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Assessment of clinical, functional and radiological outcomes in young patients with grade 3 and 4 osteoarthritis of the knee joint undergoing knee joint distraction with and without arthroscopic debridement and chondroplasty-a prospective, comparative and randomized controlled study

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ABSTRACT

Background: Treatment of severe osteoarthritis (OA) in relatively young patients is challenging. Although successful, Total knee arthroplasty (TKA) has a limited lifespan, with the risk of revision surgery, especially in active young patients. Our study aims to assess the comparative clinical, functional and radiological outcomes of knee joint distraction (KJD) with and without arthroscopic debridement and chondroplasty in OA of knee in the young, in a randomized controlled trial.

Methods: Our study was a prospective randomized trial with equal allocation. A total of 160 patients needing intervention for knee arthritis, in the age group of <55 years were included as per the inclusion criteria, and were randomized into 2 groups. Group A included 80 patients who underwent KJD alone. Group B included 80 patients who underwent KJD with arthroscopic debridement and chondroplasty. All patients were followed up to 24 months post intervention. Clinical (Visual analogue scale-VAS), functional (Western Ontario and McMaster universities OA index-WOMAC) and radiological (Joint space width-JSW) outcomes were then compared and assessed.

Results: Both the groups showed statistically significant improvement of clinical, functional and radiological outcome scores compared to baseline levels. The mean improvement in KJD+SCOPY group was statistically superior to that of KJD group with regard to clinical and functional outcome scores; however, the radiological improvement though being statistically significant in both groups compared to baseline levels, but one group was not superior to that of other.

Conclusions: KJD in patients with OA of knee (Kellegren Lawrence grade 3-4) aged <55 years results in improvement of clinical, functional and radiological parameters at 2 year follow up. Addition of arthroscopic debridement and chondroplasty to KJD makes it superior to KJD alone in terms of improvement in clinical, functional and radiological outcomes. We recommend arthroscopic debridement and chondroplasty coupled with KJD for compliant patients of less than 55 years with grade 3-4 OA of the knee.

Keywords: TKA, KJD, Arthroscopic debridement and chondroplasty, VAS, WOMAC, JSW, Kellegren Lawrence

INTRODUCTION

Degenerative osteoarthritis of the knee joint is a challenging problem in orthopaedics, where optimum solutions are not worked out. Though TKA is considered the gold standard treatment for osteoarthritis in the elderly, it is not so in the young. Joint arthroplasty is not without drawbacks, with up to 20% of patients dissatisfied with their TKA and up to 44% reporting continuing pain, a third of whom reported extreme persistent pain in one study.¹

Patients younger than 55 years have an almost fivefold increase in the lifetime risk of revision surgery compared with those aged 65 years or older.² One of the main reasons for this is aseptic loosening, a characteristic of implant wear, which is responsible for more than 30% of revisions. Since wear increases with both time and activity, a young patient with relatively higher functional demands can experience significantly more wear than their older and more sedentary counterparts. In addition, with 40% of TKAs performed in patients aged less than 65 years, a burden of revision arthroplasty may well be generated.³ This calls for joint preservation surgeries in the young patients, which is an emerging area of interest in orthopaedic surgery. High tibial osteotomy is applicable only for isolated medial compartment osteoarthritis and the long term evidence of its effectiveness is still not known.⁴ Arthroscopic joint debridement was one of the most popular options, but is becoming less supported by modern evidence as an isolated treatment modality.^{5,6}

KJD has been proposed as a temporizing technique for symptomatic and arthritic knees in younger patients and comprises a six- to eight-week period of distraction of the knee by means of an external fixator. A prospective, uncontrolled study of 20 patients aged below 60 years at five-year follow-up reported clinical improvement and evidence of cartilage repair. If these results were to be generally applicable, the possibility arises of delaying the requirement of TKA in young patients.7-9 A recent randomized trial concluded that KJD gives results comparable to TKA in end stage osteoarthritis of the knee in the young.¹⁰ All available review articles and metaanalyses conclude that KJD may represent a potential treatment for knee arthritis, though further trials with long term follow-up are required to establish its efficacy compared with contemporary treatments.^{11,12} Furthermore, none of the trials studied the advantage of adjuvant arthroscopic debridement and chondroplasty of the knee joint with KJD. Hence, we undertook this prospective study to evaluate the role of KJD in knee osteoarthritis, and further if the effectiveness is increased by addition of arthroscopic knee joint debridement and chondroplasty to KJD.

Aim and objectives

The current prospective and randomized controlled study aimed at assessing the comparative clinical, functional and radiological outcomes of KJD with and without arthroscopic debridement and chondroplasty in osteoarthritis of the knee in the young patients.

METHODS

The current prospective and randomized controlled study was conducted in the department of orthopaedics at Sri Sathya Sai institute of higher medical sciences, Prasanthi Gram, Andhra Pradesh from July 2017 to June 2022, wherein after the approval from the institutional ethical committee; all the patients younger than 55 years of age with Kellegren and Lawrence grade 3 and 4 osteoathritis of the knee joint coming to the outpatient department (OPD), after fulfilling the inclusion criteria were included in the study.

Inclusion criteria

Patients younger than 55 years of age with Kellegren and Lawrence grade 3 and 4 primary osteoathritis of the knee joint, with intact knee ligaments by clinical tests and having at least 120 degrees of knee flexion were included in the study.

Exclusion criteria

Patients with post traumatic, post infective or inflammatory arthritis of the knee joint; complete absence of joint space on radiographs; any history of past interventions on the knee joint in the form of any surgery or intra articular injections; coronal plane deformity (varus / valgus) or fixed flexion deformity (FFD) more than 10 degrees; any evidence of knee instability; or primary patello-femoral arthritis were excluded from the study.

A total of 160 patients fulfilling the inclusion criteria were included in the study, after taking the written informed consent; and were then randomly divided into 2 groups: Group A (80 patients) (KJD group) with those undergoing only KJD; and group B (80 patients) (SCOPY + KJD group) with those undergoing KJD along with arthroscopic joint debridement and chondroplasty. Randomization was done by the random number table.

The KJD was done with the help of an Ilizarov fixator applied under spinal anesthesia, wherein the joint was distracted up to 2 mm intra operatively and then 1mm/day for 3 days post operatively, thus achieving a total of 5 mm distraction; which was then confirmed on the radiographs (comparing the pre operative and day 3 post operative radiographs). In group B, arthroscopic joint debridement and chondroplasty using micro fracture technique was done initially, followed with an Ilizarov fixator application and distraction as described.

All the patients were allowed to bear partial weight from day 1, followed with full weight bearing as tolerated; and the fixator removal was done after 6 weeks. All the patients were then followed up at regular intervals till 2 years post surgery. The clinical, functional and radiological outcomes were assessed pre operatively, at the time of fixator removal (6 weeks), 6th, 12th, 18th and 24th month post surgery. The clinical, functional and radiological outcomes assessments were done with the help of VAS score, WOMAC score, and radiographic JSW respectively at different time frames as described. Final comparison was done between the pre operative and 24th month findings.

Statistical analysis

The data collected was entered into Microsoft excel spreadsheet and analyzed using IBM SPSS statistics, version 22 (Armonk, NY: IBM Corp). The nominal data (such as gender, side of involvement, occupation, Kellgren Lawrence grade, flexion deformity, and varus deformity) was expressed as a number and percentage. The continuous data (such as age, body mass index, range of motion, VAS scores, WOMAC scores, and JSW) was expressed as mean, standard deviation, and range. Comparisons of the categorical variables between the study groups were performed using the chi square test and Fishers exact test if needed. Comparison of the continuous data between the two groups was performed using Independent Sample t test. Comparison of the continuous data before and after intervention in each study group was performed using paired t test. A p<0.05 was considered as statistically significant.

RESULTS

All 160 patients were in age group of <55 years as mentioned in inclusion criteria above. The mean age of the patients in Group A was 49.35 ± 5.23 years, whereas in group B was 47.90 ± 4.38 years. There was no significant difference in age between the two study groups. The mean BMI was 24.77 ± 2.72 kg/m² in the KJD group whereas in the SCOPY + KJD group the mean BMI was 24.62 ± 2.41 kg/m². There was no significant difference in BMI between the two study groups (Table 1).

There were 88 men and 72 women included in the study. When the gender wise distribution was compared there was slight male preponderance in KJD+SCOPY group, but equal distribution in KJD group, without any statistical significant variation in between these groups. All 160 patients were classified according to occupation which included: 52 home makers, 24 manual laborers, 32 skilled laborers, 36 professionals and 16 belonged to other occupation. There was no significant difference between these groups. All the patients included in the study had unilateral knee involvement. In KJD group 68 patients were having Kellgren and Lawrence grade 3 and 12 patients were having Kellgren and Lawrence grade 4 arthritis; whereas in KJD+SCOPY group 72 patients were having Kellgren and Lawrence grade 3 and 8 patients were having Kellgren and Lawrence grade 4 arthritis.

There is no statistically significant difference in the distribution between the study groups (Table 1).

In KJD group 8 patient were having 5 degrees and 12 patients were having 10 degrees FFD, whereas in KJD+SCOPY group 8 patients had 5 degrees and 8 patients had 10 degrees of FFD rest all patients in both groups were not having FFD. There was no significant difference between these groups, 8 patients in each of groups had 5 degree varus deformity. There was no statistically significant difference between study groups (Table 2).

In KJD group the mean improvement in the flexion was 7 ± 8.01 degrees whereas in SCOPY+KJD group the mean improvement in the flexion was 6 ± 6.81 degrees. The improvement in flexion was statistically and clinically significant on intra group comparison (paired t test); however, the improvement was not statistically significant on inter group comparison (unpaired t test) (Table 3).

In KJD+SCOPY group the mean of VAS score in pre op was 61.00 ± 8.52 and post op was 29.10 ± 7.45 which was statistically significant (paired t test); whereas in KJD group the mean of VAS score in pre op was 58.50 ± 8.13 and post op was 31.50 ± 8.13 which was also statistically significant (paired t test). When KJD group and SCOPY + KJD group were compared, in SCOPY+KJD mean VAS score improvement was 31.9 ± 6.39 whereas in KJD mean VAS score improvement was 27.0 ± 8.64 ; improvement was both clinically and statistically significant (unpaired t test). KJD and SCOPY+KJD both are effective in improving VAS scores, when improvement is compared to baseline levels. But SCOPY+KJD is superior to KJD alone with regard to pain (VAS) (Table 4).

In KJD group the mean of WOMAC score in pre op was 57.05±14.69 and post op was 30.79±14.38 which was statistically significant (paired t test); whereas in KJD+SCOPY group the mean of WOMAC score in pre op was 59.18 ± 8.02 and post op was 29.18 ± 10.39 which was also statistically significant (paired t test). When KJD group and SCOPY + KJD group were compared, in KJD group the mean WOMAC score improvement was 26.26±1.81 whereas in SCOPY+KJD group the mean WOMAC score improvement was 30±4.33; improvement was both functionally and statistically significant (unpaired t test). KJD and SCOPY+KJD both are effective in improving the WOMAC scores, when the improvement is compared to baseline levels. But SCOPY+KJD is superior to the KJD alone with regard to the improvement in functional outcomes (WOMAC) (Table 5).

In KJD group mean of JSW in pre op was 1.58 ± 0.55 and post op was 2.97 ± 0.55 which was statistically significant (paired t test); whereas in KJD+SCOPY group the mean of JSW score in pre op was 1.63 ± 0.53 and post op 3.03 ± 0.61 which was also statistically significant (paired t test). When KJD and SCOPY+KJD group were compared, in KJD group JSW mean improvement was 1.39 ± 0.41 whereas in SCOPY+KJD group JSW mean improvement was 1.40 ± 0.26 ; this difference was not statistically significant (unpaired t test). However, improvement was radiologically significant. KJD and SCOPY+KJD both are equally effective in improving JSW, when improvement is compared to baseline levels (Table 6).

Out of 80 patients who underwent arthroscopy, all the 80 were having grade 4 cartilage defect, for all these patients in addition to joint debridement, a Steadman procedure (micro fracture) was done arthroscopically. 64 patients were having meniscal tear for which partial meniscectomy and meniscoplasty was done arthroscopically, 16 were

having loose bodies which were removed arthroscopically and 8 were found to have synovitis for which partial synovectomy was done arthroscopically.

Ten patients in KJD group and 8 patients in KJD + SCOPY group had pin tract infections which were treated effectively with oral antibiotics and regular dressings. None of the patients had signs of osteomyelitis. Also, none of the patients had treatment failure in the form of conversion to TKA, till our last follow up.

Table 1: Depicts the demographic variation of the study population.

Variables		KJD group, (n=80) (%)	SCOPY + KJD group, (n=80) (%)	P value
Age (In years)		49.35±5.23	47.90±4.38 years	>0.05*
BMI (Kg/m ²)		24.77±2.72	24.62±2.41 kg/m ²	>0.05*
Condon	Male	40 (50)	48 (60)	> 0 0 5 #
Gender	Female	40 (50)	32 (40)	>0.05#
	Homemaker	28 (35)	24 (30)	
Occupation	Manual laborer	20 (25)	4 (5)	
	Skilled laborer	4 (5)	28 (35)	>0.05#
	Professional	20 (25)	16 (20)	
	Others	8 (10)	8 (10)	
Kellgren and	Grade 3	68 (85)	72 (90)	>0.05#
Lawrence grades	Grade 4	12 (15)	(10)	>0.03"

P*: independent/unpaired t test, P#: chi square test

Table 2: Depicts the distribution of the study population depending on the pre operative deformity.

Deformity		KJD group, (n=80) (%)	SCOPY + KJD group, (n=80) (%)	P value (chi square test)
Fixed flexion deformity (FFD)	0	60 (75)	64 (80)	>0.05
	5	8 (10)	8 (10)	
	10	12 (15)	8 (10)	
Varus deformity	0	72 (90)	72 (90)	>0.05
	5	8 (10)	8 (10)	

Table 3: Depicts the comparison of flexion ROM between the study patients.

Flexion ROM	KJD group, (n=80)	SCOPY + KJD group, (n=80)	P value*
Pre operatively	115±17.01	119.5±15.04	>0.05
At 24 th month follow up	122±12.40	125.5±10.2	>0.05
P value [#]	< 0.05	<0.05	
Improvement	7±8.01	6±6.81	>0.05

P[#]: paired t test, p^{*}: unpaired/independent t test.

Table 4: Depicts the comparison of the VAS scores between the 2 study groups (intra group[#] and inter group* comparison).

VAS score	KJD group, (n=80)	SCOPY + KJD group, (n=80)	P value*
Pre operatively	58.50±8.13	61.00±8.52	>0.05
At 24 th month follow up	31.50±8.13	29.10±7.45	>0.05
P value [#]	< 0.05	<0.05	
Improvement	27.0±8.64	31.9±6.39	< 0.05

P#: paired t test, p*: unpaired/independent t test

Table 5: Depicts the comparison of the WOMAC scores between the 2 study groups (intra group# and inter group* comparison).

WOMAC	KJD group, (n=80)	SCOPY + KJD group, (n=80)	P value [*]
Pre operatively	57.05±14.69	59.18±8.02	>0.05
At 24 th month follow up	30.79±14.38	29.18±10.39	>0.05
P value [#]	<0.05	<0.05	
Improvement	26.26±1.81	30±4.33	< 0.05

P[#]: paired t test, p^{*}: unpaired/independent t test

Table 6: Depicts the comparison of the JSW between the 2 study groups (intra group# and inter group# comparison).

JSW	KJD group, (n=80)	SCOPY + KJD group, (n=80)	P value [*]
Pre operatively	1.58±0.55	1.63±0.53	>0.05
At 24 th month follow up	2.97±0.55	3.03±0.61	>0.05
P value [#]	<0.05	<0.05	
Improvement	1.39±0.41	1.40±0.26	>0.05

P[#]: paired t test, p^{*}: unpaired/independent t test.



Figure 1 (A-C): Pre operative, immediate post operative and clinical photo of the patient undergoing KJD+SCOPY.



Figure 2 (A and B): 24 weeks and 24 months and post operative x rays of the same patient.

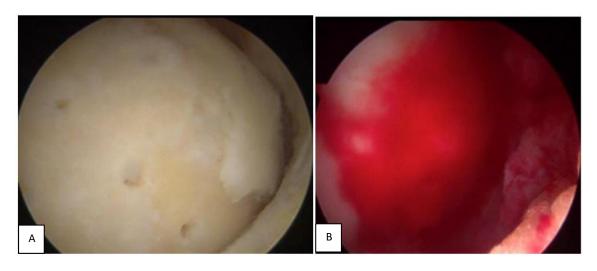


Figure 3 (A and B): Cartilage defect after micro fracture and clot formation after micro fracture and in the same patient undergoing KJD with arthroscopic debridement and chondroplasty.

DISCUSSIONS

Despite recent medical advancement in diagnosing degenerative joint condition, to date there is no effective therapy that can reverse or halt the progression of OA. It was documented in many studies that joint distraction could reduce the level of secondary inflammation, cartilage degeneration and subchondral bone aberrant change, unloading the knee joint that allows the cartilage repair or slowing down OA progression, delaying the TKA in relatively younger patients and preventing revision TKA. However, none of the trials studied the advantage of adjuvant arthroscopic debridement and chondroplasty of the knee joint with KJD. The main objective of this study is to evaluate whether KJD is comparable with the KJD with arthroscopic debridement and chondroplasty.

In our study, we evaluated 160 patients viz. 80 in both groups with a mean age being 49.35 ± 5.23 years in KJD group and 47.90 ± 4.38 years in KJD+SCOPY group. In study conducted by Wiegant et al the mean age was 49 ± 1 years; while in the study conducted by Van der Woude et al the mean age was 48.5 ± 1.3 in years 8 weeks group, and 54.6 ± 1.7 18 17 years in 6 weeks group. In study conducted by Dong et al and Jansen et al the mean of the study group was <55 years.^{8,13,14} All these patients were young and high demanding patients as in the case of our study groups.¹⁵

In our study there were 88 male and 72 female patients. In study conducted by Wiegant et al there were 11 male and 9 female patients; while the study by Van der Woude et al included 11 male and 9 female patients in the 8 weeks group, and 10 male and 10 female patients in 6 weeks group respectively.^{8,13} In study conducted by Dong et al included 7 male and 8 female patients; while study by Jansen et al included 11 male and 9 female patients.^{14,15} Thus, our study had more sample size as compared to the previous studies, though the gender wise distribution of the study patients was similar to the previously published studies.

In our study when KJD group and SCOPY + KJD groups were compared, in the SCOPY+KJD mean VAS score improvement was 31.9 points (52.3%) whereas in the KJD the mean VAS score improvement was 27.0 points (46.15%); the improvement was both clinically and statistically significant. These findings are in accordance with the study conducted by Van der Wounde et al with 1 year follow up, where he found the improvement in the mean VAS score by 38.33% in the 6 weeks group and 58.10% in 8 weeks group.¹³ The improvement was both clinically and statistically significant as in our study. Similarly, the study by Wiegant et al with 2 years follow up, it was found that the mean improvement in the VAS score was 61% at the last follow up.⁸ In study by Dong et al with 15 months follow up, it was found that the mean improvement in the VAS scores was 55.3 points; while the study by Jansen et al with 9 years follow up, the mean improvement of the VAS scores was found to be 46.8 points.^{14,15} The higher improvement in the mean VAS scores seen in these studies may be due to the small sample size in these studies. In all the studies the improvement in the mean VAS scores was both clinically and statistically significant as in our study.

In our study when KJD group and SCOPY + KJD groups were compared, in the SCOPY+KJD mean WOMAC score improvement was 30 points (50.7%) whereas in the KJD the mean WOMAC score improvement was 26.26 points (46%); the improvement was both functionally and statistically significant. These findings are in accordance with the study conducted by Van der Wounde et al with 1 year follow up, where he found the improvement in the mean WOMAC score by 46.33% in the 6 weeks group and 72.89% in 8 weeks group.13 The improvement was both functionally and statistically significant as in our study. Similarly, the study by Wiegant et al with 2 years follow up, it was found that the mean improvement in the WOMAC score was 74% at the last follow up.⁸ In study by Dong et al with 15 months follow up, it was found that the mean improvement in the WOMAC scores was 21.1

points; while the study by Jansen et al with 9 years follow up, the mean improvement of the WOMAC scores was found to be 29.9 points.^{14,15} In all the studies the improvement in the mean WOMAC scores was both functionally and statistically significant as in our study.

In our study when KJD group and SCOPY + KJD groups were compared, in the SCOPY+KJD mean JSW improvement was 1.40mm whereas in the KJD the mean JSW improvement was 1.39 mm; the improvement was both radiologically and statistically significant. These findings are in accordance with the study conducted by Van der Wounde et al with 1 year follow up, where he found the improvement in the mean JSW by 0.9±0.2 mm in the 6 weeks group and 1.1±0.2 mm in 8 weeks group.¹³ The improvement was both radiologically and statistically significant as in our study. Similarly, the study by Wiegant et al with 2 years follow up, it was found that the mean improvement in the JSW was 1.7 mm at the last follow up.8 In study by Dong et al with 15 months follow up and Jansen et al with 9 years follow up, it was found that the mean improvement in the JSW was 1.3 mm.^{14,15} In all the studies the improvement in the mean JSW as compared to the baseline was both radiologically and statistically significant as in our study. However, we found that there was no statistical significance between the two groups as far as the improvement is concerned. Similarly Van der Wounde et al and Jansen et al and in their studies also concluded the improvements to be significant when compared to the baseline; but insignificant when compared within the two comparing groups.¹³

In study conducted by Gaonkar et al, which included cohort of 53 patients; it was concluded that arthroscopic debridement does not influence the ongoing pathological process and is only useful for symptomatic relief in cases of low grade osteoarthritis.¹⁶ In 2016, Flouzat-Lachaniette et al reported a randomized controlled study in 45 patients to assess the clinical, functional and radiological outcomes of joint distraction in knee osteoarthritis.¹¹ It was concluded that joint distraction results in substantial clinical, functional and radiological improvements in patients with knee osteoarthritis, as in our concluded in our study.

Takahashi et al (United Kingdom) published a metaanalysis to determine whether KJD is beneficial for knee osteoarthritis in 62 knees, with age more than 18 years.¹⁷ Outcomes were assessed at baseline and 1 year and 5 years and was concluded that the functional outcomes and structural assessments of joint remain improved compared with baseline. Law et al (Singapore) reported retrospective, single-surgeon study of 180 consecutive knee arthroscopies performed between 2009 and 2013 in 169 patients, aged 40 years and above.¹⁸ They concluded that arthroscopic knee debridement can provide good symptomatic relief and sustained benefits in significantly symptomatic patients with early degenerative knees who have failed conservative management. Goh et al (UK) reported a systematic review in 507 patients aiming to assess the short and long-term outcomes following KJD and compare this with currently available treatment modalities.¹⁹ They concluded that joint distraction confers short-term clinical and structural benefit in patients with knee osteoarthritis, with the clinical benefits persisting till 9 years.

Our study had little strength. Firstly, it was a prospectively randomized study with age of patients selected less than 55 years where biological options are relevant. Secondly, standard technique for arthroscopic debridement and chondroplasty was used by single fellowship trained experienced surgeon, similarly standard technique for Ilizarov assisted KJD was used by single experienced, fellowship-trained surgeon in a planned way, with no protocol violations. Lastly, systematic follow-up of all patients was done till 2 years with zero dropout rate.

Our study had few limitations. Firstly, because of external fixator and 6 weeks of abstinence from their routine lifestyle many of the patients were not ready for the procedure which would have led to selection bias. We could have documented who accepted the procedure and who did not which would have given us more insights into acceptability and applicability of this procedure. Secondly, the patients themselves did the pin site dressings after a comprehensive counselling and training session. Out of the patients who developed pin site infection, we found out that some of them were not compliant with pin site care protocol. Thirdly, the sample size of 160 patients, in spite of being statistically significant puts restriction in concluding and generalizing the outcome for a wider population. Fourthly, our study was open label design. Blinding would have definitely strengthened the conclusions. But that would involve doing a sham arthroscopy in the KJD group, which we thought was not ethical. Fifthly, short duration of follow-up is an obvious demerit in a procedure like this that has long-term implications. Lastly, though our patients in both groups showed statistically significant improvement in all parameters, the average values of improvement were lesser than reported in previous studies. Data on more patients with longer follow-up is definitely needed to make conclusions about the relevance of this procedure in the management of osteoarthritis of the knee.

CONCLUSION

KJD in patients with osteoarthritis of knee (Kellegren Lawrence grade 3-4) aged less than 55 years results in improvement of clinical, functional and radiological parameters at 2 year follow up. Addition of arthroscopic debridement & chondroplasty to KJD makes it superior to KJD alone in terms of improvement in clinical, functional and radiological outcomes. Pin site infections are the most common complications of KJD. Our data, even in the light of data available in existing literature is insufficient to make generalized conclusions about the long-term implications and applicability of this relatively new philosophy of management of knee joint osteoarthritis in the young; we recommend arthroscopic debridement and chondroplasty coupled with KJD for compliant patients of less than 55 years with Kellegren Lawrence grade 3-4 osteoarthritis of the knee. We would also recommend correlating the improvement in clinical and functional parameters with the improvement in MRI based cartilage mapping to understand how this procedure works. Basic science studies must be undertaken to understand the mechanism of arthro-distraction in improvement of osteoarthritis.

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