

COMPARATIVE EFFECTS OF KNEE BRACE VERSUS LATERAL WEDGE FOR PATIENT WITH MEDIAL COMPARTMENT KNEE OSTEOARTHRITIS

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ABSTRACT

Aim: To compare the effect lateral knee wedge verses knee braces in medial compartment knee osteoarthritis

Methods:an experimental study were conducted in isra university hyderabad. In this study 30 patient were included in which lateral wedge is applied to 15 patients and knee braces is applied to 15 patients. Purposive sampling technique were use in this study.NPRS and KOOS quuestionare is used in this study for pre and post assessment.

Results: there are 30 pateint included in this study in which 12 are male which is estimated as 44.6% and 18 were female which is estimated as 55.4.mean pre value of koos score in lateral wedge is 45.75 and post is 78.08. mean pre value of NPRS in lateral wedge is 7.6 and post value is 4.8. in knee braces pre value is 4.9 and post value is 3.2.

Conclusion:lateral wedge is more effective in medial compartment of knee osteoarthritis when comparing with knee braces.

Keywords:

CHAPTER I

1. INTRODUCTION

Osteoarthritis

Definition

Osteoarthritis is an abnormal condition of a variety of disorders that may causes anatomical and functional dysfunction of synovial joints.²in traditional terms osteoarthritis is also known as a pathology of joint cartilages. But newly done medical research says that osteoarthritis surrounds whole joint organ, which includes the sub chondral bone, menisci, ligaments, muscles surrounding the joint, capsule, and synovium.

Anatomy of Medial Compartment of Knee

The extensor retinaculum supports the knee joint medially ,while the muscles of thigh provide dynamic stability to the knee joint. All the joint planes of motion are stabilized by ligaments. At the antereomedial part of tibial tubercle of the knee joint the pesanserinus group is attached, these fibers cross up to the postereomedial area of the joint. On the femoral condoyle of the femur, there is an adductor tubercle for the attachment of adductor Magnus muscle .Another important muscle of the knee joint which

provides medial support to the knee is the semi membranous muscle and its five branches. (2)

Prevalence of osteoarthritis

In older population, most common degenerative condition of the joints is Osteoarthritis of the knee joint .This increasing prevalence of OA causes pain and reduces the ability of individual for physical activity, and ultimately all of these affects self-dependency of the patient and healthy and a good lifestyle quality.⁹ Various researches says that Knee OA is directly proportional to the body Mass Index (BMI) and one's advancing age.⁽²⁾

Kellgren-Lawrence Grading Scale For Osteoarthritis

Grade 1: undetermined joint space narrowing along with probably osteophyticclipping.

Grade 2: clear osteophytes, clear joint space narrowing.

Grade 3: limited several osteophytes, clear joint space narrowing ,slight hardening and probably unsymmetrical bony contour.

Grade 4: big osteophytes, clear joint space narrowing, extreme Hardening of joint and clear unsymmetrical bony contour. (3)

Etiology Of Osteoarthritis

Actual cause of Knee OA is not known still but there are various contributing factors of this joint degeneration. Age: secondary OA may occur in younger population but exact OA is more often seen in elderly population. Gender: Another contributing factor is Sex, one study of Framingham Knee Osteoarthritis says that females are more prone to get OA in advancing age as compare to males. Obesity: increased body weight increases the chances of knee OA while weight loss prevents it's development. Genetic :Hereditary works in few cases as in case of Hip osteoarthritis, which has important genetic component. Bone density :this factor is inversely proportional to OA i.e. if bone thickness decreases as in case of osteoporosis, chances of OA increases.²⁰ Cigarette smoking :various studies suggests that OA may occur due to smoking.²¹ Local factors : this term refers to direct trauma on knee joint which may results in joint fracture.²²

any injury or fracture of the joint in younger age may convert into knee OA in older age .Other factors include Chondrocalcinosis, crystals in joint fluid / cartilage, immobility for prolonged duration, instable or hyper mobile joint, neuropathy in peripheries, one involved in sports from longer time duration or any occupation which causes stress on joint. (3)

Pathophysiology of OA

Previously OA was totally considered as a disorder of cartilage deterioration. But new medical researches says that OA involves whole joint organ, including it's capsule, surrounding tissues and ligaments. It is caused by various contributing factors like joint and soft tissue injury, any stress from outside mechanical forces, biochemical reactions going on, inflammation of the limb, or any metabolic changes. Thus these all suggests that not only cartilaginous tissues get involved. Infect, cartilaginous tissues alone themselves even do not produce any symptoms of pain or inflammation in the joint because theses are non vascularized and denervated.

Thus, pain mostly come from tissues other than cartilage component like, subchondral bone, muscles around the joint, ligaments, capsule, synovium, etc. In later stages of the disease all joint structures get involved and deformity becomes obvious like remodeling of bone, formation of bony Spurs, muscles get weakened, laxity of ligaments, and effusion around the synovial joint which appears as swelling above the skin. (4)

there is some changes in the formation of cartilage, as it depends on the loading during walking. So cartilage is more thick laterally on tibia and more thin medially, because during walking more stress apperas on lateral tibia.¹⁹ if hair pattern changes, i.e. load is shifted from lateral to medial than this altered kinematics helps in decreasing degeneration on the more often loaded areas. Injury to anterior cruciate ligament, periarticular muscle weakness, laxity of joint ligaments, or stiffness around the joint can change the joint kinematics and increase chances of medial knee osteoarthritis.⁽⁵⁾

Treatment of OA

Non-pharmacological management

Treatment of OA without using any medicine, but with the help of remedies to decrease painful symptoms is the non-pharmacologic treatment. It aims to provide better quality of life and healthy lifestyle by removing painful symptoms.

Pharmacological management

The vast majority of Osteoarthritis patients are elderly and most of them will have multiple comorbidities. So, a healthcare professional should pay special attention before prescribing drugs to these patients to avoid any side effects. Widely used medicine for knee osteoarthritis is cyclooxygenase inhibitors like, acetaminophen and NSAIDs.

Corticoids (CS), has anti-inflammatory and immunosuppressive effects. These decrease the production of IL-1, leukotrienes and prostaglandins. Providing pharmacological therapy slows down the degenerative process and enhances joint mobility. (6)

Interventional management

This includes targeted joint therapy. There are various new researches done on this localized joint treatment. Like; variety of intra-articular (IA) injections. Inserting medication only on affected area will result in decreased systemic side effects and more readily direct effect of the drug. This management is more effective than pharmacologic management.

The Lateral Wedge

The lateral wedge insole (LWI) is a wedge positioned beneath the sole of the foot and angulated so that it is thicker at the lateral part than the medial edge, transfer load from the medial to the lateral knee joint during weight bearing. Even though special groups have promulgated different recommendations, biomechanical studies have demonstrated an effect size in reduction of EKAM ranging from 4% to 12% with an LWI of at least 5 degrees. However, the LWI can be painful for patients with knee OA owing to the more prolated position. The LWAS are lateral wedge insoles

with added medial arch support (also called lateral wedge arch support insoles) aimed at minimize the boost in the subtalar valgus angle to make patients more relaxed while maintain their skill to reduce the EKAM through the late stance phase of gait. (7)

Knee Brace

These are the supports of different designs. They decrease pain by shifting the weight from the most affected area of the joint. Ultimately this helps in to move around and in easy and comfortable walk.

Types of Knee Bracing

Different types of knee braces there are, which can be used to treat knee problems. Because of variety of disorders and pathology, various different types of mechanical support is required. For example, if anyone compartment of knee is affected then knee braces of unloading type is used. These are used to shift weight and for proper joint alignment. (7) Some most commonly used Braces are briefly discussed here.

Different varieties of knee braces are there. Each one is used for different causes.

Functional Braces

These provide prop up to knees that have been injured in the long-ago. Athletes often put on them after a main injury has healed. They stabilize the knee and control motion to prevent another injury. (7)

Rehabilitative Braces

These are frequently used for a period of weeks right after an injury or surgery. They keep the knee stable but still allow restricted movement while it is healing. a few doctors haven't seen a benefit from these braces and no longer recommend them. (7)

Unloader Braces

These are designed to ease pain in people who have arthritis in their knees. They shift the weight ("unload" it) from the spoiled area of the knee to a stronger area. (7)

Prophylactic Braces

These are designed to guard knees from injury during contact sports such as football. They have become popular among athletes. Research has not proven that they work, but studies are ongoing.(7)

Knee sleeves

Commonly used support of the knee are knee sleeves, whose basic function is to provide compression to the knee joint. Besides supporting the knee they also reduces swelling and pain.(7)

Osteoarthritis is an abnormal condition of a variety of disorders that may causes anatomical and functional dysfunction of synovial joints. It is among those disorders which causes disability in older adults. In developed countries, it is the most commob joint disorder which may leads to disability at chronic stage, mostly incase of knee and hip joints. (8)

As it is mentioned above Osteoarthritis is a commonly occuring joint disorder in elderly population and the only cause of disability in this age section. As age increases, it's incidence also increases in general population but some contributing factors of the disease includes firstly age, then body weight, injury or trauma to the joint, repetitive movements causing minor injruy, adapting kneeling and squatting position. Pathogenic factors of knee OA are abnormal mechanical forces, biomechanical substances like cytokines, leptin, etc. In most of the cases of knee OA it is difficult to diagnose it early on starting stage because it's symptoms are not clear, patient do not feel much pain and even radiographs are also not clear at this stage..(9)

To understand the pathophysiology of osteoarthritis under knee joint is also imp. Pain is produced by nociceptive receptors. When unmyelinated and small myelinated fibers of joint and surrounding tissues get stimulated them pain is produced but stimuli must be repeatedly or spatially clusered. These stimuli on reaching spinal cord faces two inhibitory effectors namely interneurons and descending central neurons.nociceptiondion present on capsule,

ligaments, synovium, bone and menisci. Threshold for nociception is decreased by inflammation.(10)

The changes in relation of decrease in joint space and knee pain can be explained by biomechanical component. These factors may change a radiograph of OA with no symptoms to a symptomatic disease. As in the case of X-ray of grade 2 i.e. mild knee OA, patients having more symptoms show increased medial load than patients without symptoms.(11)

In knee OA inflammatory markers like erythrocyte sedimentation rate (ESR) and C-reactive proteins are usually normal althoughsynovitis will be present. Becuase in knee OA synovial fluid has non inflammatory property. Serum and synovial fuidlevel of C reactive protein in OA is lower than inflammatory arthritis. anti-cycliccitrullinated peptide antibody is negative in serum and synovial fluid of knee OA patients. During differential diagnosis of OA and RA, anti CCP test is performed. (12)

Generally management of knee OA successfully reduces pain but do not eliminates disability but proper exercise plan can help in improving this disability. Exercises for knee OA Includes both aerobic exercises and strengthening exercises, depending on the severity of disease theses exercises are variable. Different studies show variability in the results of knee exercises. These changes may be due to different study designs, different targeted population and exercise plans. But even though these differences most of the studies show decrease in symptoms of pain and disability.more successful at decreasing pain rather than disability. Still studies do not show the complete mechanism of exercises behind the disability but researches are going on and in future there will be a planned exercise protocol for these patients to provide a healthy lifestyle. (13)

Physical therapy doing manually gives results in daily life activities up to 1 year. Same is with exercise Physical therapy which has benefit in physical activity of daily life. The Management of OsteoArthritis (MOA) is Trial consists of: (1) a personalized manual physical therapy programme along with daily life care; (2) a personalized,

multi-modal, supervised exercise physical therapy along with daily life care and (3) combining both of two including daily activities.(14)

There are some specially designed insoles which works in decreasing pain of medial knee OA. For this, lateral wedge insoles are used, which are placed on lateral side of foot so as to shift weight from medial to lateral side by changing biomechanics of foot and thus, reduces pain.

Lateral wedge is lean from the instep and wide at the outside of foot, its angle is variable for different patients. In the inner side of shoe, lateral wedge is placed.

Intense knee pain and x-ray reports of knee osteoarthritis have been combined with even higher knee adduction (inward or medial movements) during walk. Lateral wedge insoles are used for this disorder to improve this varus malalignment. Individuals who have medial knee osteoarthritis are aided by lateral-wedge insoles. In medial knee osteoarthritis, due to joint space narrowing knee alignment becomes varus (move medially). The lateral-wedge improves this misalignment by shifting the load away from the medial component of the knee...

Determining the prevalence of knee OA in terms of percentage ratio shows that medial knee OA is more common i.e. about 67% while lateral is about 10 to 16% , rest of the population are affected by OA in area behind the knee cap.

Researches shows contradictory results of the use of lateral wedge and its efficacy. According to few studies these are not much effective in case of the knee osteoarthritis and its progression. While some shows that wearing lateral wedge in medial knee OA results in a way that these patients reduced their non steroidal anti inflammatory drugs (NSAIDs) and they feel more comfortable with these insoles.(15)

Best management of knee osteoarthritis needs both pharmacological and non-pharmacological treatment. Health care professionals prescribed lateral wedge insoles for medial knee OA but its efficacy is not clear still. This study aims to know the use and benefits of lateral wedge insoles in medial knee OA that either they reduces pain and improves lifestyle or not. Addition of subtalar straps in these insoles improves painful

symptoms but still inferior to placebo insoles. Clinical and biomechanical studies of foot shows that these insoles reduces movement of the foot medially by 4 to 12% while walking, this in turn off the load from medial compartment towards lateral. (16)

The use of lateral wedged insoles for patients with medial compartment knee osteoarthritis is surely a very good treatment strategy as it is cheap, low in complex, and has no adverse effects. In japan, several studies show its benefits, new studies on the use of lateral wedges for medial compartment knee osteoarthritis is not sufficient to draw any proper results Two recent systematic reviews have shown limited evidence to support the use of lateral wedge orthotics for decreasing pain, increasing function or reducing disease progression. (17)

Knee brace presents a conservative, non-invasive treatment option to relieve the symptoms of knee OA by hi reducing biomechanical stress on the knee.various different braces have been developed, evaluated, and manufactured. These braces are manufactured to decrease loads within the knee, and accomplish so by using various hinge types (single hinge or dual hinge) as well as decreasing the load in either the medial or lateral compartments of the knee by applying a valgus or Varus outside force to the knee, respectively. The application of this stress can be applied either by the brace pushing (push brace) or pulling (pull brace) on the knee in order to apply the limited force to decrease the load on the target compartment of the knee joint.

external force to the knee, respectively. The application of this force can be applied either by the brace pushing (push brace) or pulling (pull brace) on the knee in organize to apply the required force to reduce the load on the target compartment of the knee joint.

There is wide increase seen since 2010 in researches on efficacy of knee braces in knee osteoarthritis. But still, there is lack of researches with good evidence showing the benefits of this treatment strategy. Literatures are also present on the comparative studies of differences among hinge types and brace models. It is recommended

that future studies should aimed to calculate efficacy of knee braces in knee OA also they should study the difference in functional performance among variety of bracing types. (18) A type of brace called Unloader brace, is an economical and active treatment for unicompartmental knee osteoarthritis. These braces enhances life style quality of the patient and reduces surgical treatment need. It is recommended that knee OA patients should be carefully treated with conservative management alongwith the use of knee braces before referring for surgical treatment. (19)

When talking about different scales and guidelines regarding knee braces first comes the NICE guidelines which recommend knee braces use in knee osteoarthritis in section of non pharmacological treatment. Another guidelines by Osteoarthritis Research Society International which includes certain biomechanical treatment methods to treat patients with varus or valgus deformity either mild or moderate so that it improves stability of the joint alongwith decreasing painful symptoms. In One more recommendation in 2003 by European League Against Rheumatism, knee braces are considered to be part of Knee OA management. (20)

Hypothesis:

Null :lateral wedge and knee brace both are effective.

N₁: lateral wedge is more effective than knee braces.

N₂:knee braces are more effective than lateral wedge.

SIGNIFICANCE OF THE STUDY

Knee brace and lateral wedge both are common devices used in the management of osteoarthritis and it is

worth full to know which one technique is more effective one of them.

The comparison of knee brace and lateral wedge may help to identify which technique among both of them has better efficacy for the management of medial compartment osteoarthritis.

1. RATIONALE

Medial compartment osteoarthritis is most common condition and mostly it is managed with physical therapy as conservative treatment either with knee brace and with lateral wedge. As par knowledge of therapist literature review there is lack of research articles regarding comparison of knee brace and lateral wedge among patients with medial compartment osteoarthritis, therefore I intended to compare knee brace and lateral wedge that may help to generate clinical evidence for the therapist to choose better treatment strategy for the management of medial compartment osteoarthritis.

Objective

To compare comparative effect of knee brace versus lateral wedge among patient with medial compartment osteoarthritis.

CHAPTER II LITERATURE REVIEW

Arazpour et al, in 2012 conducted a study which aims in identification and comparison of the efficacy of laterally wedged insoles and bespoke unloader knee orthoses in treating medial compartment knee osteoarthritis. Results show that both the orthosis have role in normalizing the basic parameters of entity. However, there isn't any sufficient variation in pain, cadence and step length of individuals except the range which was slightly more of insoles instead of knee orthosis. So, the author concluded that both the orthosis can improvised the patient's condition and helps in pain reduction but there is slight difference in range improvement in with knee orthosis which is few degree less. [21]

M.R. Maly et al. in 2002 study the effect of static and dynamic alignment and biomechanical forces impact on foot orthosis in medial knee osteoarthritis. There wasn't alteration in conditions such as; static alignment, the peak adduction moment or excursion of the center of pressure in the medial-lateral direction. There wasn't any co relation found between the adduction moment and center of pressure excursion in the medial to lateral plane whereas, there was reduction in displacement of centre of

pressure excursion in anterior/posterior direction with orthosis in relation to adduction moment when compared with controlled condition. The results suggest that there was decrease in the center of pressure excursion in the anterior-posterior direction put forward that foot positioning was varied, perhaps due to a toe-out position, when subjects wore the orthoses. Based on the available data, toe-out positioning may decrease medial joint loading [22].

J. F. Maillefert et al in 2001 conducted the study to prospective controlled study to compare the effectiveness of lateral and neutral wedges among the patient having medial femoral tibial osteoarthritis. Patients were divided and placed within two groups with similar disease characteristics and reassessment was done at the interval of 1, 3, 6 months by using multiple subscales such as; WOMAC pain, joint stiffness, and physical functioning subscales which showed the improvement with disease condition. The study found that there is decrease in intake of NSAIDs at 6 months as compared with 3 months in patients with lateral wedge insoles while it remained same within other group. There was also difference in compliance and tolerance among the group with lateral wedge insoles when compared with other given neutral wedge insole. This study concluded that there is no immediate relief with lateral wedge insole. However, there was reduction in NSAIDs utilization and improvement in compliance of patients with Medial Femoral Tibial Osteoarthritis [23].

This study was conducted by Khan et al in 2018. This study aims to find out whether there was decrease in second peak adduction moment with toe-out and effect of knee brace when combined with laterally wedged insole and its impact on toe-out gait when decrease in knee adduction moment and increase fall risk in knee osteoarthritis patients. The results show that there was decrease in peak adduction moment when combined with toe out and high risk of fall when knee brace combined with lateral wedge insole and toe-out. The study concluded that there was collaborative impact of toe-out in combination with knee brace and lateral wedge insoles accompanying reduce second peak

adduction moment in knee with high chances of risk of fall along with reduced patient comfort [24].

Moyer et al in 2015 conducted the study, to appraise the impact of valgus knee bracing on pain and function, and compliance and complications, in patients with medial knee osteoarthritis (OA). There are total 6 studies that were included in this meta-analysis. Valgus knee brace has prominent role in reduction of pain and enhancing the functional level when compared with other group that did not use orthosis and have minimal effect on pain and functional level. Whereas the other group which used the orthosis has for very short time period have the least effect in reducing the pain and improving the functions. Meta-analysis of randomized trials considered valgus bracing for medial knee OA results in small-to-moderate reduction in pain [25].

FANG et al in 2006 conducted the pilot study regarding the importance of footwear, does the lateral-wedge insoles inserted into shock-absorbing walking shoes have the role in management of pain, stiffness and function in people suffering from the osteoarthritis of medial compartment of knee joint. Symptoms were reassessed by using WOMAC after 4 weeks of treatment and prescription of full-length lateral-wedge insoles with an incline of 4° in their walking shoes and subjects have significant improvement in their symptoms. It was concluded from this study that lateral-wedge insoles inserted into shock-absorbing walking shoes have striking role in pain and other symptomatic management of osteoarthritis of knee joint involving the medial compartment [26].

Abourazzak et al in 2014 concluded the study to analyze the foot posture index in people with or without the medial compartment knee osteoarthritis and its association between its abnormalities and medial compartment knee OA. So, for this purpose the participants divided into two groups; one with the condition and another without it. The analysis represents that individuals with the disease have more pronated foot with FPI, flatfoot and less high arch when

compared with the other group. Whereas, there wasn't any variation in navicular height among the two. The study concluded that pronated foot and flatfoot had association with medial compartment knee osteoarthritis [27].

R.F. 180 Moyer et al. in 2014 studied and analyzed the biomechanical effects of valgus knee bracing in the patients with medial compartment osteoarthritis. Around thirty studies were included in this meta-analysis. Analysis of biomechanical forces provided information that valgus braces mainly can reduce medial knee compressive force and also helps in even load distribution across Medio lateral border of knee, quadriceps/hamstring and quadriceps/gastrocnemius co-contraction ratios, and improving medial joint space during gait [28].

Nizai et al in 2014 conducted the study to compare the effect of shoe modification such as; offloading knee brace and lateral wedges with other non-operative treatment strategies. The study found that there was reduction in pain intensity and walking distance with off load knee brace and lateral wedges, but more pronounced in case of offloading knee brace. There was significant improvement in activity level when assessed using the visual analogy scale. The study concluded that both the orthosis aids in reduction of symptoms of osteoarthritis of knee however, offloading knee brace have significant importance in this regard [29].

Petersen et al in 2018 studied the non-operative management of effect of ankle-foot orthosis versus knee unloader brace in single compartment of knee affecting from the osteoarthritis. Participants divided into two groups, one treated AFO while the other with knee unloader brace. Symptoms were assessed at time of presentation, at 8 weeks and at 6 months by using VAS for pain and KOOS for measuring the pain, activities, sports and quality of life. The results showed equal improvement of patient outcomes at different time intervals whether it was pain, sports and other activities. It has been concluded that there wasn't difference in patient outcomes when treated with unloading knee

brace or with AFO. However there was bruising with unloading knee bracing [30].

Bennell in 2011 conducted the study and compared the role of lateral wedge insole with flat control insole, its effect on subjects symptoms which are divided into groups and how gradually the osteoarthritis progressing which involved the medial side. There was no significant difference in symptoms of both the group subject either in primary or secondary outcomes. It was concluded from the study that there was not prominent symptomatic relief and structural modification with lateral wedge insoles when compared with flat control insole [31].

Ashraf et al in 2013 conducted the study, which aim to compare the available benefits of lateral wedge insole and acupuncture in patients with medial knee OA. Twenty participants included in each group which received the interventions. There was decrease in pain while improvement in functional capacity of subjects. Whereas, there was prominent variation present about the femoral and cartilage thickness ($P = 0.005$, CI: -0.43 - 0.82 and $P = 0.037$, CI: -0.44 - 0.80 respectively) and two ($P = 0.025$, CI: -0.45 - 0.79 and $P = 0.035$, CI: -0.29 - 0.96 respectively) in both groups. The study concluded that both the interventions are equally effective in regard with treatment of medial side knee osteoarthritis [32].

Malvankar et al in 2012 conducted the systematic analysis to find out the role of lateral wedges in management of medial side knee osteoarthritis. There were 10 studies which correlated with the authors inclusion criteria of research analysis. Some studies suggest the role of lateral wedges and its importance in symptomatic relief while in some there was not any importance of lateral wedges in management of knee osteoarthritis. However, some said early osteoarthritis and higher BMI may benefit to a greater extent than those with a greater extent of degenerative changes and lower BMI. The literature is unclear picture with gaps in knowledge and lack of availability of significant amount of data required further studies fill the gap in knowledge about the duration and many other with proper clinical findings and evaluation.

Kerrigan et al in 2002 conducted the study about the role of lateral wedge insole, inclined with 5° or 10° in reducing the varus knee torque in patient with osteoarthritis when walking compared with subjects not using insoles and using non wedge insoles. The results show variation. But in majority cases there was decrease in knee varus torque while walking when compared with groups; not using it and using non wedge insole. When compared group with 5° wedge and group with not using wedge there was approximately 6% reduction in varus knee torque and 8% in case of 10° wedge insole. Although there was no significant difference in speed of walking but 10° wedges were responsible for causing the discomfort among the subjects. The study concluded that 5° wedge soles are more effective than 10° wedge insoles especially when wearing inside the shoes.

Zhang et al in 2013 conducted the study regarding the evaluation of lateral wedges and its role in pain management and improving functional level of individual with knee osteoarthritis involving medial compartment. Meta-analysis of RCT included 10 studies with 938 patients, of which 478 patients prescribed lateral-wedge insoles and 460 patients were set as control group. Statistically, there was no significant difference in pain and functional level when compared group with lateral wedge and control group. The study concluded that lateral wedges didn't help in decreasing pain and optimizing the functional level [33].

Parker et al in 2013 conducted the study about the pain reduction with lateral wedge insole in people with medial side knee osteoarthritis and compare it with control group. There were about twelve study that match with the criteria, some of them received the treatment with lateral wedge insole. The results suggested the favorable association with lateral wedges when compared with control group. This meta-analysis concluded that there were some studies that support the lateral wedge usage but some opposed the intervention in medial side knee osteoarthritis. The findings of various studies doesn't support the intervention for the condition [34].

A study conducted by s.sattari in 2011 to examine lateral wedge and knee brace use in knee OA patient with medial knee compartment involvement. Study shows that lateral wedge have more effective in treatment of medial compartment knee OA as compare to knee brace, ability to walk increase. There was more marked outcome of brace in patients with harsh Degenerative Joint Disease(DJD) during walk at distance when comparing with moderate Degenerative Joint Disease(DJD), usually no effective in high degree pain. Study Conclusion indicates that three point valgus stress knee support effective in pain reduction. Reverse radiological results in lateral wedge insoles(LWI) while using in medial compartment OA. (35).

According to a study conducted by Tom M. van Raaij et al in 2010 that aimed to find the effect of Brace or insoles for managing Medial Knee Osteoarthritis. Results stated that there was no any difference in pain or WOMAC scores between the two different groups. No any device achieved for modification of knee varus malalignment in the frontal plane. According to the OMERACT-OARSI criteria, patients responded 17% to the allocated intervention. Insole group clients respond better with their intervention. Conclusion revealed that laterally wedged insole may be a substitute to the braces of valgus for symptoms of medial knee OA treated noninvasively. (36)

Wolf Petersen et al conducted a study in 2016 that aimed to evaluated effect of unloaded braces for medial compartment osteoarthritis of knee. Results illustrated that twenty articles showed that valgus unloaded braces significantly lessen the knee adduction moment. Seven of those studies reported a decline of pain in braced patients (secondary outcome measure). Positive impression on the knee adduction moment found as custom-built braces for traditional knee braces and for a foot ankle orthosis. It was concluded that this systematic review determined that unloaded braces caused reduction in the adduction moment of the knee. (36)

Study conducted by Kerrigan DC in 2002, aimed to evaluate effectiveness of laterally wedged insole for OA. Results suggested that lateral-wedge

insoles considerably reduced the knee varus torque while walking compared with walking without insole and with non wedged walking 3.175-mm and 6.35-mm controlled insoles. It concluded, Data implied that wedged insoles are effective biomechanically and reduces loading of the medial side in persons with medial knee osteoarthritis. (37)

According to a study conducted by Rana Hinmen in January 2012 to evaluate 73 participants with knee osteoarthritis experienced gait analysis with and without 5° lateral wedges. Conclusion of this study states that lateral wedges significantly reduces knee adduction angular impulse and highest knee adduction moment. It seems a reduced knee-ground reaction force lever arm with lateral wedges is that the central mechanism explaining their load-reducing effects. (38)

Robert J. Butler, conducted this study in april 2007, aimed to guage customised laterally wedged foot orthotic device for the management of medial compartment osteoarthritis. Result stated that walking within the laterally wedged orthotic device significantly reduced the height adduction moment during early stance ($p < 0.01$) compared to the non wedged device. Similarly, the wedged orthotic device extensively reduced the knee adduction excursion from heel strike to peak adduction ($p < 0.01$) compared to the non wedged device. Consistent with the conclusion of the study a subject-specific laterally wedged orthotic device was ready to reduce the peak knee adduction moment during early stance. (39)

Seiichiro Shimada conducted this study in November 2006. To determine the effects of lateral wedged insoles on knee kinetics and kinematics during walking. Results shows that Application of lateral wedged insoles significantly compact the peak external adduction moment in Kellgren-Lawrence grades I and II knee OA patients. Conclusion of the study states that kinematic and kinetic effects of wearing lateral wedged insoles were considerable in Kellgren-Lawrence grades I and II knee OA. (40)

Matthew J. Parkes conducted this study in june 2015, to figure out the outcomes of lateral wedge insoles reduce pain in patients with medial knee osteoarthritis compared with an appropriate

control. Consistent with the results although meta-analytic pooling of all studies showed a statistically significant association between use of lateral wedges and lower pain in medial knee osteoarthritis, restriction of studies to those employing a neutral insole comparator did not show a major or clinically important association. These findings do not support the utilization of lateral wedges for this indication. (41)

John B. Arnold conducted this study in 2015. The objective of the study was to evaluate lateral wedge insoles for progression of biomechanical risk factors of medial knee osteoarthritis (OA), such as increased knee joint load. Results stated that lateral wedge insoles cause minor reductions in the KAAI and EKAM throughout walking in people with medial knee OA. It is concluded that existing evidence demonstrates that lateral wedge insoles came out ineffective at easing structural changes in people with medial knee OA as a whole and may be better suitable to targeted use in biomechanical phenotypes associated with major reductions in knee load. (42)

Ryan T Lewinson conducted this study in November 2016, to find knee osteoarthritis (OA) progression that has been linked to increased maximum external knee adduction moments (KAMs). Results of this study declared that although some trials have attempted to decrease pain and recover function in OA with a wedged shoes insole intervention by reduction in KAMs. Therefore with this study it concludes that it has strong clinical implications regarding personalized recommendation of wedged insoles. (43)

Henry Ch Fu conducted this study in 10 march 2015, to estimate the effectiveness of diverse orthotic treatments for patients with medial section OA. Compared with pretreatment results, lateral-wedged insole(LWI) with arch support, the lateral wedged insole(LWI) and valgus knee brace groups confirmed significant reductions in WOMAC pain score. According to the conclusion the use of orthotic treatment support for initial medial compartment knee osteoarthritis. (44)

Yoann Dessery conducted this study in august 2016, to assess the effects of foot orthoses with medial arch support and lateral wedge(LW) on patients with medial osteoarthritis(OA). Results shows that a significant increase of 7% in knee adduction moment during the loading response was observed in the modified foot orthoses without lateral inclination. Conclusion of the study suggests that customized foot orthoses with a medial arch support may only be suitable for the management of medial knee osteoarthritis(OA) when a lateral wedge(LW) is included. (45)

RoshanakaBaghaeiRoodsari conducted this study in march 2016. The aim of this study was to calculate the consequences of knee braces and foot orthoses on knee adduction moment, function and pain in individuals with knee osteoarthritis(OA). The results of the analysis of those studies proved that orthotic devices reduce knee adduction moment and also improve pain and performance in individuals with knee osteoarthritis(OA). Conclusion of this study states that foot orthoses could also be simpler in improving pain and function in subjects with knee osteoarthritis(OA). Both knee braces and foot orthoses reduce the knee adduction moment in knee osteoarthritis(OA). (46)

Bilge Yilmaz conducted this study in august 2016. The purpose of this study is to look at the effect of 5 and 10° LWI on unilateral lower extremity load carrying line in clients with medial knee OA. The load carrying lines measured as the results shows with 5° and 10° LWI were remarkably laterally situated compared to that with not wearing insole. 10° LWI caused a important more lateral shifting of the load carrying line than 5° LWI. Conclusion affirms that both wedge insoles were effective in rotation of the unilateral lower extremity load carrying line to the lateral. In clients with medial knee osteoarthritis Lateral wedge insole(LWI) are biomechanically effective and reduce loading of the medial compartment .

(47)

YoannDessery conducted this study in May 2016. Lower-extremity gait kinetics were characterized by a significant decrease, greater than 6%, in

second peak knee adduction moment in laterally wedged insole conditions compared to the other conditions . Conclusion suggests that customized foot orthoses with a medial arch support may only be suitable for the management of medial knee osteoarthritis when a lateral wedge is included. (48)

Pollo FE et al conducted a study in 2002 regarding effectiveness of knee bracing to reduce load from medial compartment of knee among osteoarthritis patients. Results shows that with valgus bracing Pain and activity level enhanced in all subjects. The net varus moment about the knee valgus bracing reduce During gait, by an average of 13% (7.1 N.m) and the medial section load at the knee by an average of 11% (114 N) in the valgus brace 4 degrees calibrated setting. Conclusion suggested that it was effective reducing medial compartment load and subsequent pain in Adjustable valgus bracing while also improving knee function in a group of clients with OA. (49)

Pagani CH et al conduct study to evaluate the effect of knee orthosis among patients with osteoarthritis. Results stated that improvement in function compared with the condition without orthosis and both orthosis adjustments induced subjective pain release. It is concluded that however, a decrease in knee loading was more effective using the 4° valgus adjustment, which could contribute to avoidance of disease progression, orthosis adjustments were effective in decreasing symptoms. (50)

ClinBiomech et al studded in 2011 regarding effect of knee brace unloading for patients with medial knee OA. According to the results in stance phase the ipsilateral hip in the braced condition show that a lower adduction angle by an average of 2.58° (range, 1.05°-4.16°) during 1%-49% , during the stance phase the lower abduction moment at the second peak of the hip in the unbraced condition. Conclusion states that During gait the contralateral knee adduction angle pattern the unloading modified brace at a specific time point . when treating knee OA the Consideration should be provid to the other joints . (51)

Lewinson et al in 2012 studied the reduction in knee joint loading and its relationship with medial and lateral wedge insoles in medial compartment osteoarthritis. There was inconsistency in results of this study due to severe problems including inadequate controlled intervention application. But the purpose of this study primary to identify the effects of reduced KAMs on knee OA pain and function (52).

In 2015 a study conducted by campos et al to explore the role of lateral wedge in OA in RCT. Study results shows that the WOMAC and VAS have no such differentiating point when compare to pain at 8 and 24 weeks interval after intervention. Hence conclusion of study shows that lateral wedge having no such role in OA (53).

A study conducted by merchant et al in 2019, to analysis the orthosis role in knee OA. Study results shows that knee braces that reduced the load over knee causes adduction movement decrease and also helps in reduction of stiffness in knee joint and pain ultimately results in improved quality of life. lateral wedge in shoes as insole also decrease the load on joint. Conclusion of study suggest that effectiveness knee orthosis in OA is questionable. (54).

CHAPTER III METHODOLOGY

1. STUDY DESIGN

This study was experimental study

2. STUDY SETTING

Participants were selected from "ISRA hospital", Hyderabad.

3. DURATION OF THE STUDY

Three months after the approval of synopsis.

4. SAMPLING TECHNIQUE

Purposive sampling was used

5. SAMPLE SIZE

30 participants were selected for the study.

5.1 Inclusion Criteria

1. Age range of patients 40 to 60 years.
2. Patients with Grade 3 and Grade 4 of arthritis were selected.
3. Both Male and Female participants were selected.
4. Patients with moderate to severe pain in NPRS scale were selected.
5. Diagnosed cases of osteoarthritis were selected.
6. Patients with narrowing of medial compartment of knee were selected.
7. Participants who willing to participate.

5.2 Exclusion Criteria

1. Patients with Grade 1 and Grade 2 of osteoarthritis were excluded.
2. Patients with narrowing of lateral compartment of knee were excluded.
3. Patient with fracture of lower limb were excluded.
4. Open wounded patient or knee and foot were excluded.
5. Patients who were using any medications 1 week prior to the participation.

6. Data Collection Tool

- Knee injury and Osteoarthritis Outcome Score (KOOS)
- Numeric Pain Rating Scale

7. Radiography:

- In osteoarthritis of knee when we go for radiography it is noted than narrowing of space, osteophytes, sclerosis



8. Data Collection Procedure

30 participants were selected and was divided into two groups by chit method. Group "A" was given Knee brace and Group "B" was given lateral wedge insole.

Application of Knee Brace

For Group "A" 3 point varus correction custom molded knee brace that was fitted for each patient individually by an orthotist.

Donning and doffing:

patient will be instructed to do it on and off every 2-3 hours for the first week. Then after 1-week patient will be instructed to wear knee braces whole the day and take off at night. (48)



Knee brace

Application Of Lateral Wedge Insoles

For Group “B” 1/4 inches lateral wedge insoles. They will be instructed to apply the wedge all the

time they wear shoes. Measurements will be taken before the interventions and 3 month after the interventions. (48)



Lateral wedge

9. Ethical Consideration

Data will be collected after approval of ethical review committee of ISRA institute of rehabilitation sciences Karachi campus. Confidentiality of data will be secured and the

identity of patients will be coded. Informed consent from each participant will be taken.

10. Budget

The budget of the study will be around 50,000 PKR.

CHAPTER IV

RESULTS

Table 1 Lateral wedge and Knee brace distribution among genders

Gender	Lateral wedge	Knee brace
Male	7	5
Female	8	10
Total	15	15

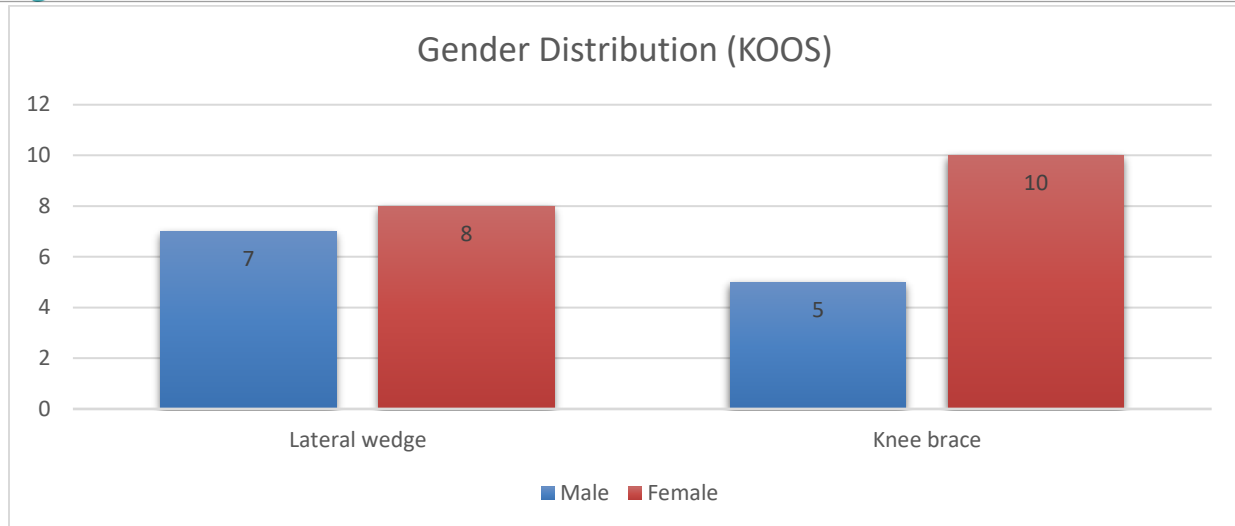


Figure 1 Lateral wedge for gender with 15 participants, 8 of them were female and 7 of them were male

Table IV-2: Age of the participants

	N	Percent	Mean	SD
Age of participants in Lateral Wedge group	15	100.0%	51.1	6.51226
Age of participants in Knee Brace Group	15	100.0%	49.6	4.35343

Table 2 Age wise gender in Lateral Wedge and Knee brace

Gender	Age	Lateral wedge	Knee brace
Male	40-50	4	3
	50-60	3	2
Female	40-50	5	9
	50-60	3	1
Total		15	15

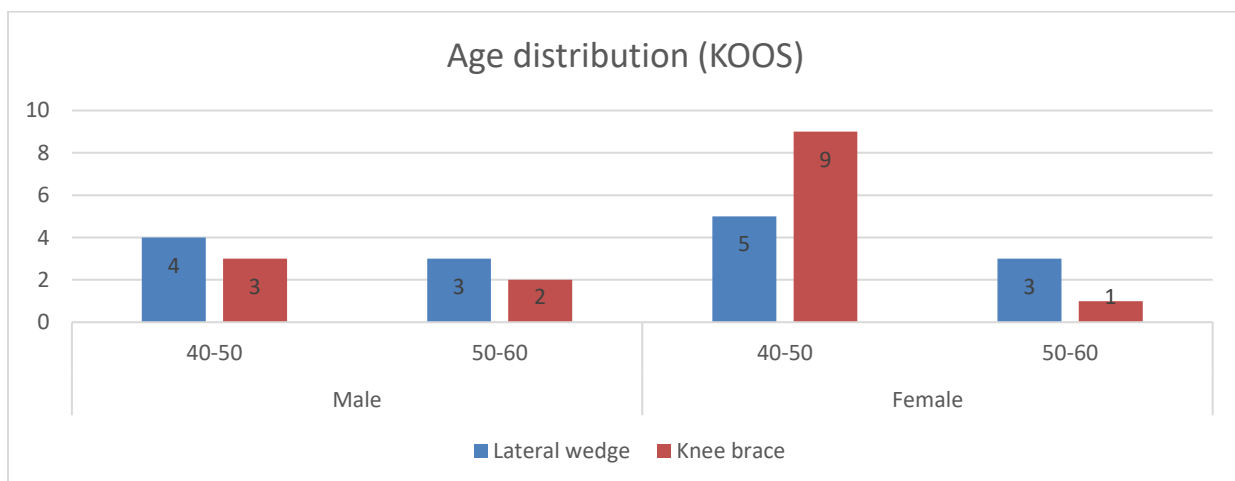


Figure 2 Age distribution of lateral wedge and knee brace, from the figure its clear that female ration in both later wedge and knee brace is more than male.

Table 3 Mean, SD, and p-value of later wedge and knee brace

KOOS Score	Lateral Wedge		Knee Brace		p-value
	Mean	SD	Mean	SD	
Pre	45.75	6.04	47.44	4.86	> 0.05
Post	78.08	8.92	59.87	3.8	< 0.05

*p<0.05 was considered significant using Paired Sample t-test

Result of the KOOS shows that pre and post deference was in lateral wedge group as compare to knee brace group.

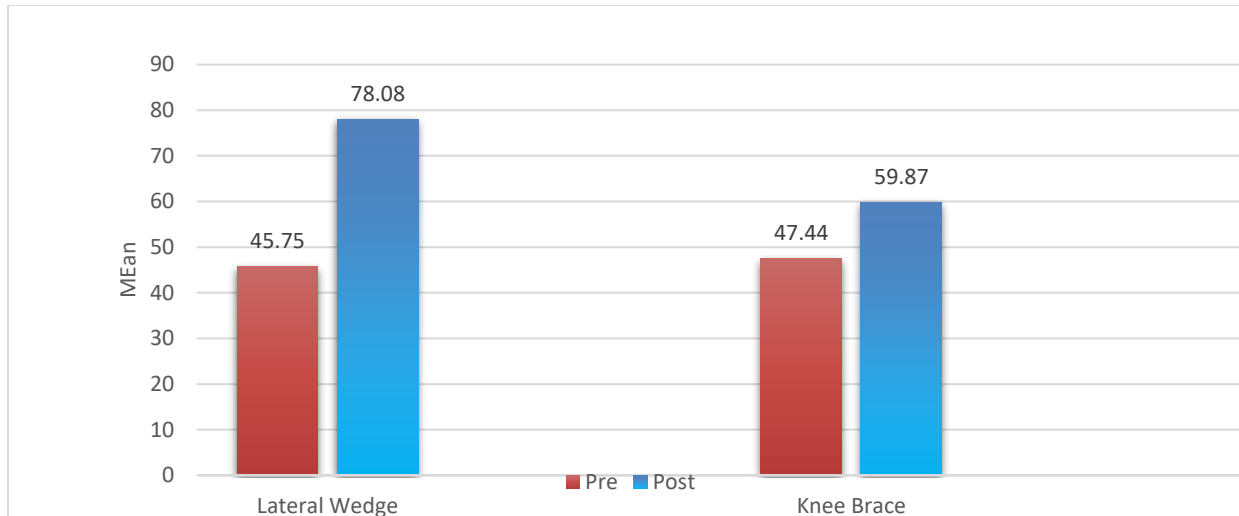


Figure 3 Mean comparisons of lateral wedge and Knee brace patients at pre and post level of treatment

Table 4 t-Test of pretreatment of (Lateral wedge and Knee brace)

t-Test: Two-Sample Assuming Unequal Variances

	Pre-Lateral Wedge	Pre-Knee Brace
Mean	45.74667	47.44
Variance	36.5741	23.65829
Observations	15	15
Hypothesized Mean Difference	0	
df	27	
t Stat	-0.84503	
P(T<=t) one-tail	0.20276	
t Critical one-tail	1.703288	
P(T<=t) two-tail	0.405519	
t Critical two-tail	2.051831	

Table 5 t-Test of Post treatment of patients of (Lateral wedge and Knee brace)

t-Test: Two-Sample Assuming Unequal Variances

	Post-Lateral Wedge	Post-Knee Brace
Mean	78.08	59.86667
Variance	79.59314286	14.46095
Observations	15	15
Hypothesized Mean Difference	0	

df	19
t Stat	7.273546346
P(T<=t) one-tail	3.34403E-07
t Critical one-tail	1.729132812
P(T<=t) two-tail	6.68806E-07
t Critical two-tail	2.093024054

Table 6 Lateral wedge and Knee brace distribution among genders

NPRS Score		
Gender	Lateral wedge	Knee brace
Male	6	5
Female	9	10
Total	15	15

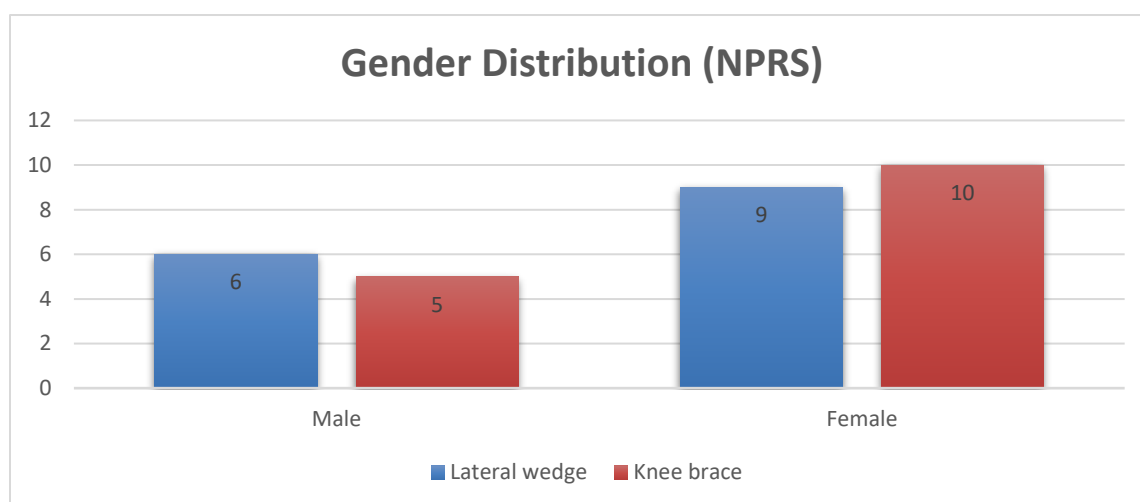


Figure 4Lateral wedge and Knee brace for gender with 15 participants

Table 7Age vise gender in Lateral Wedge and Knee brace

NPRS			
Gender	Age	Lateral wedge	Knee brace
Male	40-50	3	2
	51-60	3	3
Female	40-50	6	9
	51-60	3	1
Total		15	15

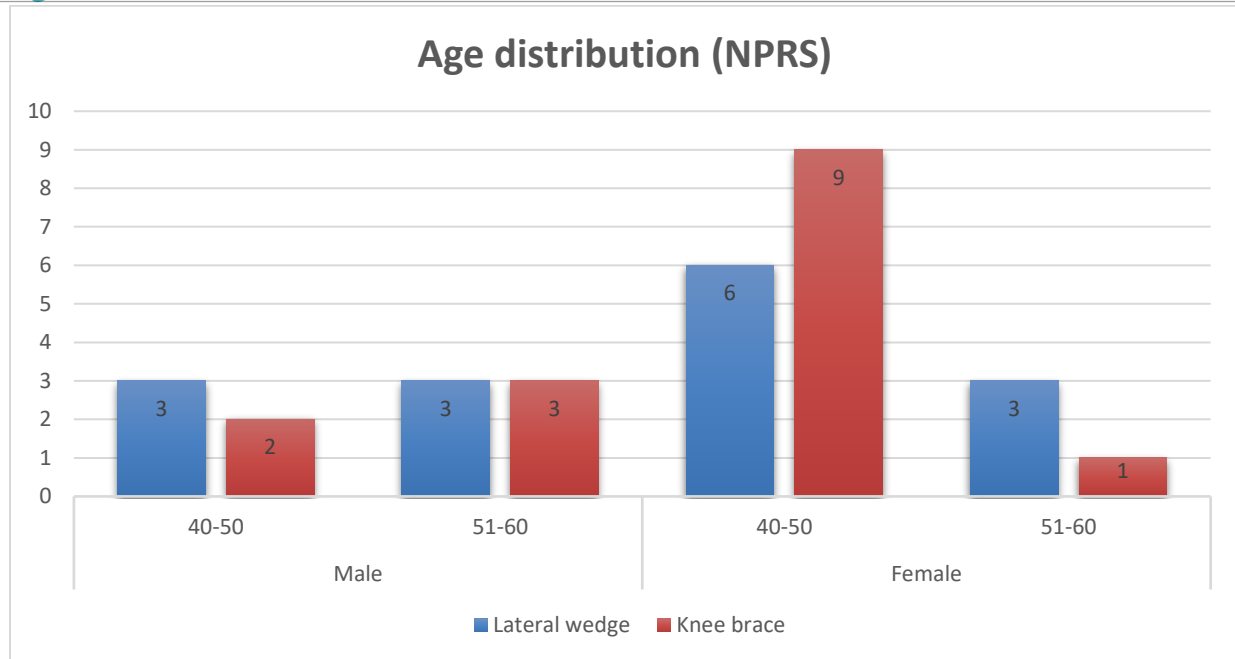


Figure 5 Age distribution of lateral wedge and knee brace, from the figure it is clear that female ration in both later wedge and knee brace is more than male.

Table 8 Mean comparison of KOOS and NPRS Scores between Lateral wedge and Knee Brace patients after treatment

Post Treatment	Lateral Wedge		Knee Brace		p-value
	Mean	SD	Mean	SD	
KOOS	78	8.92	59.8	3.802	<0.05*
NPRS	4.8	0.915	4.9	0.798	>0.05*

*p<0.05 considered significant using independent sample t-test

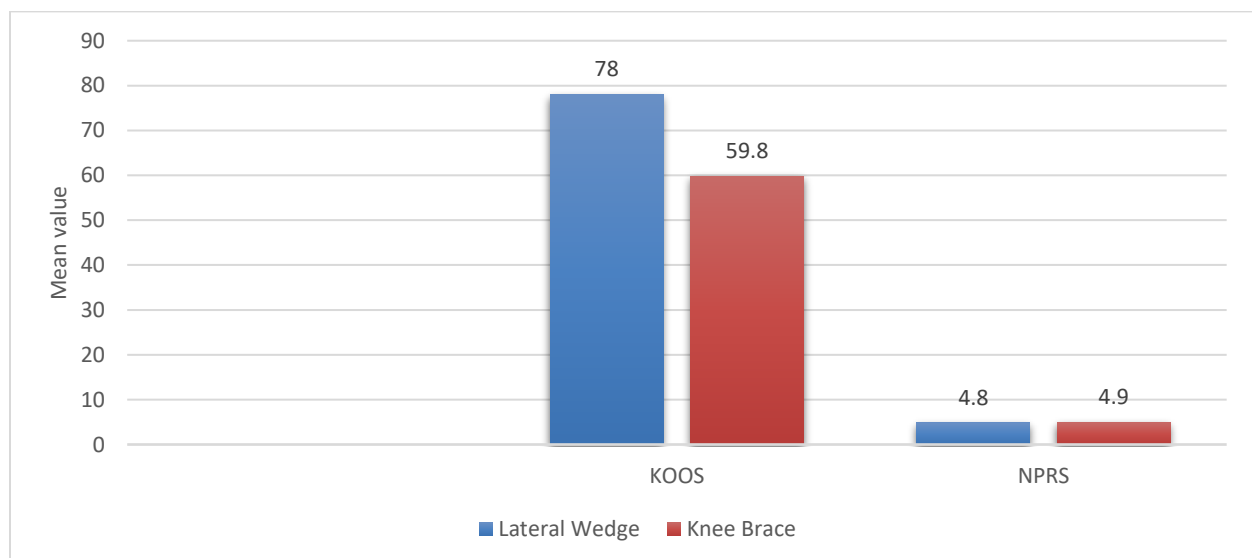


Figure 6 Figure 3 Post treatment of mean values of lateral wedge and Knee brace patents at pre and post level of treatment

Table 9 t-Test of Post treatment of both Lateral wedge and Knee brace
t-Test: Two-Sample Assuming Equal Variances

<i>NPRS</i>	<i>Post-Lateral wedge</i>	<i>Post-Knee brace</i>
Mean	5.866666667	4.266666667
Variance	0.838095238	1.495238095
Observations	15	15
Pooled Variance	1.166666667	
Hypothesized Mean Difference	0	
df	28	
t Stat	4.056740423	
P(T<=t) one-tail	0.000180419	
t Critical one-tail	1.701130934	
P(T<=t) two-tail	0.000360837	
t Critical two-tail	2.048407142	

Table 10 t-Test of pre treatment of both Lateral wedge and Knee brace
t-Test: Two-Sample Assuming Equal Variances

<i>NPRS</i>	<i>Pre-Lateral Wedge</i>	<i>Pre-Knee Brace</i>
Mean	7.6	7.533333333
Variance	0.828571429	1.123809524
Observations	15	15
Pooled Variance	0.976190476	
Hypothesized Mean Difference	0	
df	28	
t Stat	0.184787287	
P(T<=t) one-tail	0.427363913	
t Critical one-tail	1.701130934	
P(T<=t) two-tail	0.854727826	
t Critical two-tail	2.048407142	

Table 11 Mean comparisons of NPRS Scores of Lateral wedge and knee brace patients at pre and post level of treatment

NPRS Score	Pre		Post		p-value
	Mean	SD	Mean	SD	
Lateral Wedge Patients (n=15)	7.6	0.910	4.8	0.915	<0.01*
Knee Brace Patients (n=15)	4.9	1.06	4.9	0.798	<0.01*

*p<0.05 was considered significant using Paired Sample t-test

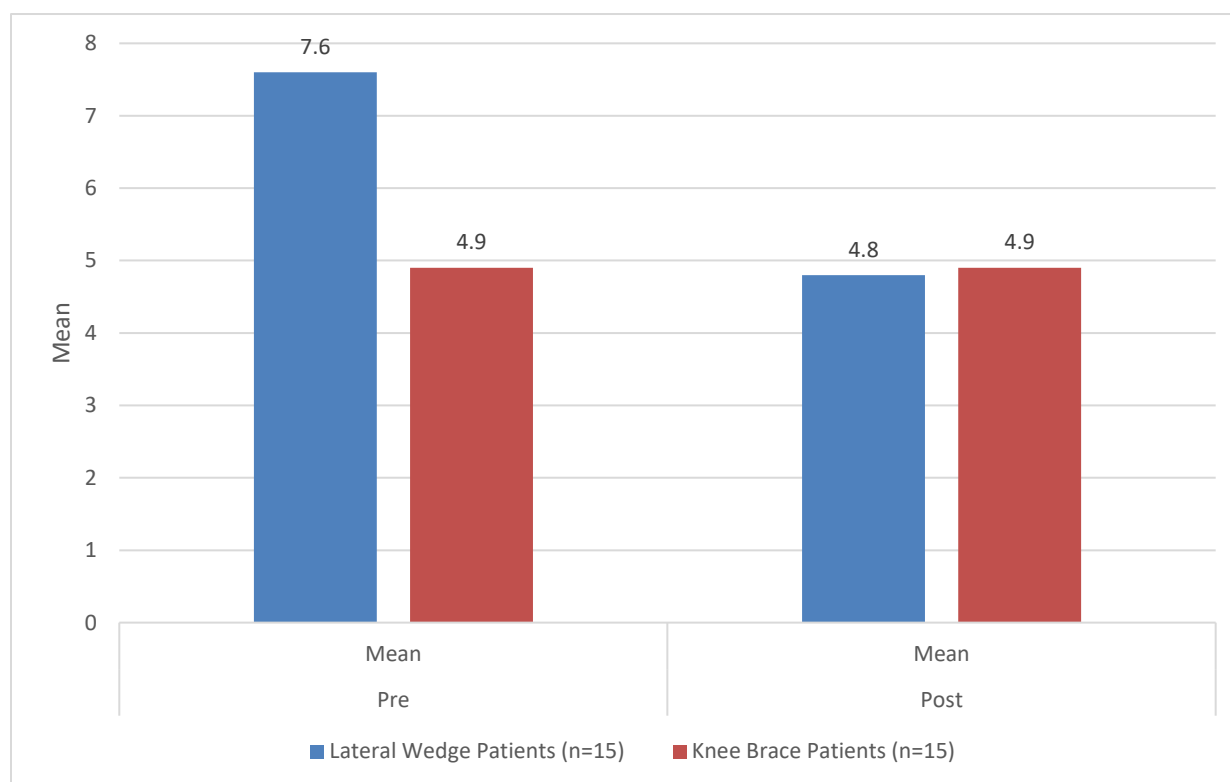
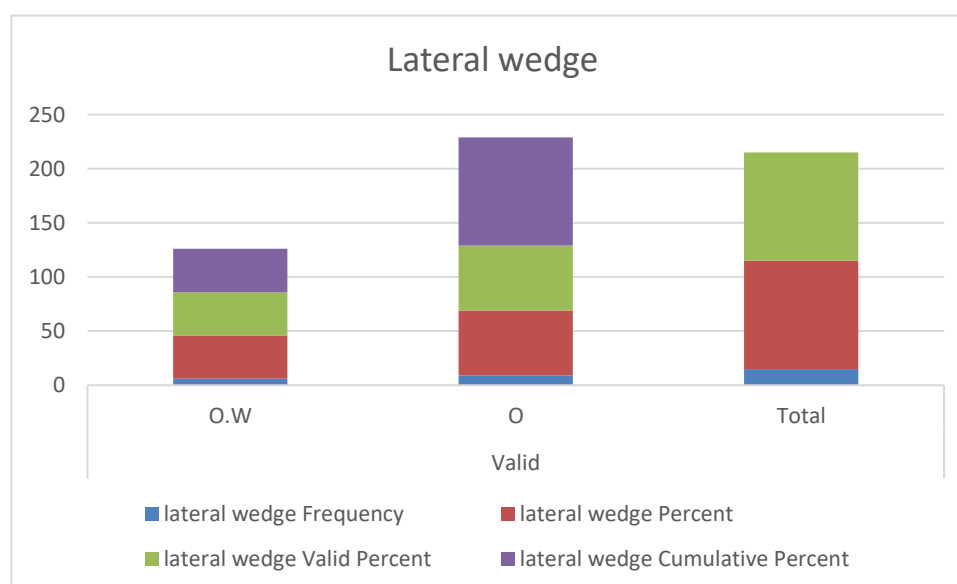


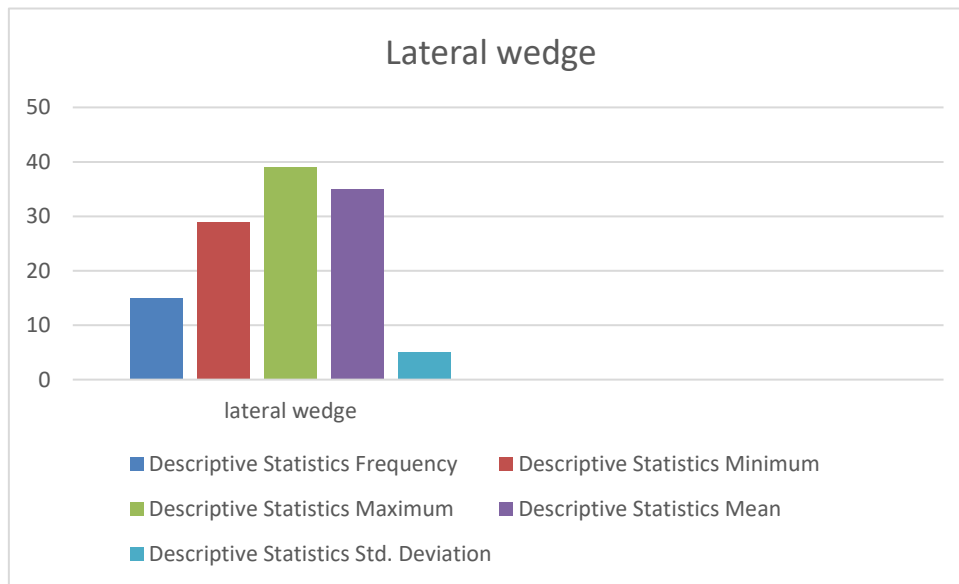
Figure 7 Mean comparisons of lateral wedge and Knee brace patients at pre and post level of treatment lateral wedge

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	O.W	6	40	40	40
	O	9	60	60	100
	Total	15	100	100	



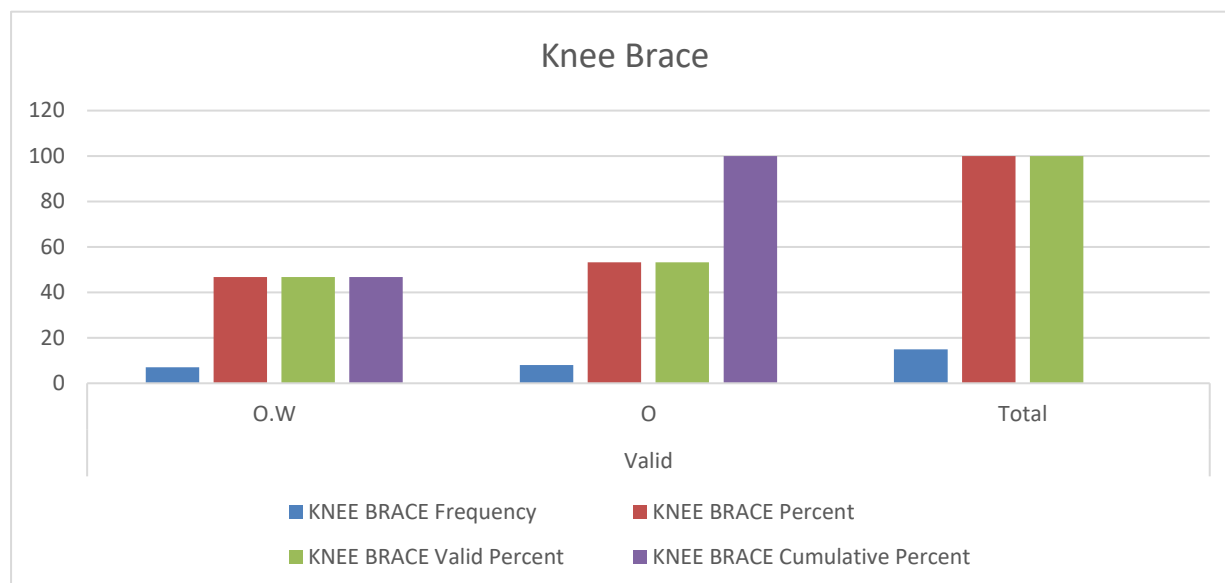
Descriptive Statistics

	Frequency	Minimum	Maximum	Mean	Std. Deviation
lateral wedge	15	29	39	35	5.07093



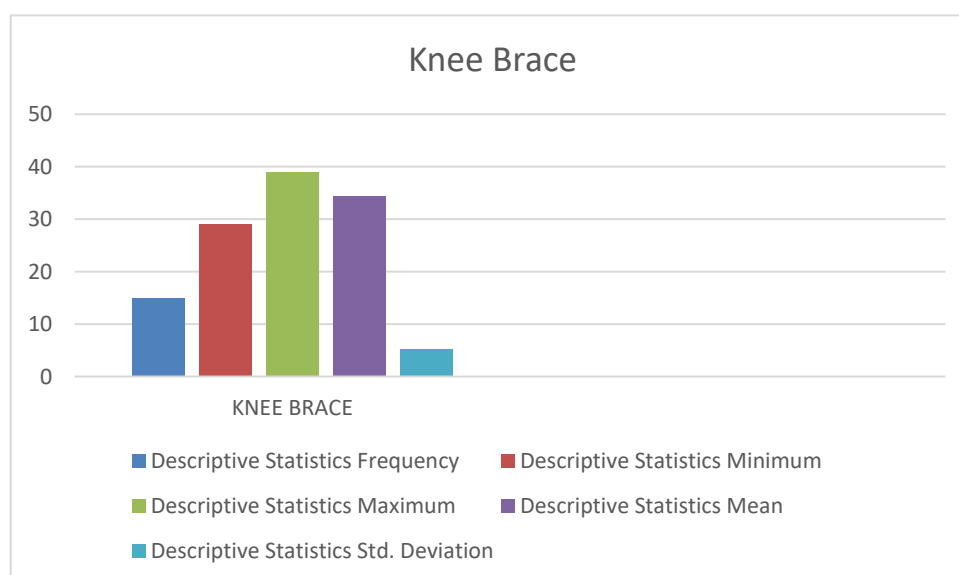
KNEE BRACE

	Frequency	Percent	Valid Percent	Cumulative Percent
Valid O.W	7	46.7	46.7	46.7
O	8	53.3	53.3	100
Total	15	100	100	



Descriptive Statistics

	Frequency	Minimum	Maximum	Mean	Std. Deviation
KNEE BRACE	15	29	39	34.3333	5.16398



CHAPTER V DISCUSSION

This experimental study was conducted on 30 patients having knee OA. Aim of this study was to find out the effectiveness of knee brace and lateral wedge among patients with medial compartment knee OA. There were many studies done previously on same objective. In our study lateral wedge group comprises of 15 participants while knee brace group also of 15 patients.

According to KOOS score, patients with lateral wedge had mean value of 45.7 (6 SD) at the pre-level of treatment, which was increased upto 78 (8.9 SD) at post-level. Similarly mean value 47.4 (4.8 SD) at the pre-level treatment of patients with knee brace and 59.8 (3.8 SD) at the post-level of treatment.

In our study, according to NPRS score mean value was 7.6 (0.9 SD) in the lateral wedge group at pre-level of treatment while it was 4.8 (0.9 SD) at post-level. In patients with knee brace mean value was 4.9 (1.0 SD) at the pre-level treatment which was almost same at post-level i.e. 4.9 (0.79 SD).

On comparing results of both KOOS and NPRS scores after treatment of both groups. Mean value was 78 (8.9 SD) in lateral wedge group according to KOOS score while mean value was 4.8 (0.9 SD) according to NPRS score. Mean value was 59.8 (3.8 SD) according to KOOS score in patients with knee brace while 4.9 (0.7 SD) according to NPRS score.

Another study was conducted by Kerrigan DC in 2002. Results of which suggested that lateral-wedge insoles (LWI) significantly reduced the knee varus torque during walking compared with walking with no insole and walking with non wedged 3.175-mm and 6.35-mm control insoles. It is concluded that data imply that wedged insoles are biomechanically effective and should reduce loading of the medial compartment in persons with medial knee osteoarthritis.

Henry ChFu conducted a study in 2015, Results stated that Compared with pretreatment, the lateral wedged insole, lateral-wedged insole with arch support, and valgus knee brace groups demonstrated significant reductions in WO-

MAC pain score. The conclusion supports the use of orthotic treatment for early medial compartment knee osteoarthritis.

Another study was conducted by Bennell in 2011 conducted to compare the role of lateral wedge insole with flat control insole. There was no significant difference in symptoms of both the groups subjected either in primary or secondary outcomes. It was concluded from the study that there was no prominent symptomatic relief and structural modification with lateral wedge insoles when compared with flat control insole. In short, this study shows that lateral wedge is more effective than knee brace in the treatment of medial compartment knee OA.

Another study mentioned by Wilson (2011) that an un-loader brace is effective in providing short-term pain relief and improved function; however, most patients subsequently opt for total knee replacement on the symptomatic knee, found statistically significant difference in osteoarthritis grades (3.47 vs. 2.0; $P \leq 0.05$) for patients who had undergone arthroplasty versus patients with un-loader brace, we also demonstrate the similar result. All patients who underwent arthroplasty reported that brace use had been effective in temporarily relieving pain. A further study by Tom et al (2010) examined no differences in pain scores between the wedged insoles or valgus braces as (5.7 ± 3.0 vs. 5.6 ± 2.2 ; $P\text{-value} > 0.05$) and WOMAC score (46.5 ± 18.9 vs. 46.8 ± 18.2 ; $P\text{-value} > 0.05$), although laterally wedged insole may be an alternative to valgus bracing for noninvasively treating symptoms of medial knee OA, also observed no differences between the insole group and the brace group for VAS pain scores and WOMAC function scores. (22)

Conclusion

The conclusion of my research is patients were more satisfy with the lateral wedge Because they feel more comfortable with the lateral wedge then knee orthosis. Knee orthosis is heavy in weight as compare to lateral wedge. It is difficult to hide knee orthosis. Whereas lateral wedge is easily fit in the shoe and reduces pain while walking.

But some patients say that they want to use the knee orthosis because they feel secure while using

the KO. The females were give positive response of lateral wedge because they were more prone to cosmoses.

The overall results and discussion shows that the patient having osteoarthritis were more satisfy with the lateral wedge as compare to knee orthosis.

The weight of the lateral wedge is less than the knee orthosis, so the patients were more likely to use lateral wedge as they are old age and feel difficult to carry the heavy brace.

Recommendation:

I will recommend that future research should be large sample size and I choose only grade 3 and 4. Future study should include grade 1 and 2. My study population is only from isra university Hyderabad for future it should be on large area.

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