

Topical Phytotherapy: Management of Deranged Anatomical and Abnormal Biochemical Risk Factors during Failed Total Knee Arthroplasty: A Unique Case Study

Abstract

Total knee arthroplasty (TKA) is the ultimate answer to treat knee osteoarthritis (KOA) worldwide. The main purpose of TKA is to relieve pain and to improve the day to day functional activities. But during failed TKA, various abnormal anatomical features and other biochemical risk factors develop in the serum of the patients along with pain and disability of performing daily activities persist.

The present case study was aimed to normalize the deranged anatomical features and elevated levels of biochemical parameters, to relief pain syndromes and to improve daily physical functional abilities without revision of failed TKA correlated with radiological images with the help of topical phytotherapeutic treatment protocol.

Five Indian patients were advice to undergo revision of TKA. They refused to do the further surgery and treated in OPTM Health Care (P) Ltd for 13 weeks. Anatomical measurements included the gap at the knee between the short head of the biceps femoris and the level of the bed, diameter of muscles at the thigh, the calf and, straight leg raising and knee flexions and extensions in different postural positions for both the legs, and biochemical parameters such as serum C-reactive protein (CRP), creatine kinase-muscle (CK-MM) and aldolase A (Aldo A) were measured pre- and post-treatment of 13 weeks using appropriate instruments.

The results indicate the percentage of improvements for all abnormal anatomical and biochemical features were highly statistically significant ($p < 0.0001$), pain under VAS ($p < 0.0001$), pain, stiffness and physical functions under WOMAC Index all are highly significant ($p < 0.0001$) and parameters under KOOS ($p < 0.0001$) and BMI ($p < 0.0001$) with improved radiological images after 13-week of post-treatment. In conclusion, the deranged anatomical and elevated levels of biochemical risk factors, impaired acute pain syndromes, and day to day functional activities including quality of life with abnormal increased body weight developed during failed total knee arthroplasty can be normalized with the help of topical phytotherapeutic treatment protocol within 13 weeks.

Keywords: Total knee arthroplasty; Anatomical; Biochemical and imaging markers; Topical phytotherapy; Biochemical risk factors management

Abbreviations

KOA: Knee Osteoarthritis; KGB: Gap at the Knee between the Short Head of the Biceps Femoris Muscle in the Lateral Part of The Knee-Joint and at the Level of the Bed in the Supine Position; DTM: Diameter of the Group of Thigh Muscles; DCM: Diameter of the Group of Calf Muscles; SLR: Straight Leg Rasing; KFS: Knee Flexion in the Supine Position; KFP: Knee Flexion in the Prone Position; KFSt: Knee Flexion in the Standing Position; KES: Knee Extension in the Supine Position; KEP: Knee Extension in the Prone Position; KESt: Knee Extension in the Standing Position; OA: Osteoarthritis; SD: Standard Deviation; AP: Anterior-Posterior; BMI: Body Mass Index; CI: Confidence Interval; MD: Mean Difference



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Introduction

Total knee arthroplasty (TKA) is a common treatment method to relief pain and proper knee movement in knee osteoarthritis (KOA) worldwide [1,2]. However, it has been observed that revision of TKA requires in most patients due to infection, obesity, physical activity, loosening, osteolysis etc. [3-6]. The author had already established earlier that abnormal muscle morphology and musculo-postural-features of the legs and abnormal biochemical features and imaging markers are suitable diagnostic protocol for the detection of early progression and risk of KOA [7-10].

Moreover, during failed TKA, various abnormal anatomical features were further increased such as obesity, muscular wasting, unable to rise the legs while lying on bed or walking, unable to fold the knee joints and such other complications. Besides these, other biochemical risk factors develop in the serum of patients such as elevated levels of C-reactive protein (CRP) due to inflammation, creatine kinase-muscle (CK-MM) due to muscle degeneration and aldolase A (Aldo A) due to bone erosion and skeletal muscle damage along with pain and severe disability of performing daily activities also persist.

The present case study was aimed to normalize the deranged anatomical features such as bilateral gap of knees between the point of short head of the biceps femoris at the lateral knee joint and the surface of the bed while supine (KGB), bilateral diameters of the thigh muscles (DTM) and calf muscles (DCM), bilateral straight leg raising (SLR), bilateral angles of flexion in supine, prone and standing positions (KFS, KFP and KFSt respectively) and bilateral angles of extension in supine, prone and standing positions (KES, KEP and KESt respectively), which become asymmetrical between the legs due to damage of various connective muscles and tissues during KOA and normalize the elevated levels of biochemical parameters such as C-reactive protein (CRP) levels increase due to inflammation, creatine kinase-muscle (CK-MM) levels elevated due to muscular dystrophy, connective tissue damage, etc. and Aldolase A (Aldo A) levels increase due to skeletal muscle damages and bone erosion,

to relief pain syndromes and to improve daily physical functional abilities without revision of failed TKA correlated with radiological images such as the Kellgren-Lawrence (KL) grading systems with the help of topical phytotherapeutic treatment protocol for 13 weeks.

Case Study

Five patients (4 females and a male) aged between 55-73 years old were suffering with severe pain, inflammation and stiffness on both the knee joints, massive muscular wasting in the thigh and calf regions, unable to raise their legs while supine, prone and standing positions, impaired function, and limitations of daily activities after TKA had undergone 2.5 to 4 years back. Two of them were walking with the help of cane and walker and rest three of them were in wheel chairs. They were advised to further revision of unilateral TKA. But they were refused to undergo further surgery and came to OPTM Health Care (P) Ltd, India, for treatment during the period January 2016 to August 2016. The study protocol was evaluated and approved by the OPTM Research Institute Ethics Committee. An institutional review board-approved consent form for physical examinations, blood sample collections and bilateral knee-joint images (X-rays) required for the study was signed by all five patients. Baseline demographic characteristics of four patients were shown in the previous study by Ganguly A and that of the 5th patient is shown in Table 1 [11]. The

physical examinations were made at the baseline and at the end of 13 weeks of post-treatment including anatomical measurements such as KGB, DTM, DCM, SLR, KFS, KFP, KFSt, KES, KEP and KEST respectively and shown in Table 2.

A meter scale was used to measure KGB, DTM and DCM measurements were performed using a meter tape and a goniometer was used for straight leg raising, flexion and extension measurements in accordance with the American Academy of Orthopedic Surgeons (AAOS) [12]. The methods of anatomical measurements had already elaborated in the earlier studies [7-10].

Evaluation of risk factors such as inflammation, muscle degeneration, bone erosion, and skeletal muscle diseases were recorded through the estimation of biomarkers, CRP, CK-MM, and Aldo A levels at the pre-treatment stage and at the end of post-treatment of 13-week using appropriate kits [13-16].

The author had already elaborated in details the treatment protocol based on the aims, principles and theories, accessories and mode of stimuli used in the therapy, effects of chemical, mechanical, thermal and electrical stimuli used in the treatment protocol, the specific programmed postural positions for the regimentation of neuromuscular strength required in the therapy and period of treatment for 13 weeks in the house with necessary documentation in the previous studies [7-11,19].

The graphical representations of percentage of improvements on pain, stiffness, physical function and quality of life under VAS, WOMAC Index and KOOS, reduction of body weight as assessed by BMI for five patients are depicted in Figures 1-4. The percentage of improvements at the end of topical phytotherapy treatment of 13 weeks of anatomical features for five patients such as KGB, DTM and DCM is exhibited in Figure 5A, SLR, KFS, KFP, KFSt, KES, KEP and KEST is depicted in Figure 5B. The mean, SD, mean differences (MDs) and 95% confidence intervals of biochemical markers such as CRP, CK-MM and Aldolase A at the pre-treatment stage and at the end of post-treatment and their improvements were shown in Table 3. The overall improvements of pain under visual analogue scale (VAS), pain, stiffness and physical function under WOMAC index and pain, other symptoms, activities of daily living, function on sports and recreation activities and quality of life under KOOS, reduction of body weight as assessed by body mass index (BMI), were also evaluated for five patients at pre-treatment and at the end of post-treatment of 13 weeks of phytotherapy (Figures 1-4). All the five patients were not being treated by oral medications; injections; massage with any type of herbal gels; and any type of alternative treatments such as homeopathic, ayurvedic, herbal or such others for diminishing pain or inflammation, for muscle relaxation, or to improve the skeletal muscles one day prior to post-treatment of 13 weeks. The Kellgren-Lawrance grading system of radiographic KOA of five patients at the pre-treatment stage and at the end of post-treatment were evaluated for bone erosion, reduction of the gap between the femoral and tibial compartments, varus deformities for both operated and non-operated knee joints (Table 4). The radiological images of four of them were shown in the previous study and that of the 5th patient was evaluated at pre- and post-treatment in the present study (Figure 7) [11].

Table 1: Demographic data and baseline characteristics of the 5th patient.

Parameters	Patient-5
Age (years)	68
Gender	Male
Period of suffering (years)	15
Under gone TKR (right or left knee)	Right knee
TKR done at the age	64
Weight (kg)	86.84
Height (m)	1.63
BMI (kg/m ²)	32.2
Indian ethnic group	Punjabi
Dietary habit	Non-vegetarian
Work status	Self employed
Marital status	Married
Classification of KOA (K-L system)	
Right knee	Prolapsed prostheses
Left knee	≥Grade 4
Pain under VAS (mm)	
Right leg	55
Left leg	96
Lower back	60
Under WOMAC index (%)	
Pain	18.72
Stiffness	7.22
Physical function	68.63
Multiple complaints	
Constipation	Present
Acidity & reflux	Present
Insomnia	Present
Varicose vein	Not present
urinary incontinence	Present
Crepitus during knee flexion	Present
Morning stiffness (<30 min)	Present

Table 2: Statistical analysis of anatomical features at the end of post-treatment for five patients who had undergone TKA.

Anatomical Parameter	PRE-TREATMENT		POST-TREATMENT		Improvement after post-treatment for 13-week							
	OPKJ	NOKJ	OPKJ	NOKJ	Operated knee joint (OPKJ)				Non-operated knee joint (NOKJ)			
					p-value	MD	95% CI		p-value	MD	95% CI	
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)			Lower	Upper			Lower	Upper
KGB (cm)	11.16 (2.07)	10.90 (0.69)	3.93 (0.27)	3.96 (0.30)	<0.0001	7.22	5.07	9.37	<0.0001	6.94	6.16	7.72
DTM (cm)	46.60 (3.49)	48.02 (3.30)	48.50 (3.29)	48.54 (3.25)	0.8081	-1.9	-6.85	3.05	0.3293	-0.52	-5.3	4.26
DCM (cm)	35.8 (3.12)	37.12 (3.14)	37.76 (2.84)	38.18 (3.21)	0.3293	-1.96	-6.31	2.39	0.6119	-1.06	-5.69	3.5
SLR (degree)	34.48 (8.70)	41.06 (6.46)	69.52 (2.65)	69.62 (2.78)	<0.0001	-21.76	-27.54	-15.98	<0.0001	-28.56	-35.81	-21.31
KFS (degree)	83.62 (4.84)	88.80 (4.71)	136.16 (1.45)	136.38 (1.33)	<0.0001	-52.54	-57.75	-47.33	<0.0001	-47.58	-52.63	-42.53
KFP (degree)	84.56 (95.37)	89.12 (5.22)	134.00 (1.62)	134.18 (1.51)	<0.0001	-49.44	-55.23	-43.65	<0.0001	-45.06	-50.66	-39.46
KFSt (degree)	81.38 (3.86)	84.86 (5.09)	133.36 (2.00)	133.82 (5.09)	<0.0001	-51.98	-56.46	-47.5	<0.0001	-48.96	-54.49	-43.42
KES (degree)	22.78 (1.95)	21.02 (2.60)	11.30 (0.48)	11.30 (0.47)	<0.0001	11.48	9.41	11.55	<0.0001	9.72	6.99	12.44
KEP (degree)	22.88 (1.34)	21.26 (1.71)	11.30 (0.46)	11.16 (90.42)	<0.0001	11.58	10.12	13.04	<0.0001	10.1	8.28	11.91
KESt (degree)	21.62 (2.63)	20.42 (2.70)	11.02 (0.33)	11.00 (0.28)	<0.0001	1.6	7.87	13.33	<0.0001	9.42	6.62	12.22

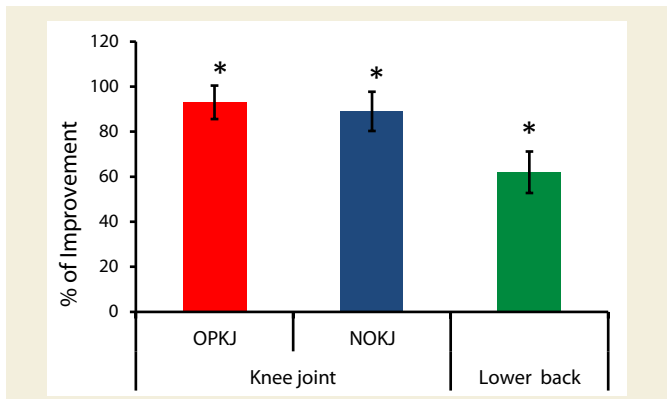


Figure 1: Graphical representations of percentage of improvement of pain under VAS at the end of post-treatment for 13-week for five patients who had undergone total knee arthroplasty (*p<0.0001).

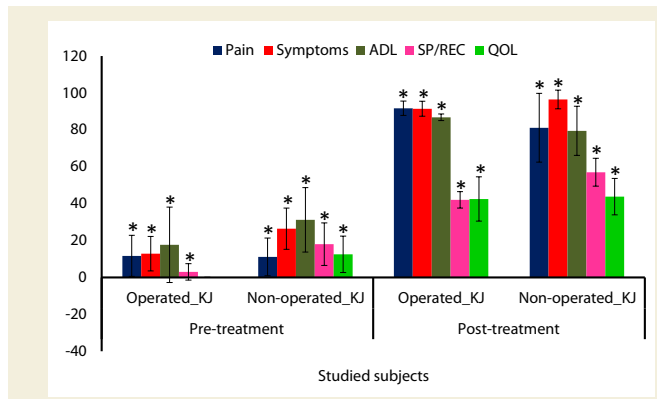


Figure 3: Graphical representation of subscales of KOOS of pre-treatment stage and post-treatment of 13-week for five patients who had undergone total knee arthroplasty (*P<0.0001).

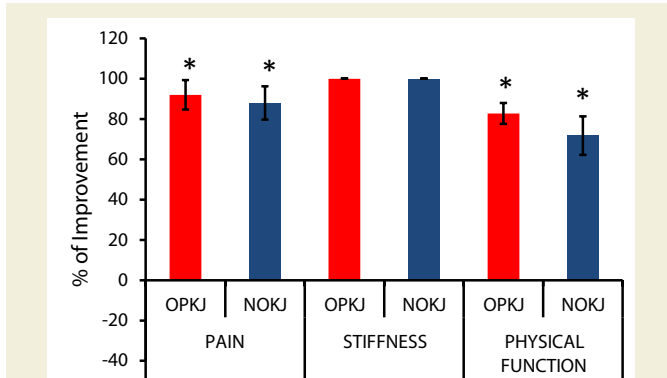


Figure 2: Graphical representations of percentage of improvement of Pain, stiffness and physical function under WOMAC Index at the end post-treatment for 13-week for five patients who had undergone total knee arthroplasty (*P<0.0001).

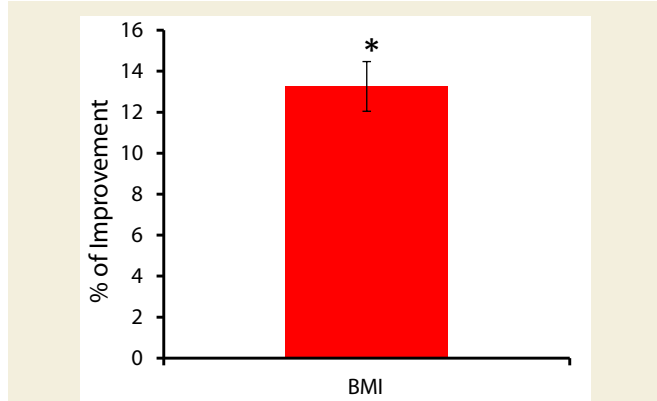


Figure 4: Graphical representation of percentage of improvement of body weight as assessed by BMI for five patients at post-treatment for 13-week with phytotherapy (*P<0.05).

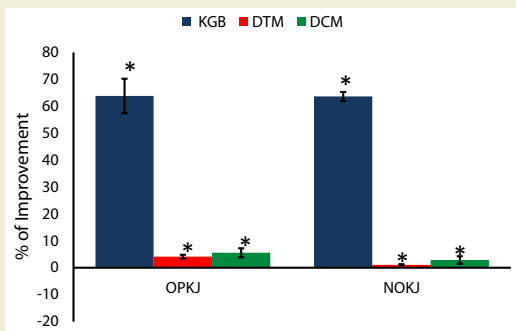


Figure 5A: Graphical representations of percentage of improvement of anatomical features such as KGB, DTM and DCM at the end of post-treatment for 13-week for five patients who had undergone total knee arthroplasty (*p <0.0001).

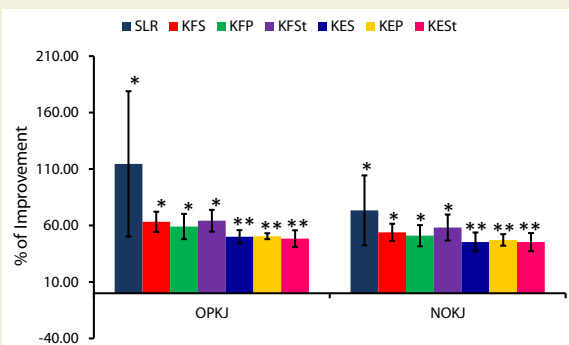


Figure 5B: Graphical representations of percentage of improvement of anatomical features such as SLR, KFS, KFP, KFSt, KES, KEP and KESSt after post-treatment for 13-week for five patients who had undergone total knee arthroplasty. (*P<0.05 and **P<0.0001).

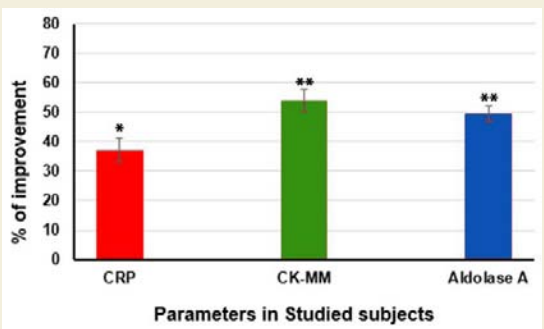


Figure 6: Percentage of improvement of biochemical parameters (CRP, CK-MM and Aldo A) of five patients who had undergone TKA (*P<0.01; **P<0.0001).

Table 3: Statistical analysis of biochemical parameters of five patients who had undergone TKA.

Parameter	Baseline	End of 13-week	Biochemical improvements at end of 13-week					
			CRP		CK-MM		Aldolase A	
			Mean (SEM)	Mean (SEM)	p-value	MD 1 (95% CI)	p-value	MD (95% CI)
CRP (mg/L)	7.48 (0.291)	4.84 (0.393)	0.0006	2.64 (1.51, 3.77)				
CK-MM (U/L)	191.88 (5.917)	88.85 (2.871)			<0.0001	103.03 (87.86, 118.19)		
Aldo A (U/L)	10.20 (0.622)	5.11 (0.385)					<0.0001	5.09 (3.40, 6.77)

Discussion

Several researchers had already reported the medical effects (specially on pain, inflammation and stiffness of muscles) on human body of the phytochemicals contained in *Cissus quadrangularis*, *Rosemarinus officinalis*, *Calotropis gigantea*, *Zingiber officinalis*, *Boswellia serrata*, *Curcuma longa*, *Withania somnifera* and *Sesamum indicum* and their mechanism of actions [11,17,18].

It has attempted earlier that the topical application of phytoconstituents from the extracts of seven Indian medicinal plants namely *Cissus quadrangularis* (whole plant), *Calotropis gigantea* (root and leaves), *Zingiber officinalis* (rhizome), *Rosemarinus officinalis* (leaves and flowers), *Boswellia serrata* (resin), *Curcuma longa* (rhizome) and *Withania somnifera* (root) mixed with virgin sesame oil (extracted from seeds at room temperature) and beehives wax to make viscous phyto-based oil without using any preservatives or chemicals in order to preserve the phytochemical properties of plants intact is extremely useful for the treatment of osteoarthritis [11,17,18]. According to Ganguly A, this is a novel technique and observed first time with the help of aqueous phytoextraction as remedial measures [7]. An established research work when phytochemicals applied topically, phytoconstituents help in normalization of anatomical derangement in knee-joints supported by radiological images but no one has not been reported before that biochemical markers such as CRP, CK-MM and Aldo A can be in a normal range after the topical application of phytoconstituents from medicinal plants along with normalization of anatomical derangement, pain, stiffness and functional activities in knee-joints after TKA supported by radiographic changes as assessed by K-L grading scale [7-11,19].

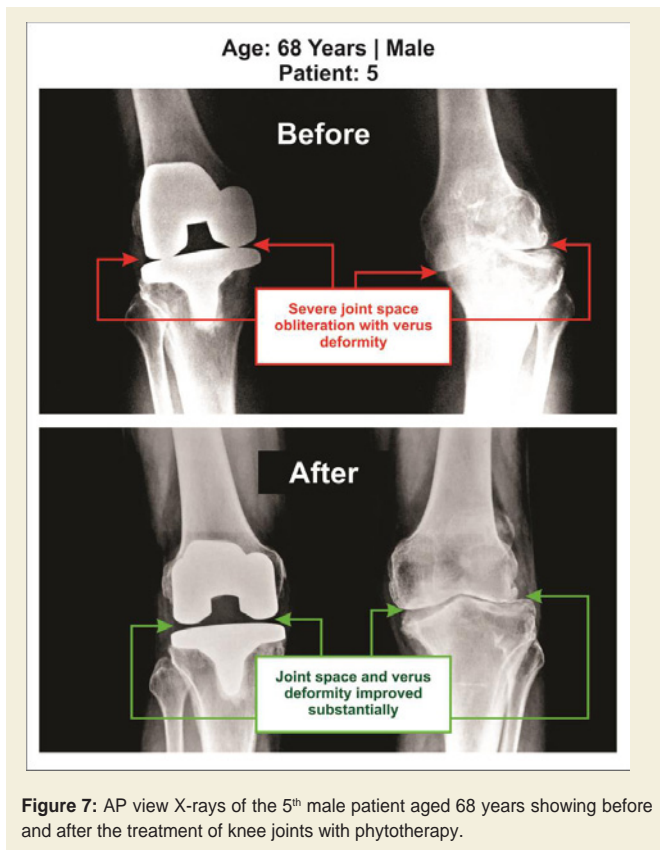
It is interesting to note that the measurements of bilateral KGB, KES, KEP and KESSt were widely and asymmetrically increased, and the bilateral DTM, DCM, SLR, KFS, KFP and KFSt were widely and asymmetrically decreased at the baseline because of cumulative effects of muscle wasting, and diminished strength of various connective muscles and tissues during KOA and they were almost symmetrical after the treatment of 13-week (Table 2) [7-10].

The present case study was aimed to normalize the deranged anatomical features and elevated levels of biochemical markers along with improvement of pain, optimization of joint and limb functions and improvement of quality of life with highly statistically significant (p<00001) in all the cases correlated with radiological images as assessed by K-L grading scale are absolutely possible with the help of specialized topical application of phytochemicals within 13 weeks in case of failed TKA (Tables 2-4) (Figures 1-7). Moreover, in the recent studies, the author had already shown no need of revision of TKR and normalization of elevated levels of biomarkers such as CRP, CK-MM and Aldo A developed during osteoarthritic changes in patients with the help of topical phytotherapy treatment [11,19].

Table 4: Analysis of improvements of operative and non-operative knee joints at the end of 13 weeks post-treatment under the Kellgren-Lawrance grading scale.

Patient	PRE-TREATMENT		POST-TREATMENT	
	OPKJ	NOKJ	OPKJ	NOKJ
#1	Severe joint space narrowing almost like Grade 4	Grade 3	Doubtful joint space narrowing almost like Grade 1	Grade 2
#2	Severe joint space narrowing, bone erosion almost like Grade 4	Grade 3	Doubtful joint space narrowing almost like Grade 1	Grade 2
#3	Severe joint space narrowing with verus defomity almost like Grade 4	Grade 3	Doubtful joint space narrowing almost like Grade 1	Grade 1
#4	Stucking the pin at the edge of the femoral compartment	Grade 3	Divider pin shifted to the centre with gap	Grade 1
#5	Severe joint space obliteration with verus deformity almost like Grade 4	Grade 4	Doubtful joint space narrowing almost like Grade1	Grade 3

Grade 0: No Radiographic Features of OA Present; Grade 1: Doubtful Joint Space Narrowing (JSN) with Possible Osteophyte Lipping; Grate 2: Possible JSN with Definite Osteophyte Formation; Grade 3: Definite JSN, Moderate Osteophyte Formation, Some Sclerosis and Possible Deformity of Bony Ends; Grade 4: Large Osteophyte Formation, Severe JSN with Marked Sclerosis and Definite Deformity of Bony Ends



Conclusion

The main purpose of TKA is to reduce the pain, increase the functional ability through the improvement of knee flexion [1,2]. This phytotherapeutic treatment may have synergistic effect of the phytochemicals used in the therapy. But, TKA is failed due to infection, obesity, physical activity, loosening, osteolysis, etc.

From the results and discursion, it is firmly concluded that deranged anatomical features and elevated levels of biochemical risk factors, impaired acute pain syndromes, and day to day functional activities including quality of life with abnormal increased body weight as assessed by VAS, WOMAC Index and KOOS and BMI and

imaging markers developed during failed total knee arthroplasty can be normalized with the help of topical phytotherapeutic treatment protocol within 13 weeks (Tables 2-4) (Figures 1-7) [11,19].

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