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ORIGINAL STUDY

The partial femoral condyle focal resurfacing (HemiCAP-UniCAP) for treatment of full-thickness cartilage defects, systematic review and meta-analysis

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Knee osteochondral defects are a common problem among people, especially young and active patients. So effective joint preserving surgeries is essential to prevent or even delay the onset of osteoarthritis for these group of patients. This study aims to critically appraise and evaluate the evidence for the results and effectiveness of femoral condyle resurfacing (HemiCAP/ UniCAP) in treatment of patients with focal femoral condyle cartilage defect.

Using the search terms : HemiCAP, UniCAP, Episurf, focal, femoral, condyle, inlay and resur-facing, we reviewed the PubMed and EMBASE and the Cochrane Database of Systematic Reviews (CDSR) to find any articles published up to March 2020.

The short term follow-up of the HemiCAP shows (6.74 %) revision rate. However, 29.13 % loss of follow up let us consider these results with caution especially if the revision rate progressively increased with time to 19.3 % in 5-7 years with no enough evidence for the long term results except the data from the Australian Joint Registry 2018, where the cumulative revision rate was 40.6 % (33.5, 48.4) at ten years. The UniCAP that used for defect more than 4 cm² has a high revision rate (53.66 %) which is considered unacceptable revision rate in com-parison to another similar prosthesis such as Uni-Knee Arthroplasty (UKA).

The evidence from published studies and our meta-analysis suggests that partial resurfacing of the femoral condyle (HemiCAP) doesn't support its usage as a tool to treat the focal cartilage defect in middle-aged patients.

The UniCAP as femoral condyle resurfacing has very high revision rate at 5-7 years (53.66 %) which make us recommend against its usage.

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None of the authors have a conflict of interest.

Keywords : knee focal metallic implant ; HemiCAP ; UniCAP ; Wave prosthesis ; inlay design.

INTRODUCTION

Recently, the number of revision total knee replacement (TKR) is continuously increasing *(1).* there are expectations of increasing the number of the primary TKR in the next two decades *(2),* so, it is critical to delay the onset joint replacement surgeries and preserve healthy articular surfaces and bone stock *(3).* Focal article defect of the femoral condyle of the knee is commonly associated with symptomatic knee *(4,5),* and more common in patients over forty years old *(6,7)*, which if left untreated it will progress to knee osteoarthritis (OA) *(8-10).*

There are many different methods to treat knee articular cartilage defects *(11,12)*, however, the age

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of the patient, site and size of the defect are essential factors before taking the treatment plan *(31)*.

Biological repair methods such as microfractures, autologous chondrocyte implantation (ACI) can be used with good clinical outcome *(13-18)*, but its effectiveness decrease with increase of age to be less effective for patients older than 40 years *(18,19)*.

Total knee replacement in young patients is associated with early failure with wear and loosening due to hyper activities in comparisons to older patients *(20,21)*. So, revision surgeries are more likely before the normally expected life span (15-20 years) of primary knee arthroplasty *(22-26)*.

The partial femoral condyle resurfacing is a surgical option between the biological cartilage reserving surgeries and knee arthroplasty in patients between 40-60 years old with full-thickness cartilage defects *(27)*.

Focal femoral condyle resurfacing (HemiCAP) was introduced in the USA for the first time in 2003, was being used for both femoral condyle and trochlear osteochondral defect or after failed biological cartilage graft for defects less than 4 cm^2 and UniCAP for lesion more than 4 cm^2 *(3,28-32)*.

The current evidence to date for the use of femoral condyle resurfacing is inconsistent with many studies involving small participant numbers or low follow-up rates. To date, there has not been a systematic review and meta-analysis to accurately assess if the use of HemiCAP and UniCAP in patients with femoral osteochondral defects are associated with better outcomes and a reduced need for further surgeries. We, therefore, aimed to carry out a systematic review and meta-analysis of the current literature to assess the effectiveness of femoral condyle resurfacing in the treatment of patients with focal femoral condyle cartilage defects.

MATERIALS AND METHODS

A systematic review and meta-analysis were conducted according to Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines. Our inclusion criteria were any study about the HemiCAP/UniCAP or focal femoral condyle resurfacing prosthesis with

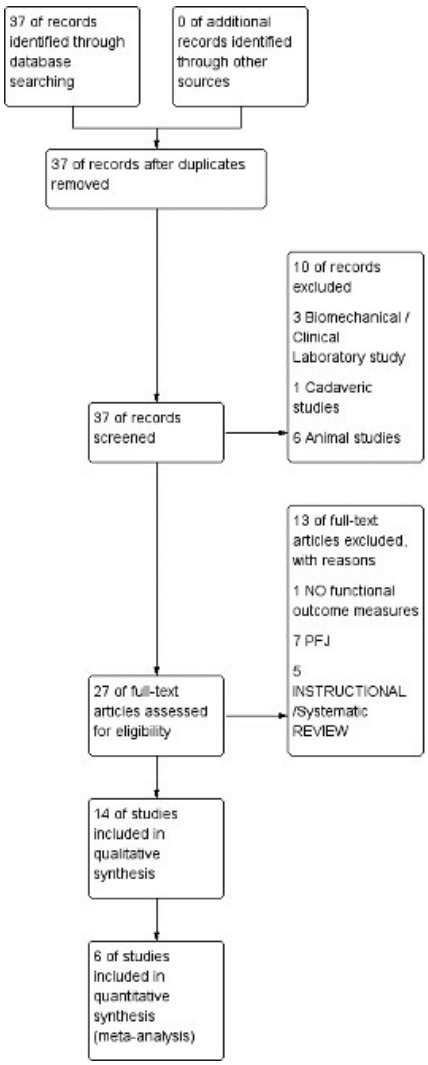

Figure 1. — PRISMA Study flow diagram, PFJ (Patello femoral Joint)

recorded follow-up not less than two years and published until March 2020, the quality of the evidence was classified using the US Preventive Services Task Force system for ranking the level of evidence. Descriptive statistics and methodological quality were calculated for each study.

The first stage we initially assessed only the titles and abstracts of the search result. The second stage involved a careful review of the full-text publications.

We conducted a systematic review and meta-analysis according to Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA)

guidelines (Figure 1), we conducted the search using the MEDLINE/PubMed, EMBASE and the Cochrane Database of Systematic Reviews (CDSR). These databases were searched for the terms HemiCAP/UniCAP knee implant and knee focal metallic implant. Backward chaining of the reference lists from the retrieved papers was also undertaken to maximise the search. The first step was the initial assessment of only the titles and abstracts of the search results. Followed by the second step by careful review of the full-text publications, the difference between reviewers were reviewed by the third reviewer (JH) until an agreement was achieved.

Our inclusion criteria were any clinical trials involving HemiCAP, UniCAP or focal resurfacing implant with mean follow-up at least two years.

We excluded all cadaveric, biomechanical studies and studies about partial resurfacing of the patellofemoral joint (PFJ). Three studies *(27,30,31)* were excluded from the meta-analysis as they used outcome measures (HSS, KSS and SF-12 subdomain scores respectively) didn't commonly been used in other studies. Additionally *(30,33),* used the KOOS score as an outcome measure, but didn't have any pre-operative KOOS data, another study *(34)* used KOOS score but the only quality of life component was reported. Another two studies *(35,36)* have been excluded due to using UniCAP prothesis for defects larger than 4 cm^2, that not used by other studies and one study *(37)* been excluded as his study was on two patients only and the same author published another earlier study *(3).* He didn't mention that those two patients were not included in the previous study. We ranked the level of evidence according to the US Preventive Services Task Force system.

From our included studies we extracted the following : study ID (author, publication year, journal) participants (total number of subjects, mean preoperative age, gender, body mass index (BMI) duration of symptoms. If the study has inclusion/ exclusion criteria or not, (defect site, size , type of prothesis , classification and aetiology), follow-up period, loss of follow up and sources of funding.

The risk of bias (figure 2) for included studies was assessed using the Cochrane risk of bias criteria *(38).*

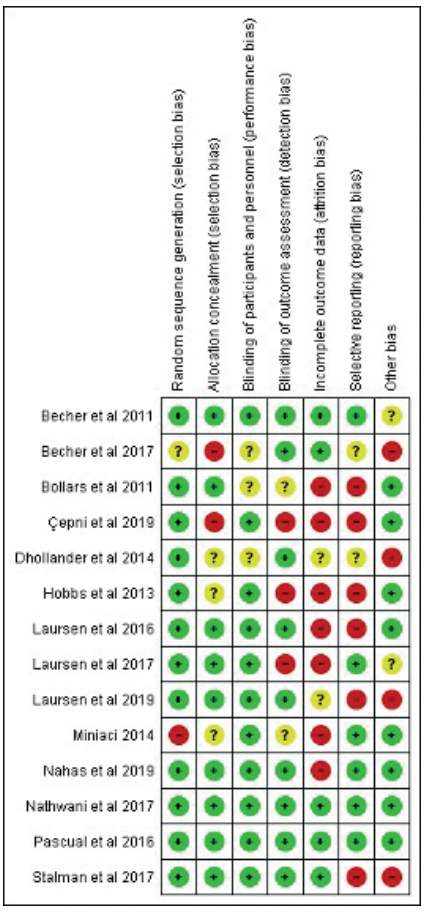

Figure 2. — Risk of bias summary: review authors' judgements about each risk of bias item for each included study(the green colour means low risk of bias the red means high risk of bias and the yellow stands for unclear risk of bias).

Four reviewers (HE, MN, JH and LS) independently cross-checked the risk of bias for included studies, disagreements were resolved through discussion. We extracted the following from included studies : Level of evidence, name of the journal, the total number of subjects, mean follow-up period, demographics, duration of symptoms, results (primary and secondary outcome measures, effect size, statistical significance, adverse effects), prior cartilage procedures, concomitant operation/s, defect (classification, aetiology, size, site), and funding.

Based on pre and post-operative changes, we computed mean differences (MD) with 95% CI discontinuous outcomes, using standard meta-analysis software (RevMan 5.3) *(38)*.

We used standardised mean differences (SMD) instead of MD to compute effect measures and we used the random-effects model for meta-analyses *(39)*. Evaluation of the risk of bias in included studies was done by (HE) and reviewed again by the other co-authors, One reviewer (HE) entered data into RevMan 5 software for statistical pooling, while the other three reviewers (JH, LS and MN) independently cross-checked data entry.

We planned to do subgroup analyses by evaluating the five components of the KOOS score (pain, symptoms, activities of daily living (ADL), quality of life(Qol) and sport & recreational activities).

We checked the heterogeneity using the I^2 statistic ; values of 25% and less indicated low statistical heterogeneity. The results were presented in a Forrest plot of comparison between the preoperative and postoperative scores.

Our electronic searches returned 37abstracts we excluded three Biomechanical / Clinical Laboratory study *(40-42)*, and one cadaveric study *(20)*, six animal studies *(43-48)*, five instructional/systematic reviews *(49-53)*, seven partial resurfacing of the PFJ *(29,54-59)*, and one study that has no functional outcome measures *(60)*. Furthermore, eight studies *(27,30,31,33-37)* were included in the systematic review but were excluded from the meta-analysis because they didn't use the KOOS score as an outcome measure. The details of the included studies are demonstrated in Tables 1,2 and 3.

RESULTS

Fourteen studies on 464 patients(no bilateral cases) , 116 males, 193 females, four studies(155 patients) didn't mention the gender *(3,33,61,62)*, the mean age was 47.9 years ; the mean BMI was 27.8 (two studies didn't mention the BMI *(32,63)*, one study indicated that all BMI was more than 30(64), another claimed that was less than 35 *(65)*, one mentioned the weight by the kilogram, the mean was 63 kg *(30)*.

All studies were level IV evidence except one(27), which was level III.

We did a meta-analysis of KOOS score (figure 3) for six prospective cohort studies *(3,32,61-63,65)*. We compared between the preoperative

Table 1. — Demographics of the patients included in the literature review

Study	Level of evidence	Journal	Total No. of subjects	Follow-up years (range) months	Gender (male/ female)	Mean preoperative age, (range years)	BMI (range)	Duration of symptoms, months (range)	Numbers of follow up loss (0ercentage)
Becher et al.2011	IV	AOTS	21	5.3(60–71)	N/A	53.7 (38-63)	26.8 (22.9-33.9)	14.9 (2-60)	0(0%)
Becher et al.2017	IV	AOTS	2	11.7 (139-140)	1/1	54 (52-56)	28 (27-29)	N/A	0(0%)
Bollars et al.2011	IV	KSSTA	19	2.8 (20–57)	1/18	49 (43–78)	63 Kg (53-82)	N/A	1(5.3%)
Dhollander et al. 2014	IV	KSSTA	14	2.2 (13.3-38.9)	6/8	45.7 (52.6-38.8)	N/A	53.1 (61.6-44.6)	5(36%)
Laursen et al. 2016	IV	KSSTA	36	2 (clinical) 7(complications /reoperations)	17/19	51(35-65)	29(24.8-33.2)	N/A	12(33%)
Laursen 2017	IV	KSSTA	64	2 (clinical) 7(complications /reoperations)	28/36	51 (35-65)	29 (24.2-33.8)	N/A	30(46.9%)
Laursen et al. 2019	IV	KSSTA	59	7.2 (58.8-109.2)	N/A	51(47–57)	28.3 (20–38)	N/A	36(61.01%)
Miniaci 2014	IV	CSMJ	35	1.56 (12–27)	N/A	48.3 (23–80)	> 30	N/A	0(0%)
Nahas et al. 2019	IV	KSJ	14	9.75 (59–135)	13/1	40.3 (28–49)	N/A	N/A	10(71.4)
Nathwani et al. 2017	IV	JBJS	33	2	N/A	42.7 (54.3-31.1)	26.7 ± 3.8	N/A	21(63.6)
Pascual et al. 2016	III	JARS	32	2	21/11	47.9 (37-68)	26.7 (19.0-33.5)	N/A	0(0%)
Stalman et al. 2017	IV	KSSTA	10	2	7/3	40.2 (36–56)	< 35	N/A	0(0%)
Çepni et al 2019	IV	AOTS	118	2	22/96	56.31 (50-62)	27.56 ± 2.67	N/A	21(17.8%)
Hobbs et al 2013	IV	SAOJ	7	4.7 (24–72)	N/A	N/A	N/A	N/A	2(28.6%)

Table 2. — Patient-specific and defect-specific data of the patients included in the literature review

Study	Prior Cartilage Procedures index, knee, mean (range)	Concomitant operation/s	Defect classification	Defect aetiology	Defect size , mm^2 (range), prothesis used,	Defect site,	Follow-up years (range) months	Number of revisions/total numbers (revision rate)
Becher et al.2011	1.05 (0–2)	N/A	Isolated full thickness chondral or osteochondral defect	N/A	Diameter less than or equal to 20 mm2, HemiCAP	MFC	5.3(60–71)	2 /21(9.5 %)
Becher et al.2017	N/A	N/A	N/A	N/A	N/A, HemiCAP	N/A	11.7 (139-140)	0/2 (0%)
Bollars et al.2012	NO	3/19 (15.7%) HTO		63% early arthritis 5 % AVN 32% post traumatic	37% 20mm^2 63% 15mm^2, HemiCAP	17/19(89.4 %) MFC 2/19 (10.6%) LFC	2.8 (20–57)	0/19 (0%)
Dhollander et al. 2014	2 ACI 5 microfractures 2 mosaicplasties 4 debridement 1 acellular scaffold	1/14 ACL reconstruction	(ICRS III–IV)	focal degenerative lesions	50% 15mm^2 50% 20mm^2, HemiCAP	MFC	2.2 (13.3-38.9)	0/14(0%)
Laursen et al. 2016	N/A	N/A	(ICRS III–IV)	N/A	< 4 cm^2, HemiCAP	N/A	2 (clinical) 7(complications /reoperations)	9/36 (25%)
Laursen et al. 2017	N/A	N/A	(ICRS III–IV)	N/A	> 4 cm^2,UniCAP	N/A	2 (clinical) 7(complications /reoperations)	30/64 (47 %)
Laursen et al. 2019	N/A	N/A	(ICRS III–IV)	N/A	> 4 cm^2,UniCAP	N/A	7.2 (58.8-109.2)	36/59 (61%)
Miniaci 2014	27 meniscectomies 14 microfractures, 4 ACLreconstruction 3 mosaicplasties, 2 osteotomies 2 refixations of OCD	18 partial menisectomies 3 ACL reconstructions 1 HTO 8 Medial and trochlear resurfacing	(ICRS III–IV)	N/A	N/A, HemiCAP	MFC	1.56 (12–27)	0/35 (0%)
Nahas at al. 2019	N/A	1 ACI	N/A	N/A	N/A, HemiCAP	11/14(78.6%) MFC 3/14 (11.4%) LFC	9.75 (59-135)	2/14 (14.3%)
Nathwani et al. 2017	25 (75.8%) Cartilage repair (microfracture, ACI, MACI, and OATS) 19 (57.6%)	meniscal, ligamentous, PFJ surgery, or car-tilage shaving surgery15 (45.5%)	N/A	Nontraumatic, gradual 13 (39.4%) Traumatic, non-contact 8 (24.2%) Traumatic, contact 6 (18.2%)	2.7 ± 0.6, HemiCAP	75.8% MFC 24.2% LFC	2	0/33 (0%)
Pascual et al. 2016	Microfracture 10 Debridement 36 Osteochondral allograft 1 ACI 1 Abrasion arthroplasty 7	N/A	N/A	N/A	N/A, HemiCAP	N/A	2	8/32 (25%)
Stalman et al. 2017	microfracture 7 ACL recon 3 medial meniscus injuries with small flap tears that were resected 3	N/A	(ICRS III-IV)	N/A	≤ 3.2 cm2 (diameter ≤ 2 cm), HemiCAP	MFC	2	0/10 (0%)
Çepni et al 2019	21	N/A	(ICRS III-IV)	N/A	3.64 ± 0.47, HemiCAP	MFC	2	13/118 (11.01%)
Hobbs et al 2013	N/A	N/A	(ICRS III-IV)	N/A	< 4 cm^2, HemiCAP	MFC	4.7 (24–72)	2/7 (28.57 %)

Table 3. — Studies outcome scores

Study	Outcome score
Becher et al.2011	KOOS, SF-36,Tagner activity level
Becher et al.2017	KOOS, Tagner activity level
Bollars et al.2012	KOOS, HSS, IKDC evaluation
Dhollander et al. 2014	KOOS
Laursen et al. 2016	KSS
Laursen et al. 2017	KSS
Laursen et al. 2019	KSS
Miniaci 2014	KOOS, VAS pain, SF-36, Tagner activity level
Nahas at al. 2019	KOOS,
Nathwani et al. 2017	KOOS, VAS pain, Tagner activity level
Pascual et al. 2016	WOMAC,SF-12
Stalman et al. 2017	KOOS, VAS pain,EQ5D
Çepni et al 2019	KOOS, VAS pain, Tagner activity level
Hobbs et al 2013	KOOS, IKDC evaluation

and post-operative KOOS score at two years. The preoperative number of patients was 127 ; the post-operative was 90 (70.87 %) with 29.13 % loss of follow up. The Standard Mean Difference for pain was 5.61 (3.11-8.11), symptoms 4.96 (2.63-7.28), -ADL 5.08(2.76-7.40), Sport&Rec 4.35 (1.61-7.09) and QOL 5 (2.51-7.49). Test for overall effect : Z = 9,62 (P<0.0001), test for subgroup differences Chi^2=0.45, df=4 (P=0.98), $I^2$0% (low heterogeneity).

A total number of 464 patients recruited from fourteen studies were included in the systematic review. There was a significant improvement in all outcomes scores (P< 0.001) in two years follow up for eight studies (n= 268) ; however, the revision rate was 6.74 %. In medium-term follow up (5-7 years)

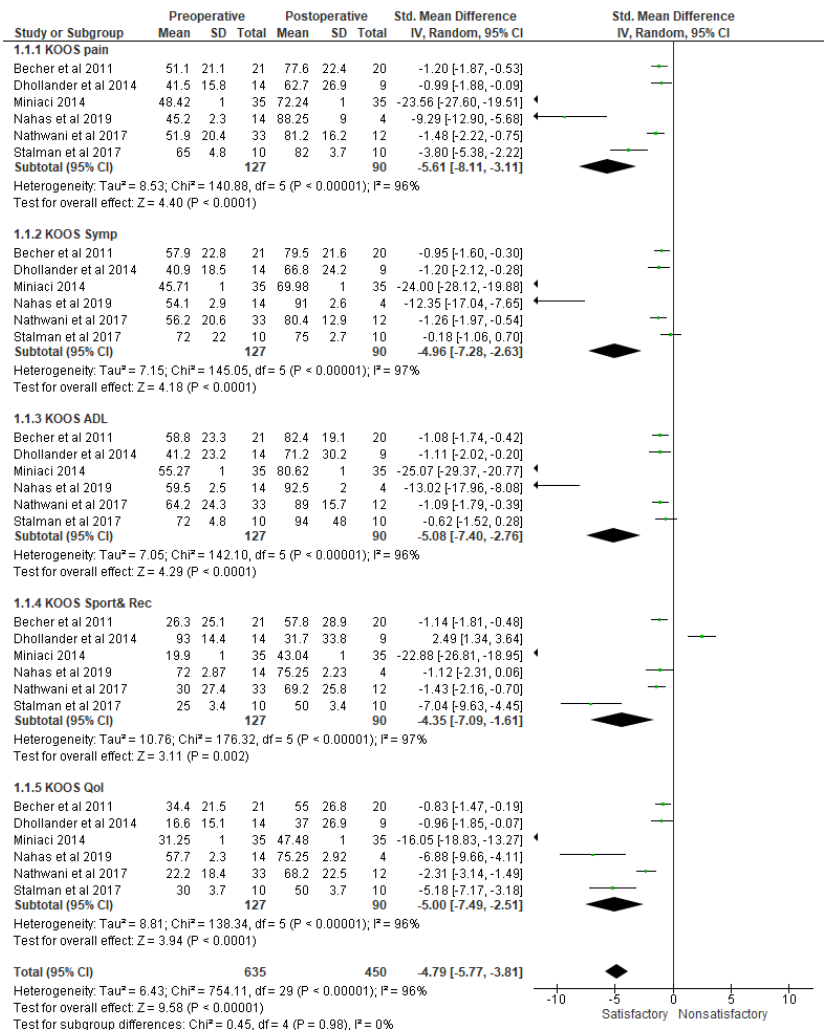

Figure 3. — Forest plot of KOOS score.

in two studies (n=47) the revision rate was 19.3 %, no enough data to evaluate the long term follow up as only two studies (n=16) which have long term follow up period (10-12 years) the revision rate was 12.5%.

The five years revision rate for UniCAP (which is used for large chondral size more than 4 cm^2) is 53.66 % .

DISCUSSION

In comparison between the preoperative and post-operative KOOS score in the meta-analysis, there was an improvement in all components of the score. However, the KOOS mean change values in patients with knee OA varies with intervention and increased with length of follow-up *(66)*, so, that degree of improvement in our meta-analysis doesn't reflect the success of the HemiCAP. Additionally, (29.13 %) loss of follow up let us consider these results with caution.

For short term follow up (2 years) the revision rate is (6.74 %) among 341 patients got HemiCAP. *(27,30,32-34,61,62,65)*, in comparison with other evidence with a larger volume of patients such as The Australian Joint Registry 2018 that reported 16.6 % (12.2- 22.3) revision rate at two years which is almost 2.5 times the revision rate in our review which raise the concern of publication bias of the included studies that have low level of evidence.

For medium-term follow (5-7 years), the revision rate was 19.3 % *(3,36)*, which is also less than the revision rate of the Australian Joint Registry 2018 which was 27.7 % (22.0, 34.6) at five years and both values is considered high if we compare it to the revision rate of the UKA which is 8.3 (7.2, 9.6). *(67)* that makes the UKA is better option with stronger evidence to support its usage.

No enough date for long term results of the HemiCAP. However , the limited number of studies in literatures showed revision rate (12.5%,) at 9.4 years *(37,63)* but the proportion of loss of follow up was 62.5 % which doesn't give this figures any weight. In the Australian Joint Registry 2018 *(67)*, the cumulative revision rate was 40.6 % (33.5, 48.4) at ten years which is considered high.

For larger defect more than or equal to 4cm^2, the UniCAP was used however the revision rate for UniCAP is 53.66 % *(35,36)* which is consider unacceptable revision rate in comparison to another similar prosthesis such as UKA while its revision rate in five and ten years is 8.0 % (7.8, 8.3) and 14.6 % (14.3, 15.0) respectively *(67)*, even the revision rate in seventeen years for the UKA is 25.7% (24.5, 26.9) *(67)*, which is less than half of the revision rate for UniCAP after 5-7 years only.

We couldn't find any data about the UniCAP for the femoral condyle in any National joint registry which means that it is not popular among orthopaedic surgeons, the result of these two studies, (35,36) with reported high revision rate justifies the unpopularity of this kind of prosthesis.

Acknowledgements

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Contributions of authors

HE was involved with data extraction, data analysis and interpretation, and drafting of the review, JH, MN and LS took responsibility for the integrity of the work as a whole, from inception to finished article.

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