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Implant Survival of Constrained Acetabular Device in Primary Total Hip Arthroplasty Based on Data From the Finnish Arthroplasty Register

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ABSTRACT

Background: Constrained acetabular devices were developed to prevent dislocations after total hip arthroplasty (THA). However, the data on their success have been contradictory. In this study, we aimed to assess implant survival of the constrained acetabular device in primary THA based on the Finnish Arthroplasty Register data.

Methods: A total of 373 primary THAs with constrained acetabular devices inserted from 2006 to 2017 were included. A reference group was formed on a 1:3 basis and matched for age, sex, and diagnosis, consisting of 1118 conventional THAs. Implant survival estimates using death as a competing risk were assessed with revision for any reason and for any aseptic reason as the endpoints. The Cox multiple regression models were adjusted for age, sex, and diagnosis. The mean follow-up time was 3.3 (0-12.4) years for the constrained device group and 3.8 (0-12.0) years for the reference group.

Results: Overall, there were 21 revisions in the constrained device group and 49 in the reference group. The 8-year survivorship for any reason was 94% (confidence interval [CI]: 91-96) for the constrained device group and 93% (CI: 89-97) for the reference group. With revision for any aseptic reason as the endpoint, the 8-year survivorships were 97% (CI: 95-99) and 94% (CI: 90-98), respectively. During the first 1.5 years, the constrained acetabular device group had a similar revision risk (hazard ratio: 1.09 [CI: 0.57-2.07], $P = .8$) to that of the reference group.

Conclusion: The constrained acetabular device had good survival in primary THA, and our results support its continued use even in high-risk patients.

Dislocation is one of the most common reasons for revision surgery after primary total hip arthroplasty (THA), covering 17%-21% of all first-time revisions [1,2]. The dislocation incidence during the first postoperative year after primary THA varies from 2% to 4% [3–5]. Both patient-related and surgical factors such as posterior approach, poor component positioning, small femoral head size, poor repair of soft tissues, and implant choice may predispose to THA dislocation [3,4,6–8]. As the outcome after revision THA is generally poorer than that after primary THA and the complication rate is higher, it is important to prevent first-time dislocations.

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Fig. 1. Study devices. (A) Freedom constrained liner made of ArCom isostatically molded polyethylene and a titanium constraint ring. (B) Freedom constrained cemented cup.

Implant choice is one of the critical steps in preventing unstable THA. Currently, the three main options available that provide some protection against dislocation are dual mobility implants, large-diameter femoral heads, and constrained acetabular devices. Despite some variability in the data on the ability of constrained acetabular devices to prevent dislocation and restore stability to prevent recurrent dislocation, they have become a generally accepted option worldwide for treating instability in revision THA [9–11]. However, the role of constrained cups in primary THA in preventing dislocations in high-risk patients has not been settled. Despite their advantages in terms of stability, constrained devices may result in a restricted range of motion and have a greater prevalence of impingement of the femoral neck on the cup. Impingement is responsible for high stress transmission to multiple interfaces, leading to liner damage, locking mechanism failure, dislocation, and loosening [10]. Therefore, the constrained acetabular device system is intended only for special situations where the patient has a high risk of dislocation because of a previous history of dislocation, severe joint laxity, palsy of the surrounding musculature, or abductor muscle deficiency.

The purpose of this study was to assess the revision rate associated with the constrained acetabular device in primary THA and to compare it with a conventional THA reference group with (1) revision for any reason, (2) revision for dislocation, (3) revision for any aseptic reason, and (4) revision for infection as the endpoints, based on data from the Finnish Arthroplasty Register (FAR).

Patients and Methods

This study is based on data from the FAR, which covers most of the total hip implants performed in Finland since 1980 [12]. Orthopedic units are obligated to provide all the information essential for maintenance of the register to the Finnish National Institute for Health and Welfare. In Finland, the data completeness for primary THA is >95%, and for revision THA, 81% [2]. Dates of death are obtained from the Population Information System maintained by the Population Register Center. Since May 2014, implant identification has been performed by electronic scanning of reference codes in operating theaters, and the operative information is then sent electronically to the register [2].

Study Device

The Freedom (Zimmer Biomet, Warsaw, IN) constrained acetabular device system was introduced in Finland in 2006 and is currently the most commonly used constrained device in the country. It incorporates an equatorial flat section at 15° to the vertical axis along the sides of the constrained liner and a modular chrome-cobalt head which is always 36 mm in diameter (Fig. 1-A). The components are manufactured in such a way that fluid creates a suction effect between the head and liner. This constrained acetabular device provides a 110° range of motion and lever-out strength of 198 inch-lbs [12]. The acetabular liner can be locked into a standard locking mechanism for use in primary and revision acetabular components. A cemented version (Fig. 1-B) is available for cementing into a well-fixed acetabular shell of differing locking design or in cases where the locking mechanism is no longer functioning properly. The cemented version may also be directly cemented to the pelvic bone without any further complementing parts.

Study Population

Between January 2006 and December 2017, 373 primary THAs were performed using either a cemented constrained cup (n = 220) or constrained liner attached to an uncemented cup (n = 153) (Fig. 1). The uncemented cups used with the liner were Vision RingLoc (Zimmer Biomet, Warsaw, IN), Regenerex (Zimmer Biomet, Warsaw, IN), Exceed (Zimmer Biomet, Warsaw, IN), and Trabecular Metal shell (Zimmer Biomet, Warsaw, IN). The head size used with

Table 1
Demographic Data.

Data	Constrained Acetabular Device	Reference
Mean age years and SD	71.0, SD: 12.1	70.5, SD: 12.0
Mean follow-up time in years, minimum-maximum	3.3, 0-12.4	3.8, 0-12.0
Age group		
<49	17 (4.5)	51 (4.5)
50-54	15 (4.0)	45 (4.0)
55-59	28 (7.5)	84 (7.5)
60-64	43 (11.5)	129 (11.5)
65-69	61 (16.3)	183 (16.3)
70-74	48 (12.8)	144 (12.8)
75-79	64 (17.1)	192 (17.1)
80+	98 (26.2)	293 (26.1)
Gender		
Male	163 (43.6)	489 (43.6)
Female	211 (56.4)	632 (56.4)
Diagnosis		
Primary osteoarthritis	78 (20.9)	234 (20.9)
Rheumatoid arthritis	4 (1.1)	12 (1.1)
Other	292 (78.1)	875 (78.1)
Status		
Not revised	352 (94)	1069 (96)
Revised	21 (6)	49 (4)
Operation year	2006-2017	2006-2017

Percentage values are in parentheses (%).
SD, standard deviation.

the constrained device is always 36 mm because of the eccentric head mold. The reference group consisted of conventional THAs with 36-mm femoral head size operated during the same time period from 2006 to 2017. The groups were matched by age group (<49, 50-54, 55-59, 60-64, 65-69, 70-74, 75-79, 80+ years), sex, and diagnosis (primary osteoarthritis, rheumatoid arthritis, other) in a 1:3 ratio, making a total of 1118 THAs in the reference group (Table 1). The most common cup models used in the reference group were Continuum (Zimmer Biomet, Warsaw, IN), Pinnacle (DePuy, Warsaw, IN), Trident (Stryker, Mahwah, NJ), Exeter (Stryker, Mahwah, NJ), and Lubinus (Waldemar Link, Hamburg, Germany).

Statistics

Implant survival for the constrained acetabular device and reference groups was calculated from the corresponding cumulative incidence function adjusted for patient death as a competing event for revision for any reason and revision for any aseptic reason as the endpoints. Death of the patient and revision are competing risks in registry studies. Mortality in the constrained acetabular device group as a whole was 51.7%, and in the control group, 16.3%. Therefore, we used competing risk survivorship analysis instead of Kaplan-Meier survivorship. In a Cox regression model, implant revision hazard ratios (HR) with 95% confidence intervals for any reason for revision were assessed. Implant revision HRs were also assessed separately for revisions performed due to dislocation and for revisions for infection.

Including stem fixation in the Cox model as a confounding factor did not change the results, and as stem fixation data were missing from 60 operations in the constrained acetabular device group (16% of all hips in the constrained device group), we decided to exclude it from the model.

Revisions were linked to the primary operation through a personal identification number. The survival endpoint was defined as revision when either one of the components or the entire implant was removed or exchanged, including isolated liner exchanges. Patients who died during the follow-up period (until December 31, 2017) were censored at that point. Mean follow-up time was 3.3 (0-12.4) years for the constrained acetabular device group and 3.8 (0-12.0) years for the reference group.

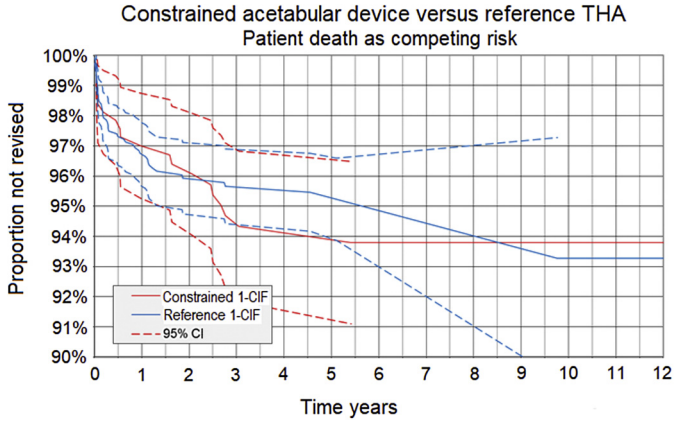

Fig. 2. Implant survival for the constrained acetabular device and the reference groups with revision for any reason as the endpoint, using patient death as competing risk. The 95% CI levels shown around the curves in blue (the reference group) and red (the constrained acetabular device group). CI, confidence interval; THA, total hip arthroplasty; CIF, cumulative incidence function.

The proportional hazards assumption of the Cox models was checked by inspecting the corresponding log-log graphs. For Cox analyses comparing the constrained device group with the reference group, we divided the total follow-up time into three periods (1 to 1.5 years, 1.5 to 3 years, and the 4th year onwards), as the proportional hazards assumption was not fulfilled for the total follow-up.

Inclusion of bilateral cases in a survival analysis violates the basic assumption that all cases are independent. However, several reports have shown that the effect of including bilateral cases in studies of hip and knee implant survival is negligible [13,14]. Therefore, in this study, we included seven patients with a primary constrained acetabular device THA in both hips (14 hips altogether), 43 patients with a conventional THA in both hips (86 hips altogether), and one patient with a constrained device THA in one hip and conventional THA in the other.

The Wald test was used to test the estimated HRs. Differences between the groups were considered statistically significant if the *P* values were <0.05 in a two-tailed test.

Results

Revision for Any Reason

The 8-year survivorship of the constrained acetabular device group was 94% (confidence interval [CI]: 91-96) and that of the reference group was 93% (CI: 89-97) (Fig. 2). Overall, there were 21 revisions in the constrained acetabular device group and 49 in the reference group. Reasons for revisions are presented in Table 2. During the first 1.5 years, the constrained acetabular device group had a similar risk of revision (HR: 0.92 [CI: 0.48-1.75], $P = .8$) to the reference group. From 1.5 to 3 years, the constrained acetabular device group had an increased risk of revision (HR: 6.35 [CI: 1.86-21.7], $P = .003$) over the reference group. From the fourth year onwards, the constrained acetabular device group had a similar risk of revision (HR: 2.02 [CI: 0.33-12.44], $P = .4$) to the reference group (Table 3).

Revisions due to Dislocation

The constrained acetabular device group had a similar risk of revision due to dislocation (HR: 0.27 [CI: 0.03-2.05], $P = .2$)

Table 2
Reason for Revisions.

Reason for Revision	Constrained Acetabular Device	Reference
Aseptic loosening (femur and acetabulum)	0 (0)	2 (4)
Aseptic loosening (acetabulum)	2 (10)	3 (6)
Aseptic loosening (femur)	1 (5)	3 (6)
Infection	10 (48)	11 (22)
Dislocation	1 (5)	12 (24)
Component malposition	1 (5)	2 (4)
Periprosthetic fracture	3 (14)	8 (16)
Other reason	2 (10)	2 (4)
Missing data	1 (5)	6 (12)
Total	21 (100)	49 (100)

compared with the reference group. There was one revision due to dislocation in the constrained acetabular device group, and there were 12 in the reference group.

Revisions due to Any Aseptic Reason (Infections Excluded)

The 8-year survivorship of the constrained acetabular device group was 97% (CI: 95-99) and that of the reference group was 94% (CI: 90-98) with any aseptic revision as the endpoint (Fig. 3).

Revisions due to Infection

There were 10 revisions due to infection in the constrained acetabular device group and 11 in the reference group. The constrained acetabular device group had an increased risk of revision due to infection (HR: 2.99 [CI: 1.27-7.04], $P = .01$) compared with the reference group. However, the mortality was significantly higher in the constrained acetabular device group, which indicates that this study group is more fragile than the control group.

Discussion

We found that the 8-year survivorship of the constrained acetabular device group was equal to that of the reference group revision for any reason as the endpoint. There was only one dislocation revision in the constrained acetabular device group compared with 12 in the matched reference group, although the difference between the groups was not statistically significant. There was no difference in the overall revision risk between the constrained acetabular device group and the reference group during the first 1.5 years, when most of the revisions occurred. To our knowledge, this is the first published prospective, register-based cohort study assessing the use of a constrained acetabular device in primary THA.

Table 3
HR for the Constrained Acetabular Device and Reference Groups With Revision for Any Reason as the Endpoint.

Group	HR	95% CI		*P* Value
All revisions from 0 to 1.5 y				
Constrained acetabular device group (vs reference group)	0.92	0.48	1.75	.8
All revisions from 1.5 to 3 y				
Constrained acetabular device group (vs reference group)	6.35	1.86	21.70	.003
All revisions from fourth year onwards				
Constrained acetabular device group (vs reference group)	2.02	0.33	12.44	.4

Follow-up time has been divided into three parts (0 to 1.5 year, 1.5 to 3 years, and from the fourth year onwards) because the proportional hazards assumption of the Cox model was not fulfilled.
HR, hazards ratio; CI, confidence interval.

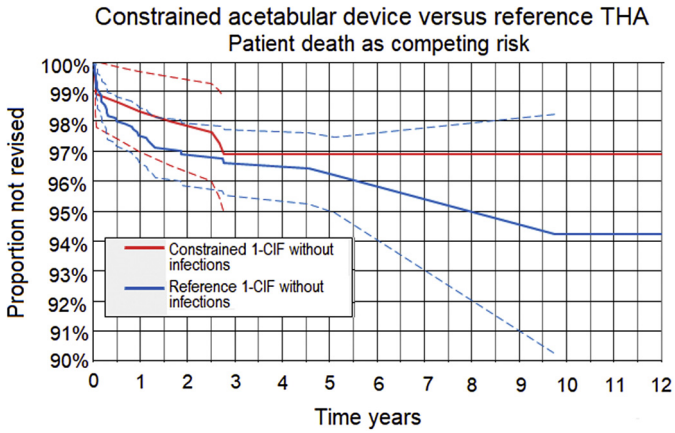

Fig. 3. Implant survival for the constrained acetabular device and the reference groups with revision for any mechanical reason as the endpoint (revisions for infection excluded), using patient death as competing risk. The 95% CI levels are presented around the curves in blue (the reference group) and red (the constrained acetabular device group).

The studied constrained acetabular device was first introduced in Finland in 2006. Since then, this device has shown reasonable results especially in hip revision arthroplasty and is currently used worldwide [15–18]. However, peer-reviewed long-term research reports of the device are still scarce. Recently, in addition to their use in revision arthroplasty, routine primary THA implant of constrained acetabular devices in high-risk patients has also been on the rise, based on only moderate evidence. In a retrospective study of 105 consecutive surgical procedures, with the same constrained acetabular device we studied, from 2007 to 2014 and for a mean follow-up time of 2.5 years, mechanical failure of the device was rare (5.7%) [9]. In that study, none of the 11 primary THAs where a constrained acetabular device was used to prevent dislocation failed. Failure rates when the constrained acetabular device was used in revision for dislocation or revision for another reason were 4.8% and 7.7%, respectively. Berend et al. [19] reviewed the outcomes of 81 consecutive constrained acetabular device components of which nine were primary THAs. A constrained acetabular device was used in 12 hips to address recurrent instability or complications with a previous constrained device. There was only one dislocation during the follow-up time, occurring 6 months after insertion of the constrained acetabular device component in a patient undergoing revision THA. The number of primary THAs has been low in these earlier single-center studies. Nonetheless, the results of our present study based on high-quality national register data are in line with these previous findings that the constrained acetabular device works well in preventing revision operations in high-risk patients undergoing primary THA.

We found no difference in overall revision rate between the constrained acetabular device group and the reference group during the first 1.5 years of follow-up, when most (77%) of the revisions occurred. From 1.5 to 3 years postoperatively, the adjusted revision risk of the constrained acetabular device group was higher than that in the reference group; the difference is probably attributable to the overall low number of revisions during this time—only 11 out of all 70. From the fourth year onwards, the revision risk returned to being similar between the study groups.

There was only one revision for dislocation in the constrained acetabular device group compared with 12 in the matched reference group in the present study. In general, constrained acetabular devices are used for patients with high risk of instability. This indicates that a constrained acetabular device may help to lower the dislocation revision rate compared with conventional primary THA

in patients at high dislocation risk, even though the difference in dislocation risk between the study groups was not statistically significant.

There was no difference in the 8-year survivorship between the two groups after excluding infections as the cause of revision. It has been stated previously that constrained implants may have an increased prevalence of impingement of the femoral neck on the cup, leading to liner damage, locking mechanism failure, dislocation, and loosening [10]. We did not find any evidence to support this assumption. Overall, there were only two revisions for aseptic loosening of the cup in the constrained acetabular device group compared with five in the reference group, and the difference was not statistically significant. Patients in the constrained acetabular device group were frailer than those in the reference group, even after matching, which is indicated by the high mortality rate (51.5% vs 16.3%, respectively). Therefore, one should be cautious in extrapolating our results to younger patients with a longer life expectancy. However, in general, these devices are not routinely used in younger and fitter patients.

Interestingly, the constrained acetabular device group had a statistically significantly increased risk of revision because of infection compared with the reference group (HR: 2.99, $P = .01$). We theorized that this is more likely to be associated with patient selection than with the implant itself, as constrained acetabular devices are used in frailer patients at increased risk of infection. Unfortunately, we were not able to adjust the data for comorbidities, which are a well-known risk factor for deep infection [20]. Furthermore, the current approach of including bilateral hip cases may in theory be biased when studying the rate of revision due to infection as there is potentially higher risk of contralateral THA developing periprosthetic joint infection when a patient has a current THA with confirmed periprosthetic joint infection and potentially septic. However, we think this bias is of theoretical importance only.

We acknowledge that our study has several limitations. As with any register research, we were limited to the data the register provides. There are several factors we did not have access to that might have an effect on instability, such as alcoholism, spinal fusion, abductor deficiency, polio, body mass index, or dementia. As mentioned earlier, patient selection in regard to constrained acetabular devices tends to lean on more fragile patients. By matching the study groups, we were able at least somewhat reduce these confounding factors. Also, we were not able to assess the patients' radiographs. Furthermore, we were only able to use revision as the outcome. Some of the patients might have suffered pain or had other problems with their implant without having a revision, for example, due to poor general health. Moreover, our results are based on a single constrained acetabular device and are not generalizable to other constrained designs. A strength of our study is the independent population-based cohort design with prospective collection of data and large sample size. The FAR has a high degree of completeness and coverage and thereby provides a representative study population.

Conclusion

In summary, we found that the 8-year survivorship for the constrained acetabular device group was equal to that of the conventional THA group with revision for any reason as the endpoint. There was only one dislocation revision in the constrained acetabular device group compared with 12 dislocation revisions in the matched reference group, although the difference was not statistically significant. Our current national register-based results indicate that the constrained acetabular device works well in patients undergoing primary THA with high instability risk.

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