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Normalization of Varus/Valgus Deformities in Osteoarthritis by External Application of Phytoconstituents: Confirmed With Anatomical Observations and Biochemical Profiles and Radiological Images

Apurba Ganguly*

Founder and Head Researcher, OPTM Research Institute, 145 Rashbehari Avenue, Kolkata – 700029, India

Abstract

In India, a large number of patients are suffering with genu varum deformities during osteoarthritic (OA) changes in their knee joints. The malaligned knees are either varus (bow-legged) or valgus (knock-kneed) alignment. When the distal part is more medial, it is called varus deformity (≤178°) while the distal part is more lateral, it is called valgus deformity (≥182°). In OA changes of knee-joints, relieving of pain only was achieved temporarily by using medicinal plants based on traditional knowledge. However, correction of malalignment of genu varum by phytotherapeutic protocols has not been attempted as yet.

The study was conducted on 196 patients (male: 65 and female: 131) aged ≥ 50 years old for genu varum deformities, normalized by the topical application of phytotherapeutic treatment protocol. To detect the normalization, anatomical measurements and biochemical parameters along with radiological images are being studied before (0 sitting) and after 42 sittings of the treatment. The present results clearly reveal that normalization of genu varum deformities are achieved by topical application of phytoconstituents (aqueous extracts) from acknowledged Indian medicinal plants (*Cissus quadrangularis, Heliotropium indicum, Rosmarinus officinalis, Calotropis gigantea*) with specialized treatment paradigm, within forty-two sittings.

It is a pioneering study for complete recovery of malalignment of genu varum by phytotherapy, which can be an alternative novel method for normalization of genu varum. The present research is corroborated by before and after anatomical observations, biochemical parameters and radiological images.

Keywords: Genu varum; Varus/Valgus deformity; Osteoarthritis; Knee symmetry; Phytotherapy; Indian medicinal plants

Introduction

In the human anatomical morphology, both the knees are delicate and complex joints, which are connected between femur and tibia with a supportive bone known as fibula connected with thick tibia. There is another cap like bone called patella, which ultimately joins the knee in both the legs. Both anterior and posterior cruciate ligaments cross on each other connected with the knee bones, which restrict the knee from sliding forward or backward on the tibia. There are also found medial and lateral collateral ligaments that support the knee from buckling sideways. Tendons are connected with the knee bones to the leg muscles that move the knee joint easily for both the legs. The two 'C' shaped, lateral and medial menisci are pads of fibro-cartilages that further cushion the joint. Besides these, many bursae or fluid-filled sacs are also found within knee joints, which support both the knee movement normally without any pain [1].

When these anatomical features show abnormalities in any of its structure then it leads to several diseases such as knee osteoarthritis, chondromalacia patella, knee effusion, rheumatoid arthritis etc. It is well established that osteoarthritis (OA) is a painful disease by several researchers and can easily be identified by anatomical measurements, biochemical profiles and radiological images [2-11]. These diseases are caused by many factors such as ageing, obesity, major injuries, jobs with heavy labour and continuous knee bend posture etc. [2,12]. The knee malalignment has been reported as major risk of knee osteoarthritis (OA) development in adult and malalignment is mainly dependent on valgus or varus alignment [13-16].

According to Sharma [15], it is very important to understand the biological mechanisms, in which difference between the impact of varus alignment and that of valgus alignment has not surprised to researchers [16] because these two alignments directly are interrelated with knee joints. It has been documented by several researchers that during gait in the neutrally aligned knee, load is disproportionately transmitted to medial tibio-femoral area. Varus malalignment has again increased due to the total load passing medially during gait. It has also been documented, valgus malalignment has been associated with an increase in the particular compartmental peak pressures laterally and medial area has continued to take more load than severe valgus malalignment, occurred by the lateral part [15,17-22]. Sharma et al. [16], have documented in their research that following three relations are closely obtained, malalignment increases in varus (as ≤178°) and valgus (as ≥182°), load increases in medial and lateral tibio-femoral bones and increases the development of knee OA. The terms valgus and varus refer to angulation (or bowing) within the shaft of a bone or

***Corresponding author:** Apurba Ganguly, Founder and Head Researcher, OPTM Research Institute, 145 Rashbehari Avenue, Kolkata – 700029, India, Tel: +91983°389616; E-mail: apurbaganguly15@gmail.com

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at a joint. It is determined by the distal part being more medial or lateral segment of the knee-joint point than it should be. It has been reported that varus but not valgus alignment enhanced the risk of tibio-femoral OA. In both knees with OA, varus and valgus alignments each leads to the risk of development in the compartment. Several researchers have already documented that biomechanically stressed conditions decrease the risk of progression in the unloaded area [16]. The malalignment in knee OA can easily be detected by BMI (body mass index) parameter [15], the knee gaps between the short head of biceps femoris muscles and the surface of the bed, knee flexions and knee extensions in supine, prone and standing positions for both the knee joints [8,9].

Generally, in osteotomy (leg bone surgery), tibial bone is commonly used to repair genu varum deformity in adults. However, corrective measures of valgus by osteotomy lead to an oblique joint line in cases of associated femur varum or majorly absence of tibia varum. According to Saragaglia et al. [23], the therapy of genu varum by osteotomy for combined distal femoral and proximal tibial bones in each leg is a difficult process. It was documented only in one research report that a conventional surgery (two closing wedge osteotomies) has been carried out on 29 knee joints of 24 patients. It has already been established through AP leg X-ray in standing position, angles for hip, knee and ankle, also both distal femoral and proximal tibial angles [23], have been described as preoperative radiological assessment. It has been found that the computer assisted surgery procedure is a suitable indication for high tibial osteotomy, double level osteotomy and distal femoral osteotomy and is a suggestive protocol for OA treatment. Furthermore, it has also been reported that varus and/or valgus deformities lead to OA changes in the knee joints. These deformities cannot be treated by osteotomy and/or total knee replacement (TKR) [24]. It has already been reported by the author in previous studies that suitable treatment protocol leads to sustainable results. The protocol has showed beneficial achievement in relation to OA changes of the knee joints with or without genu varum deformities [8-11].

An attempt has been made to identify the varus and/or valgus (genu varum) abnormalities in OA patients with an intension to normalize the deformities as well as symmetry of both legs by external application of phytoconstituents with the help of specialized treatment protocol in relation to improvements of anatomical and biochemical parameters along with the results of radiography at the end of 42 sittings comparing with the above mentioned parameters at the baseline (0 sitting).

Materials and Methods

Recruitment of patients

From ten centres of OPTM Health Care (P) Ltd located at Kolkata, Delhi and Mumbai in megacities of India, the total 1090 nos. of patients who came for treatment during the period of April, 2014 to July 2015, were selected for present research work. The study protocol was evaluated and approved by the OPTM Research Institution's Ethics Committee and the research organization is Government registered as its statutory. Thereafter, 540 patients (male: 231 and female: 309) from the total patients of 1090 were selected, based on the symptomology and radiographic features related with OA (osteoarthritic) changes in both the knee joints, during first step of study. Out of 540 patients in the final phase of screening, 196 patients (male: 65 and female: 131) were taken into consideration. The selection was based on the criteria, suffering ≥ 6 years and showed genu varum deformities, as established malalignment varus (≤178°) and valgus (≥182°) during the changes in OA for both the legs [15,16]. All patients signed consent form, approved by the Institutional Review Board for physical examinations, blood samples collection and X-ray reports required for the present work. All the data were studied and recorded for the OA changes along with marked genu varum (varus/valgus) deformities for both the legs of patients of aged ≥ 50 years old. All the demographic data as well as baseline features of the patients were presented in Table 1.

Study design

The exclusion criteria were analysed including patients unable to continue during the study period. Ultimately, 196 (male: 65 and female: 131) patients having the genu varum abnormalities or malalignment as varus/valgus due to OA changes in both knee-joints, were screened for the present research work.

The baseline study was carried out on the basis of detailed questionnaire filled up by individual patient. The questionnaire was contained details of demography, previous disease history, nutritional intake, ethnic and cultural profile and present and past job profile.

The established anatomical parameters as marked with abbreviated form expressed below and were examined and compared during the study through baseline to 7^{th}, 14^{th}, 21^{st}, 28^{th}, 35^{th} and 42^{nd} sittings in the clinic. These anatomical parameters were analysed both knee gaps between the short head of biceps femoris muscles and surface of the bed (KGB), the angles of both knee flexions (KF) and extensions (KE) parameters viz. supine (S), prone (P) and standing (St.) positions viz., KFS, KFP, KFSt., KES, KEP and KESt. respectively.

Assessment for pain, stiffness and functional disability scoring

The scoring data for pain, stiffness and functional disability of individual patient were studied by using 'The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC Scale)' as per method followed by previous researcher [25]. The comparisons were made between the baseline and 42^{nd} sitting of treatment.

Estimation of biochemical parameters from blood/serum

In the present study, biochemical parameters such as C-reactive protein (CRP), muscle creatine phosphokinase (CPK mm) and aldolase-A were recorded separately followed by the methods of other researchers [26-28]. The biochemical parameters were done from blood/serum, collected individually for all males and females. The comparisons were made between the baseline and 42^{nd} sitting of treatment.

Assessment of Body Mass Index (BMI)

The body mass index value for individual male and female patients was calculated and recorded separately. The comparisons were made between the baseline and 42^{nd} sitting of treatment.

Assessment of radiological images

The previous evaluations had done from radiological images for both legs of six patients at 42^{nd} sitting compared to baseline [8], that of two patients [9], and that of three patients [10]. Finally, all new six patients were evaluated and depicted as figures in present research work.

Indian medicinal plants and their phytoconstituents extraction in water

Following medicinal plants were used in the therapy. The phytoconstituents were extracted in water as per previous study followed by the method of Ganguly [8]. Several phytochemicals have

Sl No.	Criteria	Combined	Male	Female
1	No. of patients	196	65 (33%)	131 (67%)
2	Age (years), mean (SD)	58.66 (13.45)	61.82 (13.40)	57.22 (13.20)
3	Weight (Kg), mean (SD)	70.01 (13.44)	72.93 (13.05)	68.36 (13.48)
4	Body mass index (BMI) (SD)	30.42 (3.43)	30.90 (3.77)	30.20 (3.24)
5	Ethnic group (Indian varieties)			
	Bengali	42 (21%)	26 (40%)	16 (12%)
	Gujrati	25 (13%)	8 (12%)	17 (13%)
	Marwaree	35 (18%)	12 (18%)	23 (18%)
	Marathi	31 (16%)	7 (10%)	24 (18%)
	Tamil	11 (5%)	3 (5%)	8 (6%)
	Punjabi	22 (12%)	3 (5%)	19 (15%)
	Shindhi	20 (10%)	3 (5%)	17 (13%)
	North-east Indian	10 (5%)	3 (5%)	7 (5%)
6	Food habit:			
	Vegetarian	75 (38%)	25 (38%)	50 (38%)
	Non-vegetarian	121 (62%)	40(62%)	81 (62%)
7	Multiple complaints			
	Constipation	187 (95%)	56 (86%)	131 (100%)
	Over weight (Obesity)	196 (100%)	65 (100%)	131 (100%)
	Skin disorder	67 (34%)	28 (43%)	39 (30%)
	Acidity and Reflux	189 (96%)	58 (89%)	131 (100%)
	Insomnia	162 (83%)	39 (60%)	123 (94%)
	Varicose vein	87 (44%)	29 (45%)	58 (44%)
	Urinary incontinence	168 (86%)	52 (80%)	116 (89%)
8	Period of suffering (years), mean (SD):	9.87 (3.67)	11.26 (3.85)	9.08 (3.35)
9	WOMAC Index (%)			
	Pain Subscale, mean (SD)	78.86 (7.12)	82.27 (7.62)	76.53 (5.68)
	Stiffness Subscale, mean (SD)	76.75 (12.05)	75.26 (8.62)	77.77 (13.83)
	Physical function Subscale, mean (SD)	89.05 (3.21)	89.94 (3.51)	88.44 (2.83)
10	Measures taken for diminishing pain and inflammation			
	Using knee caps:	195 (99%)	65 (100%)	130 (99%)
	Paracetamol	195 (99%)	64 (98%)	131 (100%)
	Hyaluronic acid injection			
	Rt. Knee joints	152 (78%)	58 (89%)	94 (72%)
	Lt. Knee joints:	141 (72%)	52 (80%)	89 (68%)
	Corticosteroidal injection	89 (45%)	42 (65%)	47 (35%)
	Arthrocentesis			
	Rt. Knee joints	89 (45%)	32 (49%)	57 (43%)
	Lt. Knee joints:	77 (39%)	22 (34%)	55 (42%)
	Physiotherapy for Knee pain	196(100%)	65 (100%)	131(100%)
	Massage with various ayurvedic/herbal/oil, gel, cream over pain areas only	194 (98%)	64 (98%)	130 (99%)
	Using stick / Walker	187 (95%)	63 (97%)	124 (95%)
11	Work status			
	Employed fulltime	44 (23%)	23 (35%)	21 (16%)
	Employed part-time due to pain	7 (3%)	4 (6%)	3 (2%)
	Housewife/Homemaker:	74 (37%)	-	74 (57%)
	Unemployed because of pain	9 (5%)	6 (9%)	3 (2%)
	Retired	49 (25%)	27 (42%)	22 (17%)
	Self employed	13 (7%)	5 (8%)	8 (6%)

Table 1: Demographic data and baseline characteristics of 196 patients.

already been established by researchers and also recorded in Indian Medicinal Plants research [29].

For *Cissus quadrangularis*, whole plant was used. The phytoconstituents such as triterpenes including α- and β- amyrins, β-sitosterol, ketosteroids, phenols, tannins, carotene and vitamin C and also d-amyrin, onocer-7-ene-3a, 21b-diol, d-amyrone and 3,3',4,4'-tetra hydroxy biphenyl, 3,3',4,4'-tetrahydroxybiphenyl, flavonoids especially luteolin were reported [3]. For *Heliotropium indicum*, whole plant was used. The phytoconstituents such as pyrrolizidine alkaloids (helindicine and lycopsamine), flavonoids and geranyl aromatic derivatives were reported [30,31]. For *Rosmarinus officinalis*, the leaves and flowers were used. The phytoconstituents such as di- and triterpenoids, phenolic acids and flavonoids were documented. Also found carnosic acid, carnosol and rosmarinic acid [32]. For *Calotropis gigantea*, the

root and leaves were used. The phytoconstituents such as, flavonoids, glycosides, triterpenoids, steroids, alkaloids, tannins, phenols, flavonoids, saponins, cardenolides, flavonols etc. were reported by researchers [33-35].

All above-mentioned plants were taken after drying properly, followed by pulverisation and squeezing in deionised water with occasional stirring for 48 hours at 25 ± 2°C. Finally, the mixture was filtered after boiling at 65-70°C with particular period. The filtration was done to remove unnecessary particles and whole content was lyophilised. These aqueous phyto-extracts of combinations were mixed in virgin sesame oil, which was previously extracted at 4°C from seeds, the oil helps to maintain proper chemical nature of present phytochemicals and this was made a paste by using beehive wax [1-8].

Aims, principles and theories for treatment protocol

The aim, principles and theories of the treatment protocol was maintained same as the previous study, which the author had already expressed in details [1-8].

Usage of devices mainly Medicated Fomentation Device (MFD) and Wooden Roller Device (WRD) for treatment

The author had already established the functions and silent features of both devices viz. MFD and WRD, developed by him, which support the induction as well as inhibition uniformly, slowly and without fluctuations of the thermal and mechanical stimuli, which are the important part of 'connective tissue massage theory' and 'spine and joint stimulation theory' for the steady state of transverse wave properly require for normal muscular activities. These methods are greatly beneficial for the treatment of OA changes in knee joints along with genu varum deformities [8,9].

Different types of stimuli (chemical, mechanical, thermal and electrical) used in the therapeutic purpose

According to Ganguly [8,9], the well-established protocol for the various mechanisms as well as 'pros and corns' for all above-mentioned stimuli was undertaken in the present study including 'joint effects' of the above mentioned stimuli required for activations of various muscles, tissues etc. over the human body.

Details of postural positions for complete treatment

According to Ganguly [8-11], details of the complete treatment protocol along with reasons for choosing various postural positions with images such as supine position, prone position, right and left contra lateral positions and right and left cross contra lateral positions have already been emphasized before.

Synopsis of effects of treatment

According to Ganguly [8], previously established treatment protocols have highlighted the synopsis of effectiveness of treatment.

Statistical analysis

Statistical interpretation was carried out with the help of software (Microsoft Excel, version 8.1), The data obtained for R^2 values (Correlation coefficient) for all anatomical measurements (KGB, KFS, KFP, KFSt., KES, KEP and KESt.) and student-t test for biochemical parameters (CRP, CPK and aldolase-A) and BMI, WOMAC scale and subscales were considered with significant values at $P < .05$ level among two variables for measuring different improvement parameters of osteoarthritic patients having genu varum for combined patients of 196, mal: 65 and female : 131 for right and left knee joints separately.

Results

The present results indicate the recovery of muscles strength and power after studying anatomical measurements, range of motions both in flexions and extensions in different postural positions for both the legs having genu varum (varus and/or valgus alignments) as shown in the radiological images on both knee joints as compared to the patients at the baseline (° sitting) and at 42nd sitting of treatment. The graphical representations clearly indicate the significance of decreasing and increasing values in Figures 1-7 when compared between baseline and at 42nd sitting of treatment. At the same time, it has been shown that the genu varum can be rectified i.e. varus and/ or valgus alignment(s) in normal position when phytoconstituents are topically exposed by specialized treatment methods. Distal femoral and proximal tibial bones alignment is supported by the present results for anatomical measurements, biochemical parameters and radiological images. Thus, evidenced as normalisation of genu varum (varus and/or valgus alignments).

KGB as anatomical parameter

In anatomical feature, KGB measurements for both the knee joints were different due to varus/valgus deformity during osteoarthritis changes in knee joints as depicted in graph (Figure 1).

In this study, mean and standard deviation (S.D) of KGB for right knee joint of combined patients (196), male patients (65) and female patients (131) were 6.68 ± 1.1 cm, 6.64 ± 1.18 cm and 6.91 ± .94 cm respectively at sitting of treatment. It was found that KGB also for combined patients, male and female patients was reduced to 2.75 ± .52 cm, 2.91 ± .58 cm and 3.5 ± .62 cm respectively at 42nd sitting of treatment. The mean and standard deviation (SD) of KGB for left knee joint of combined patients (196), male patients (65) and female patients (131) were reduced from 6.74 cm ±1.41 cm to 2.75 cm ± .52 cm, 6.21 cm ± 1.43 cm to 2.91 cm ± .58 cm and 6.99 cm ± 1.28 cm to 3.5 cm ± .62 cm respectively at the end of 42 sittings. Finally the results forthe KGB of both the legs are symmetrical at the end of 42 sittings of treatment.

In case of KGB, the analysis of statistical significant levels for R^2 (correlation coefficient) values for 196 combined patients, 65 male patients and 131 female patients were calculated comparing between baseline and 7th sitting, 14th sitting, 21st sitting, 28th sitting, 35th sitting and 42nd sitting separately, all the data were showed highly significant R^2 values ranging between 93 – 96% and depicted in graph (Figure 1).

Other anatomical parameters like knee flexions in supine, prone and standing positions (kfs, kfp and kfst.)

The other anatomical parameters like knee flexion in supine, prone and standing positions for both the legs were found different due to malalignment in varus and /or valgus in the knee joints as depicted in graphs (Figures 2-4).

In the present study, it was observed that the mean and standard deviation (SD) values of KFS for the right leg of combined patients, male and female patients were increased from 116.31° ± 1.33° to 14.27° ± 3.79°, 119.26° ± 9.39° to 14.82° ± 2.89° and 114.61° ± 1.92° to 14.° ± 4.15° respectively at the end of 42 sittings of treatment. It was found that the left leg were increased from 113.84° ± 17.75° to 14.27° ± 3.79°, 119.76° ± 9.43° to 14.82° ± 2.89° and 11.89° ± 2.9° to 14.° ± 4.15° respectively at the end of 42 sittings of treatment. The mean and standard deviation (SD) of KFP for the right leg of combined patients, male and female were increased from 14.7°± 13.92° to 133.° ±4.68°, 19.4° ± 11.56° to 135.° ± 4.66° and 12.4° ± 14.45° to 132° ± 4.38° respectively at

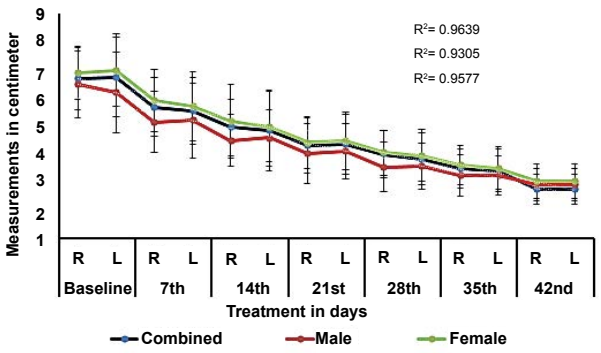

Figure 1: Knee gaps between the short head of biceps femoris and surface of the bed (KGB).

the end of 42 sittings of treatment. It was also observed that for the left leg were increased from 13.6°±19.13° to 133° ± 4.68°, 19.3° ± 12.33° to 135° ± 4.66° and 12.4° ± 14.45° to132.° ± 4.38° respectively at the end of 42 sittings treatment.

It was recorded that the mean and standard deviation of KFSt. for right leg of combined patients, male and female patients were increased from 94.85° ± 11.49° to 131.65° ± 4.89°, 98.24° ± 11.25° to 133.45° ± 4.19° and 93.15° ± 11.27° to 13°.74° ± 4.98° respectively at the end of 42 sittings treatment. The same for the left leg were increased from 95.59° ± 16.12° to 131.65° ± 4.89°, 1.88° ± 11.48° to 133.45° ± 4.19° and 92.94° ± 17.44° to 13.74° ± 4.98° respectively at the end of 42 sittings treatment. The knee flexions in supine, prone and standing positions for both the legs are symmetrical at the end of 42 sittings treatment. In case of knee flexions in supine, prone and standing positions, the analysis of statistical significant levels for R^2 (correlation coefficient) values for 196 combined patients, 65 male patients and 131 female patients were calculated comparing between baseline and 7th sitting, 14th sitting, 21st sitting, 28th sitting, 35th sitting and 42nd sitting separately were showed highly significant with R^2 values ranging between 95 - 98%, 96 - 97% and 92 - 94% respectively for flexion in supine, prone and standing positions and depicted in graphs (Figures 2 and 4).

Other anatomical parameters like knee extension in supine, prone and standing positions (kes, kep and kest)

The other anatomical measurements for knee extension in supine, prone and standing positions for both the legs were different because of varus and/or valgus deformities as depicted in graphs (Figures 5 and 7).

In the present study it was observed that the mean and standard deviation (SD) values of KES for right knee joint of combined patients, male and female were reduced to 1.59° ± .31° from 17.58° ± 1.87°, 1.19° ± °.38° from 16.24° ± 1.43° and 1.47° ± .25° from 17.7° ± 2.12° respectively at the end of 42 sittings treatment. It was found that the left knee joint with similar categories of patients were also reduced to 1.59° ± .31° from 17.82° ± 1.52°, 1.19° ± .38° from16.34° ± 1.33° and 1.47° ± .25° from 16.81° ± 2.12° respectively at the end of 42 sittings treatment.

It was further found that the mean and standard deviation (SD) values for KEP for right knee joint of combined patients, male and female were reduced to 1.51° ± .35° from 16.62° ± 2.8°, 1.12° ± .29° from 16.32° ± 1.73° and 1.31° ± .87° from 16.99° ± 2.29° respectively at the end of 42 sittings treatment. The data for left knee joint with similar categories of patients were also reduced to 1.51° ± .35° from 16.62° ± 1.95°, 1.12° ± .29° from 16.28° ± 1.58° and 1.31° ± .87° from 16.82° ± 2.16° respectively at the end of 42 sittings treatment.

It was also recorded that the mean and standard deviation (SD) values

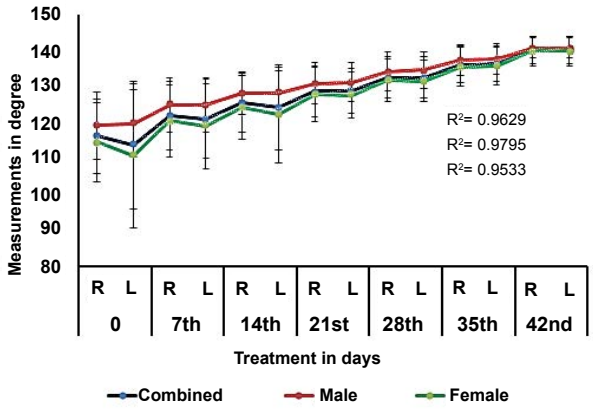

Figure 2: Flexion in supine position (KFS).

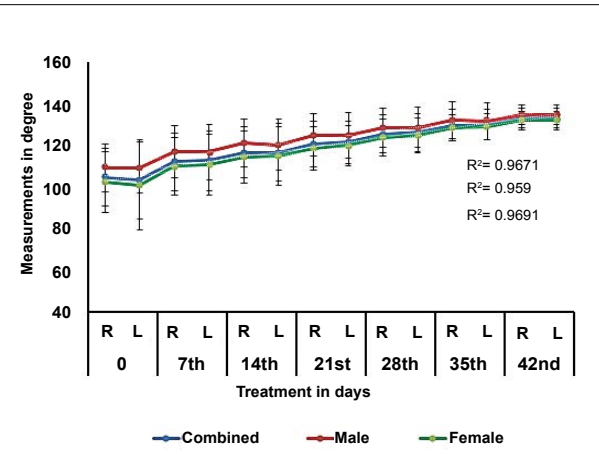

Figure 3: Flexion in prone position (KFP).

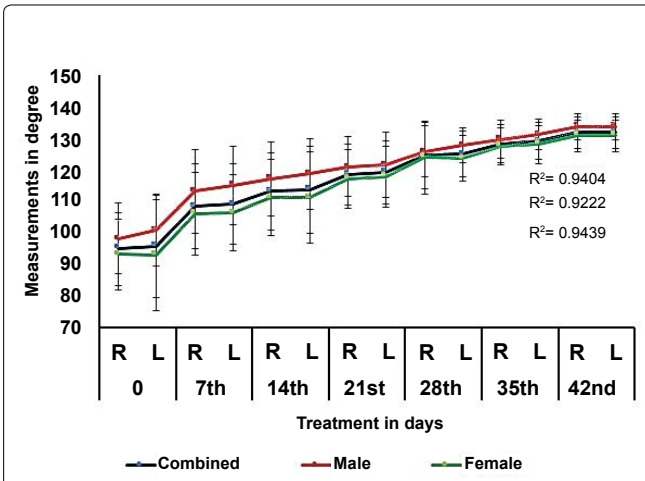

Figure 4: Flexion in standing position (KFSt.).

for KESt. for right knee joint of combined patients, male and female were reduced to 1.21° ± .3° from 16.51° ± 2.25°, 1.1° ± .45° from 16.22° ± 1.65° and 1.46° ± .6° from 16.74° ± 2.58° respectively at the end of 42 sittings treatment. The data for left knee joint with similar categories of patients were also reduced to 1.21° ± .3° from 16.21° ± 1.96°, 1.1° ± .45° from 15.89° ± 1.52° and 1.46° ± .6° from 16.43° ± 2.18° respectively at the end of 42 sittings. Finally, both the legs are symmetrical so far as knee extension in supine, prone and standing positions are concerned.

In case of knee extension in supine, prone and standing positions, the analysis of statistical significant levels for R^2 (correlation coefficient) values for 197 combined patients, 65 male patients and 131 female patients were calculated comparing between baseline and 7th sitting, 14th sitting, 21st sitting, 28th sitting, 35th sitting and 42nd sitting separately were studied highly significant with R^2 values 97% and 99% and ranging between 92 – 95% respectively for extension in supine and standing and prone positions, depicted in graphs (Figures 5 and 7).

Biochemical parameters

The pattern of improvements in biochemical parameters such as C-reactive protein (CRP), muscle creatine phosphokinase (CPK mm) and Aldolase-A of blood /serum collected from 196 numbers of combined patients,65 numbers of male patients and 131 numbers of female from the baseline to the end of 42 sittings are depicted in histograms (Figures 1 and 8).

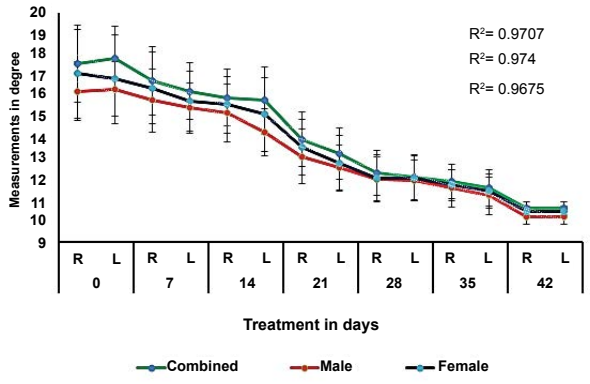

Figure 5: Extension in supine position (KES).

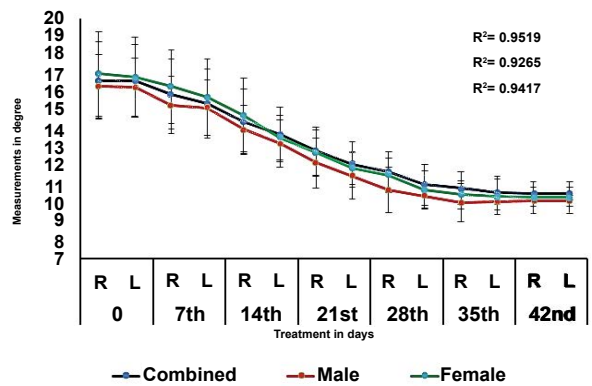

Figure 6: Extension in prone position (KEP).

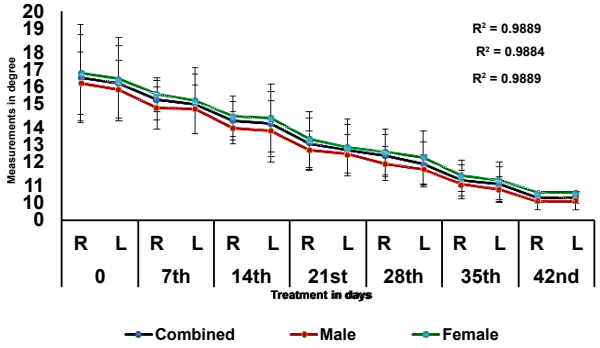

Figure 7: Extension in standing position (KESt.).

In case of 'C-reactive protein (CRP)', the mean and SD of combined patients, male and female were reduced from 1.83 ± 8.38 mg/l to 3.34 ± 2.21 mg/l, from 8.28 ± 7.49 mg/l to 2.82 ± 2.28 mg/l and from 12.57 ± 8.51 mg/l to 3.7 ± 2.9 mg/l respectively at the end of 42 sittings, which are all within the standard value of ≤5 mg/l.

In case of 'muscle creatine phosphokinase (CPK mm)', the mean and SD of combined patients, male and female patients were reduced from 298.13 ± 92.34 µ/l to 89.95 ± 22.12 µ/l, from 198.91 ± 27.23 µ/l to 11.1 ± 17.23 µ/l and from 365.98 ± 5.23 µ/l to 76.16 ± 12.37 µ/l respectively at the end of 42 sittings, which are all within the standard value of (54 to 168 µ/l).

In case of 'aldolase-A', the mean and SD of combined patients, male and female were reduced from 15.16 ± 6.37 µ/l to 3.78 ± 1.96 µ/l, from 11.28 ± 5.37 µ/l to 2.37 ± 1.82 µ/l and from 17.81 ± 5.59 µ/l to 4.74 ± .58 µ/l respectively at the end of 42 sittings, which are all within the standard value of ≤7.6 µ/l.

All the data at the end of 42 sittings were decreased in significant level of $P < 0.1°$ when compared to baseline (0 sitting) for combined, males and females respectively depicted in histograms (Figures 1-10).

Body mass index as parameter

The values for mean and SD of BMI of 196 combined patients, 65 male patients and 131 female patients were decreased to 25.61 ± 3.29 kg/m² from 3.42 ± 3.44 kg/m², 26.53 ± 3.47 kg/m² from 3.94 ± 3.77 kg/m² and 25.14 ± 3.11 kg/m² from 3°.17 ± 3.24 kg/m² respectively at the end of 42 sittings treatment due to loss of weight during the period of therapy and depicted in histogram (Figure 11). All the data were found declining significantly ($P < 0.1°$) at the end of 42 sittings of treatment when compared to baseline (° sitting).

Parameters as WOMAC scale and their subscales

The improvements were found when studied WOMAC scale and subscale parameters of WOMAC scale such as pain scale, stiffness scale and physical functional disability scale in percentage for combined patients (196), male patients (65) and female patients (131). All the data were showed declining values between baseline and at the end of 42 sittings treatment, and depicted in histograms (Figures 12 and 13). For above-mentioned two parameters, all the data at the end of 42 sittings were decreased at significant level of $P < 0.1°$ when compared to baseline (° sitting) for combined, males and females separately.

Radiological images before and after the phytotherapeutic treatment

The author had already depicted twenty-two pairs of radiological

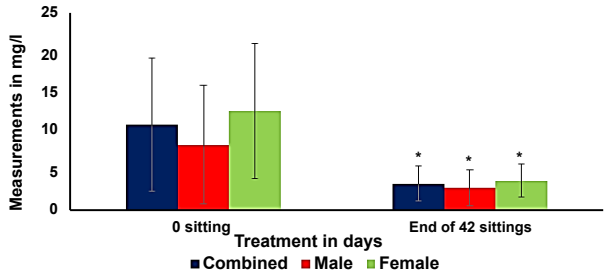

Figure 8: Biochemical Parameter (CRP) (*P<0.001).

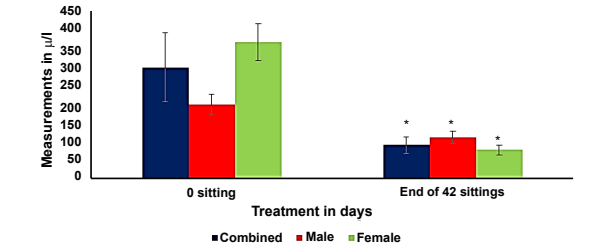

Figure 9: Biochemical Parameter (CPK) (*P<0.001) .

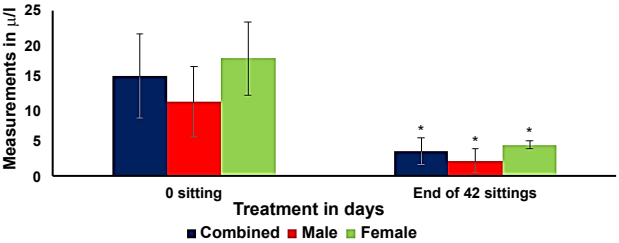

Figure 10: Biochemical Parameter (Aldolase A) (*P<0.001).

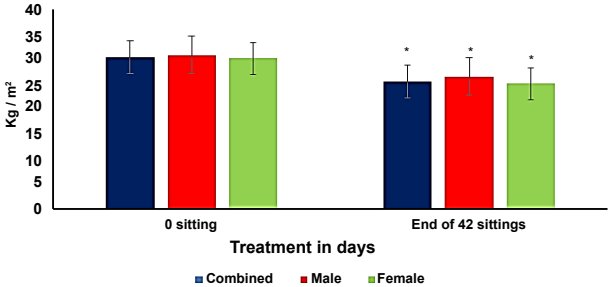

Figure 11: Body Mass Index (BMI)(*P<0.001).

images wherein rectifications of genu varum (varus/valgus) deformities have been normalized at the end of the 42 sittings with the help of programmed phytotheraputic treatment protocol [8-11]. The following radiological images distinctly identified the improvements of genu varum (varus/valgus) deformities after the phytotherapeutic treatment protocol. The radiological images for twelve pairs of images were depicted (Figures 14A-19B).

Discussion

Researchers have already investigated several types of treatment of

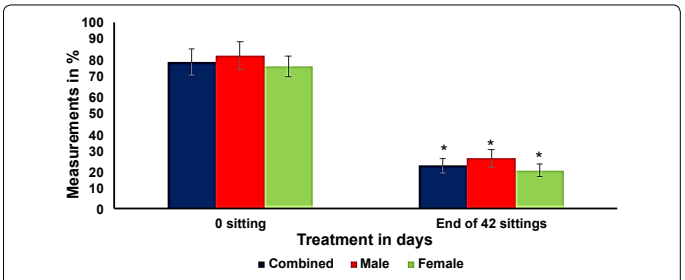

Figure 12: WOMAC SCALE (*P<0.001).

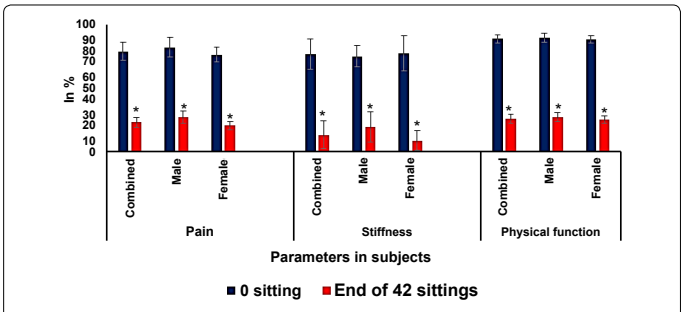

Figure 13: WOMAC SUBSCALES (*P<0.001).

OA changes in knee joints, which are basically established painkillers, hyaluronic acid injection, non-steroidal anti-inflammatory medications etc. and finally total knee replacement [36-39], but till date none of the researchers have successfully documented the rectification of genu varum (varus/valgus alignment) in OA changes for knee joints of patients aged ≥ 5 years. The present study emphasizes firstly detection of malalignment of knee joints due to varus/valgus deformity in OA changes by several anatomical measurements and biochemical parameters along with radiological images, which is documented for the first time in relation to said aged patients. The study has also elaborated potent therapeutic specialized technology that normalizes the deformities of genu varum with the administration of topical application of phytoconstituents. At the same time, the author has already explained the reasons for the back of the knees not touching the bed in supine posture, the reason for abnormal angle of flexions and angle of extensions in supine, prone and standing positions and muscles responsible for above-mentioned activities [1]. The author has further established the bilateral symmetry with normal ranges so far as the KGB, KFS, KFP, KFSt., KES, KEP and KESt., after the treatment of 42 sittings by application of the phytoextractions thrice in a day with a programmed postural positions [8-11].

The normalisation of all above-mentioned biochemical parameters after 42 sittings indicate the improvement of muscular activities probably by inhibiting the COX-2 pathway resulting in diminishing inflammation occurred during acute OA changes in both knee joints [4-42]. The muscle weakness is caused by neurological disease but aldolase A will remain high in case of muscular diseases, such as muscular dystrophy. In osteoarthritis degeneration of muscles take place [43]. Till date there is no medication available for controlling high aldolase. A level in blood of osteoarthritic patients, over a decade, important biochemical parameters such as C-reactive protein (CRP), creatine phosphokinase (CPK) and aldolase A have been estimated to identify diseases viz. osteoarthritis, rheumatoid arthritis, heart diseases, renal failure etc. Among all these diseases, osteoarthritis is very common worldwide and is a painful disease. It has already been established that assay of CRP is a biomarker in serum for OA patients [44].

Figure 14A: Radiological images before the treatment (Age = 64 years; Sex = F).

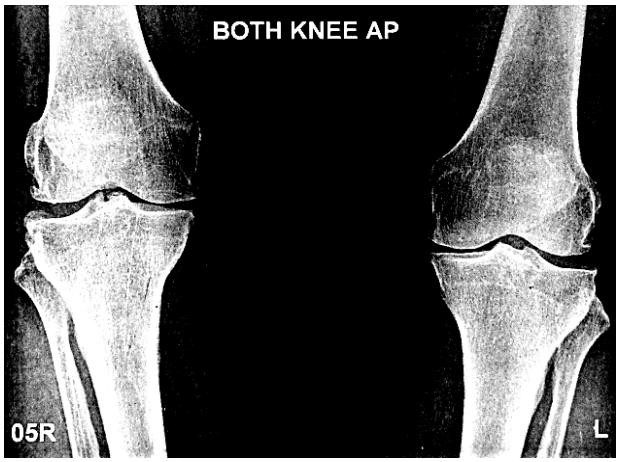

Figure 14B: Radiological images after the treatment (Age = 64 years; Sex = F).

Figure 15A: Radiological images before the treatment (Age = 65 years; Sex = M).

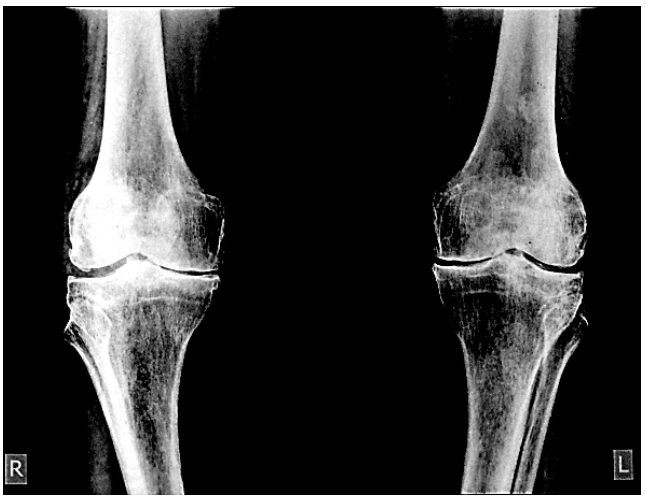

Figure 15B: Radiological images after the treatment (Age = 65 years; Sex = M).

Figure 16A: Radiological images before the treatment (Age = 65 years; Sex = M).

Figure 16B: Radiological images after the treatment (Age = 65 years; Sex = M).

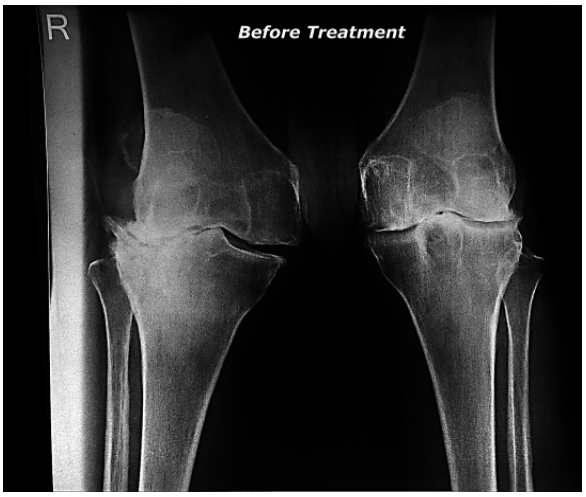

Figure 17A: Radiological images before the treatment (Age = 52 years; Sex =F).

Figure 17B: Radiological images after the treatment (Age = 52 years; Sex = F).

Figure 18A: Radiological images before the treatment (Age = 68 years; Sex =F).

Figure 18B: Radiological images after the treatment (Age = 68 years; Sex = F).

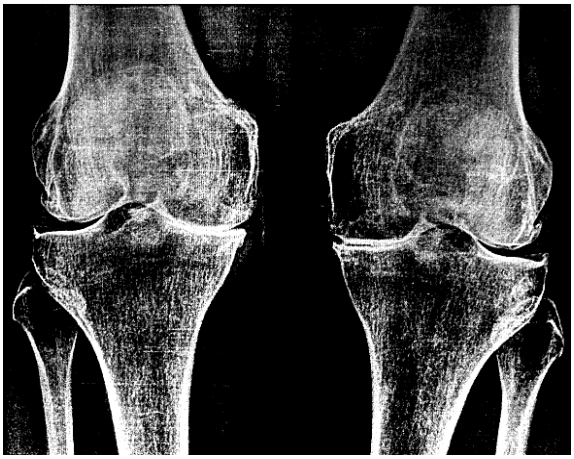

Figure 19A: Radiological images before the treatment (Age = 54 years; Sex =F).

Figure 19B: Radiological images after the treatment (Age = 54 years; Sex = F).

The present research work is supported by other researchers in relation to previously documented therapeutic efficiencies of medicinal plants such as *Cissus quadrangularis, Heliotropium indicum*, *Rosmarinus officinalis* and *Calotropis gigantea* by the traditional usage as folk medicine and researchers have reported that organic solvent extracts have been tested in disease prevention with these medicinal plants [45-48]. The present study, however, is based on aqueous extracts and preserved in sesame oil along with beehive wax as prepared for new treatment protocol [8-11]. Previous studies have supported the present therapy in respect to anti-inflammatory properties by the presence of phytochemicals in *Calotropis gigantea* [35,45], muscular pain relief and traditional treatment in osteoarthritis, rheumatoid arthritis and osteoporosis by using organic solvent extracts of *Cissus quadrangularis* [3,46,47], antioxidant activities by *Heliotropium indicum* [31] and essential oil from the areal part of plant, *Rosemarinus officinalis* have showed antiinflammatory, antiproliferative and antioxidant properties [32,48]. Moreover, all the previous studies with these medicinal plants traditionally and/or experimental may have served as temporarily in nature.

The present results indicate significant improvement in anatomical measurements such as KGB for both legs decreasing while flexion for supine, prone and standing positions for both legs were significantly increasing and extension for supine, prone and standing positions for both legs were significantly decreasing as a result of symmetrical alignments, consequently achieving the desired normal alignments of varus and valgus deformities. In case of all above-mentioned biochemical parameters, improvements were obtained within the normal limits, which are also supported by the normalisation of muscle inflammation in the present study. The BMI values were also decreasing in present result, which is supported the reduction of body weight, which may be one of the causative factor for genu varum deformities. The WOMAC scale and subscale also obtained a decreasing trend from baseline to 42 sittings, which indicates the relief of pain sensation. Finally, all the above-mentioned parameters were supported with the normalization of radiological images when compared to the results at baseline with the end of 42 sittings. In previous studies, authors had established corrections in relation to radiological images. The present study with evidenced of other twelve pairs of radiological images before and after the treatment [8], four pairs of radiological images before and after the treatment [9] and six pairs of radiological images before and after the treatment [11].

So far, this topical application of available phytoconstituents contained in aqueous extracts of Indian medicinal plants along with specific treatment protocol is a first time research based treatment for malalignment of genu varum, which can be an alternative novel method for normalization of genu varum (varus/valgus) in OA for knee-joints supported with anatomical measurements, biochemical parameters and radiological images.

Conclusion

It has been concluded that topical application of the certain phytoconstituents extracted (aqueous) from Indian medicinal plants can normalise the damages (malalignment) of knee joints during osteoarthritic (OA) changes having varus and/or valgus deformities within 42 sittings with specialized treatment protocol [8-11]. It may further be noted that before and after anatomical features, biochemical parameters and radiological images confirm the proper alignment or normalization of femur-tibial bones. This is a pioneering observation that OA changes in knee joints having varus/valgus deformity can be normalised with the help of previously established medicinal plants [8-11]. However, only pain and inflammatory disorders have temporarily been relieved, which have been documented by few researchers using these medicinal plants as folk medicine traditionally [31-36] but present novel technology is based on aqueous extracts of above-mentioned plants within 42 sittings with specific treatments protocols thrice in a day with application procedure of the above-mentioned phytoconstitutents in especially postural positions of contra lateral and cross contra lateral [8,9].

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Conflict of Interest

There is no conflict of interest for the present manuscript.

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