this study, those patients with a follow-up less than 10 years were invited to return for a new clinical and radiological

evaluation. For clinical evaluations, the Knee Society scores (KSS) [16], reduced Western Ontario and MacMasters Universities (WOMAC) [17] and Short-Form 12 (SF12) [18] questionnaires were used. The range of motion (ROM) of the knee joint was assessed with a standard goniometer. Flexion and extension lag items were also analyzed separately from KSS. The WOMAC was transformed to a 0-100 scale, so a higher value implies a better outcome. In addition, patient satisfaction was evaluated at final follow-up by a 0-10 visual analogue scale (VAS).

Radiological evaluation was performed using standard standing anterior-posterior, lateral and skyline views. The latest radiographs were analyzed by two independent surgeons who did not know the clinical evaluations of the patients. The Knee Society radiographic evaluation system [19] was used for position of components and zones of radiolucency or osteolysis. Loosening of the arthroplasty was defined by continuous or progressive radiolucent lines or by migration of any component.

Statistical analysis

Statistical analyses were performe with SPSS software v. 15.0 (SPSS Inc., Chicago, USA). Normal distribution was determined by the Kolmogorov-Smirnov test. Comparisons between categorical variables were made with chi-square test or non-parametric Fisher exact test or Mantel-Haenszel test, and for continuous variables with Student t-test or Mann-Whitney U-test. Comparisons between preoperative and last follow-up data were made by paired t-test or Wilcoxon signed-rank test. Multivariate analyses by logistic regression models were used to analyze independent factors affecting final ROM and KSS scores. These data were presented as Odds ratio (OR) with 95% confidence interval (CI). Kaplan-Meier test was used for TKA survival analysis with revision for any reason as end-point, and comparison between groups was

made by the Mantel-Haenszel log-rank test. Significance was considered for p values less than 0.05 in all tests.

RESULTS

Mean final follow-up from index TKA to the last assessment was 13.4 (range, 10-15) years in the CR group, and 12.7 (range, 10-15) years in the PS group. All clinical scores significantly improved from preoperative to last follow-up in both groups (p= 0.001).

Over the time, there were no significant differences (all, p<0.05) in any functional outcome between 3 and 5 postoperative years in both groups. Between 5 and 8 postoperative years, there were significant decreases in KSS-knee (p= 0.044) in both groups and extension lag (p= 0.032) in only CR group, and no significant differences in KSS-function (p= 0.395) or knee flexion (p= 0.128) in both groups. Between 5 postoperative years and final follow-up (Table 2), there were significant decreases in both groups for all functional scores except extension lag in the PS group. However, all these differences in numbers were small.

At the final follow-up, there were no significant differences in any KSS score or ROM between groups at either 5 postoperative years or final follow-up (Table 2). Multivariate analysis showed that only preoperative ROM had significant influence on last ROM (OR: 1.7; 95% IC: 1.1-2.3; p= 0.026), and TKA design had not influence (OR: 0.9; 95%IC: 0.3-3.7; p= 0.394). Likewise, TKA design had not significant influence on last KSS-knee score (OR: 0.3; 95%IC: 0.02-2.8; p= 0.514) or KSS-function score (OR: 1.1; 95%IC: 0.07-2.7; p= 0.613).

Regarding to the patient-reported outcomes, there were no significant differences over the time between 3, 5 and 8 postoperative years in both groups (all, p < 0.05). However, significant differences in both groups were found between 5 postoperative years and the

final follow-up (Table 3) in SF-12 scores (all, p= 0.001). There was no significant change in WOMAC score between 5-year follow-up and final in either group. At final follow-up, there were no significant differences between groups in any patient-reported scores.

The 86 % of patients in the CR group and 84% in the PS group were satisfied with the functional outcome of their knees after 10 postoperative years (p= 0.565). At final follow-up, there was no significant difference between groups in the level of VAS-satisfaction (p= 0.151). There were no significant differences in patient rate with residual pain knee between groups (8% in CR group versus 6% in PS group, p= 0.547). A higher patient rate in the PS group reported a greater frequency of swelling or tightness of their replaced knee than patients in CR group (12% versus 7%), but this difference was not significant (p= 0.109).

In the CR group, 7 unrevised knees had nonprogressive, incomplete radiolucent line less than 1 mm in at least 1 zone around the tibial component (zones 1, 3, 4), while in the PS group this was in 5 unrevised knees (zones 1 and 4). No radiolucent lines around the femoral or patellar component were found in either group.

Overall, there were 21 (5.5%) revisions, 9 (4.2%) in the CR group and 12 (7.2%) in the PS group (p= 0.259). There were no revisions of CR due to PCL deficiency. Complications with subsequent revisions included 3 early wound deep infections (1 CR and 2 PS) that were treated with 2-stage revisions, 9 aseptic tibial loosening (4 CR and 5 PS) with a time revision ranged from 4 to 9 years, 5 polyethylene insert wear (2 CR and 3 PS) with a time revision ranged from 4 to 8 years of which 2 were treated with only insert exchanges and the 3 other with tibial revision, and 4 periprosthetic femoral fracture (2 CR and 2 PS) at 4-9 years of which 3 were treated with retrograde intramedullar nail and the another with arthroplasty revision. The cumulative survival of

the TKA at 14-year for any reason (Fig. 1) was 95.7 % (95% CI, 93.0–98.5 %) in the CR group and 92.7 % (95% CI, 88.8-96.7 %) in the PS group, and this difference was not significant (log rank, p= 0.209).

DISCUSSION

Currently, controversy regarding to the advantages and disadvantages of CR and PS designs continue, and the clinical superiority of one design over the other has still not been demonstrated [3]. The main objective of the present study was to compare long-term clinical outcomes between both designs. The main findings were successful outcomes for both CR and PS arthroplasties, with no significant differences at a minimum postoperative follow-up of 10 years in functional scores, ROM, patient-related scores or patient satisfaction. Between the 5-year and final postoperative follow-up, there were a significant decrease of all clinical scores in both groups, although the differences in numbers were small. In addition, complication rate and implant survival were similar between groups.

Potential advantages of CR designs include more normal knee kinematics, especially increased femoral rollback on the tibia during flexion, intact PCL preventing anterior translation of the femur on the tibia, greater inherent stability of the prosthesis, increased proprioception, greater passive knee range of motion (ROM), enhanced quadriceps muscle power, preservation of bone, and less blood loss [20,21]. On the other hand, with PS designs have been reported advantages such as greater ease of balancing of soft tissues, more congruent articulations, increased rollback with reduced posterior tibial subluxation and greater range of flexion, and superior patellofemoral kinematics [6,22,23].

There were a large number of studies comparing clinical differences between CR and CS designs, but few of them had a follow-up of 10 years. Scott et al [12], in a randomized study compared 55 patients who received a CR design and 56 PS design with mean follow-up of 4 years, reported similar clinical and radiographic outcomes between both, although the PS patients received significantly more transfusions than CS patients. However, other studies have reported no difference in blood loss between CR and PS designs [24] or higher blood loss with the design [25]. In other randomized study of 98 patients, Chaudhary et al [9] reported similar pain, ROM, function, quality of life scores and complication rates between CR and PS groups after a follow-up of 2 years. Clark et al [26], in other randomized study of 143 patients with a minimum 2-year follow-up reported no significant differences between groups regarding to functional scores or ROM. On the contrary, other randomized studies found significant clinical differences.

Maruyama et al [27], in a randomized comparison of 20 patients whom were bilaterally operated with both CR and PS designs reported similar knee scores but higher range of motion in the PS knees after a mean follow-up of 2 years. Harato et al [10], in a multicenter randomized study of 99 CR patients and 99 PS patients with a minimum follow-up of 5 years, found no significant differences between both groups in functional outcomes, satisfaction or complication rate, but improvement in range of motion was better in the PS group. Ozturk et al [11], comparing randomly 33 CR patients and 28 PS patients with a deformity greater than 10º and follow-up of 7 years, reported that both types of prosthesis produced similarly successful functional outcomes but flexion arc was larger in PS knees. Overall, a recent meta-analysis of randomized controlled trials [2] found similar clinical outcomes with regard to knee function, pain, ROM and complications between CR and PS designs.

To our knowledge, only 3 studies have reported on the comparative clinical outcomes with follow-up over 10 years [13-15] and with controversial findings. In agreement with us, Mayne et al [15] found similar functional scores, ROM and revision rate between both designs. Likewise, Beaupre et al [13] found no differences in functional outcomes or revisions, although ROM data were not reported. On the contrary, other long-term study de 414 patients [14] reported significantly better functional outcomes and ROM with the PS design, although excellent 10-year survival was also reported for both designs. However, although clinical score differences were significant, to our understanding those differences in numbers were small. On the other hand, other large retrospective study [28], showed a significant difference in TKA survival at 15-year between CR and PS designs (90% versus 77%), although unfortunately they did not report functional results.

Strengths of the present study were the relatively large number of patients from a single center, follow-up over 10 years, and relatively low rate of loss of follow-up. To our knowledge, this was one of the largest studies on comparative long-term outcomes published to date. However, the study was not according to usual practice because patients with severe knee deformity were excluded. Moreover, inherent to any long-term study involving elderly patients, there were 13% of patients losses to follow-up.

In addition, this study had other limitations. First, this study was limited by its retrospective design. Our patient cohorts were not randomized and patient selection bias may have occurred. On the other hand, our findings could be specific to the implant used and not be generalized to other arthroplasty systems. In addition, CR model was hybrid whereas the PS was cemented which could be a confounding factor on outcomes or longevity of the prosthesis.

CONCLUSIONS

The present study demonstrated successful survival for both designs with similar clinical outcomes between CR and PS designs at long-term follow-up. Thus, the superiority of one design over the other was not found. Both designs can be used expecting long-term successful outcomes and high survival. The choice of the design depended on the status of the posterior cruciate ligament and surgeon preference. Currently, we prefer the CR design whether the ligament is sufficient because it requires less bone resection.

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354 **LEGEND OF FIGURE**

355 **Fig. 1**. Kaplan-Meier cumulative survival curves (p= 0.209)

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360 **Table 1. Baseline characteristics at the time of the TKA**

	CR group n= 268	PS group n= 211	p-value
Age at TKA	68.8 (7.1)	70.1 (8.3)	0.108
Gender (F/M)	196/72	144/67	0.142
BMI	31.6 (5.2)	32.5 (5.8)	0.118
Alignment pre	4.2º (4.8º) VR	4.6º (5.1º) VR	0.438
KSS-knee	35.9 (14.6)	36.4 (15.2)	0.746
KSS-function	45.3 (15.9)	47.2 (14.7)	0.229
ROM	91.6 (12.4)	90.8 (13.5)	0.553
Flexion	94.4 (10.7)	92.6 (11.3)	0.116
Extension lag	3.2 (3.4)	3.3 (3.7)	0.787
Global WOMAC	40.6 (9.2)	39.8 (8.7)	0.387
SF12-physical	21.5 (5.7)	20.8 (6.1)	0.255
SF12-mental	42.4 (9.8)	41.6 (9.6)	0.426

361 Continuous data as mean (SD). Alignment, preoperative. VR: varus femorotibial

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364 **Table 2. Functional outcomes over the time**

	CR group	PS group	p
KSS-knee			
At 5 years	88.3 (6.4)	87.7 (6.9)	0.382
At final follow-up	86.4 (7.1)	85.2 (7.6)	0.117
p	0.015	0.001	
KSS-function			
At 5 years	88.1 (8.4)	87.9 (9.3)	0.826
At final follow-up	84.4 (9.1)	85.6 (9.8)	0.223
p	0.001	0.029	
ROM			
At 5 years	104.3 (9.7)	102.9 (10.1)	0.174
At final follow-up	101.2 (10.4)	100.7 (10.7)	0.648
p	0.001	0.054	
Flexion			
At 5 years	105.2 (10.9)	103.1 (11.4)	0.069
At final follow-up	101.3 (11.1)	100.4 (9.6)	0.399
p	0.001	0.020	
Extension lag			
At 5 years	1.0 (1.6)	1.3 (1.4)	0.056
At final follow-up	1.4 (1.8)	1.2 (1.9)	0.299
p	0.016	0.585	

365 Data as mean (SD). KSS: Knee Society score.

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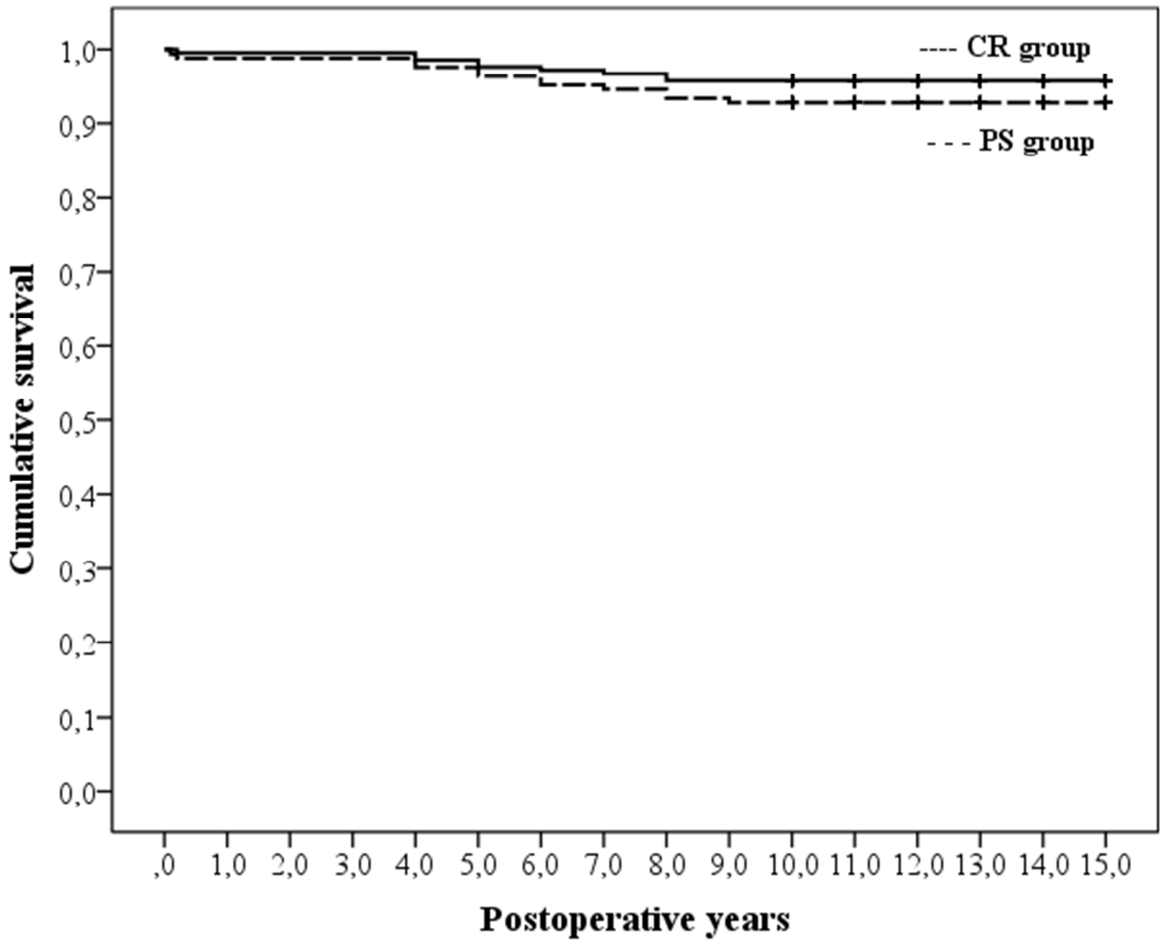
Table 3. Patient-reported outcomes over the time

	CR group	PS group	p
Global WOMAC			
At 5 years	84.4 (19.2)	86.7 (20.2)	0.262
At final follow-up	82.2 (20.1)	83.3 (19.6)	0.592
p	0.249	0.120	
SF12-physical			
At 5 years	40.6 (7.2)	41.8 (8.1)	0.134
At final follow-up	38.2 (8.1)	36.9 (8.9)	0.143
p	0.001	0.001	
SF12-mental			
At 5 years	49.4 (7.4)	48.8 (7.9)	0.446
At final follow-up	44.1 (8.2)	43.4 (9.3)	0.445
p	0.001	0.001	
VAS-satisfaction			
At final follow-up	7.9 (1.9)	7.6 (2.1)	0.151

Data as mean (SD). Global WOMAC: amount of pain and physical function. VAS: visual analogue scale for patient satisfaction.

Fig. 1. Kaplan-Meier cumulative survival curves (p= 0.209)


---- CR group
- - - PS group
Cumulative survival
1,0
0,9
0,8
0,7
0,6
0,5
0,4
0,3
0,2
0,1
0,0
,0 1,0 2,0 3,0 4,0 5,0 6,0 7,0 8,0 9,0 10,0 11,0 12,0 13,0 14,0 15,0
Postoperative years