Expert Consensus

Implication of Unloader Braces in guideline recommended knee OA management

Who, when and how?

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Guidelines for the treatment of knee osteoarthritis have been published by a number of expert groups. The goal was to provide a tool which helps medical professionals to select the right patient and to provide guidelines for when and how to use an unloader brace for different patient types. Experienced physicians discussed these questions in-depth and developed corresponding suggestions to achieve the best possible treatment outcome for the following patient groups: the younger knee osteoarthritis (OA) patient, the active & demanding knee OA patient and the older knee OA patient.

Introduction:
There is no cure for osteoarthritis (OA). Treatment is palliative in nature, starting with exercise and lifestyle modifications and simple analgesics (e.g. acetaminophen or non-steroidal anti-inflammatories (NSAIDs)), progressing to injections (corticosteroids, viscosupplementation and platelet-rich plasma) and ultimately joint replacement. However, the effect of pharmaceuticals is limited and is accompanied by a potential risk of side effects, in elderly patients these risks can be high and severe. While joint replacement is successful, its use is generally reserved for the older population (>65 years of age) because of the limited life of the prosthesis. Furthermore, patients are reluctant to undergo surgery unless they have exhausted less invasive alternatives. Finally, some reimbursement agencies are now requesting proof of tried and failed non-surgical treatment prior to the funding of arthroplasty. Actual knee OA guidelines published by OARSI and ACR (American College of Rheumatology) recommend the use of biomechanical interventions including unloader braces for knee OA patients without and with co-morbidities such as gastro-intestinal problems, renal dysfunction or other when appropriate.[1,2]

Unloader braces are designed to reduce load in the affected compartment of the knee. So far, no one has managed to measure the compartmental load in a real OA knee during gait. The most commonly used surrogate measure of compartmental load is the frontal plane moment about the knee. A meta-analysis by Moyer et al. also looked at the change in knee adduction moment. They included 17 published articles and concluded that braces do reduce the knee adduction moment and this change is highly significant (effects size 0.61, $p<0.001$).[3]

In addition to reducing knee adduction moment, knee osteoarthritis braces have been shown to increase the joint space in the affected compartment when wearing the brace, reduce compartmental load in subjects with total knee replacements and improve proprioception. Notably, Katsuragawa et al. showed a large and significant increase in bone mineral density in the lateral knee compartment relative to the medial compartment when wearing an unloader brace for medial knee osteoarthritis. This strongly supports the argument that the unloader brace shifts load off the medial compartment, as it is known that bone adapts to the loads under which it is placed.[4]

One concern that people have about the use of bracing is that it reduces strength of the muscles supporting the knee. However, to date, two studies have investigated this hypothesis and found that muscle strength about the knee increased with use of osteoarthritis knee braces.[5,6] The hypothesized explanation for this is that the reduction in pain allows for increased activity and thus increased knee strength.

As recommended by the recently published knee osteoarthritis guidelines, the patient with knee osteoarthritis should increase activity, reduce weight and increase strength. For many patients however, their pain prevents them from becoming more active, thus making weight loss and strength training more difficult. Unloader knee braces -either on its own or in conjunction with pharmaceutical treatment - can provide rapid pain relief enabling patients to increase their activity levels, thus reduce weight and build strength. By reducing the load in the affected compartment, unloader braces should also protect the affected joint compartment from mechanical overload which may otherwise result in a faster progression of the disease.

Methodology:
Questionnaires on current practice of conservative management of symptomatic knee OA were used to prepare an on-site meeting with OA experts from the US and Canada. The questionnaires were collected and the answers analyzed. Based on this feedback, a meeting was conducted and results of the questionnaires were discussed intensively. Within this discussion, the experts agreed patient group specific treatment recommendations, which have been consented thereafter in two Delphi rounds.

Recommendations:

General

Unloader braces are used in an individual OA management approach beside guideline recommended core treatment in order to avoid surgery in Kellgren-Lawrence (KL) grade I-III uni-compartmental knee OA patients suffering from moderate to severe knee pain. For patients with end stage knee OA, Unloader braces can be used to meet Center for Medicare Services (CMS) requirements for conservative treatment prior to TKA. Unloader braces can be used in patients eligible for high tibial osteotomies (HTO) in order to identify those patients who will most likely benefit from a HTO.

Who should get an Unloader brace?

Patients with varus or valgus knee OA with clinically relevant knee pain affecting activities of daily living. Also, patients indicated for total knee arthroplasty (TKA) who do not want a TKA yet or TKA is contraindicated. Patients should have an active lifestyle and understand the concept and instructions on how to use the Unloader brace.

Age and OA stage are not valid parameter to select the right patients for an Unloader brace. Therefore, the authors recommend an unloader-brace-test (UBT) after selecting the brace which fits best to their individual needs and anatomy.

After initial fitting, the brace should be tested for 5-10 minutes. Within this time, patients should walk on flat ground, walk stairs (up and down) and check if they are able to don and doff the brace. For the Unloader One brace, it is known that patients can feel an immediate onset of pain relief within the UBT.[7] Those patients are "responders" and should most likely benefit from an Unloader brace.

For patients with peripheral vascular disease, neuropathy and sensitive skin, close physician supervision is recommended.

Managing patient's expectations

Within non-surgical knee OA management, it is important to manage patient's expectations. Non-surgical knee OA management is treating symptoms and not the disease itself. If symptoms like knee OA pain and knee function are improved, patients have to adapt their lifestyle and adjust body weight if indicated. Patients should be informed that a brace, even if lightweight and easy to use, is still a brace and „You may not love this brace, but you will love what it does for you". Based on the experience and available clinical data for the Unloader One brace, patients can expect clinically relevant pain relief and improvement of knee function.[8,9]

When to use an Unloader brace?

The Unloader brace during the day while being active. To start with the brace, it is helpful to start using the brace for a couple of hours only to get used to the brace. A clinical control should take place at 2-4 weeks but can be done by the clinician as well to ensure a proper fit of the Unloader brace. Outcome of the knee OA management should be evaluated by the physician 2-6 weeks after treatment has been initiated. By experiencing less pain patients will increase their activities automatically – so there is no need to ask patients to increase their activity levels by the prescriber.

How to implement Unloader braces within individual conservative knee OA management?

In general, a stepped care approach should be considered to address patient's needs. A stepped care approach is related to the symptoms of knee OA in young, active and demanding patients and includes three different treatment phases: The acute, the subacute and the chronic phase. For the older patient (>65 years) suffering from symptomatic knee OA, the experts only identified an acute and a chronic ongoing treatment

phase and agreed that knee OA non-responders of the acute and chronic phase presenting end-stage knee OA should be referred to surgical therapy (uni-TKA or TKA).

Treatment of knee OA pain is based on adequate evaluation of patient history, psycho-social factors, clinical examination and adequate x-ray diagnostics. Guideline recommended core treatment (education, strength training, exercise (+if applicable body weight management) should be initiated. In case of knee effusion/ synovitis, cryotherapy, NSAIDs and corticosteroid injections are indicated as short term treatment, if no contraindications exist. Whenever patients have received narcotics/ opioids i.e. during a visit in an emergency room, the experts recommend discontinuing or establishing a titration schedule to discontinue.

Especially for the younger and active demanding knee OA patient, special physiotherapy techniques such as vasocompressive cryotherapy, addressing gait mechanics, performing manual therapy and restoring neuromuscular control should be considered.

In addition, core-treatment biomechanical interventions such as an Unloader brace or shoe inserts are indicated in the case of varus / valgus malalignment in all types of younger of OA patients. Whereas insoles provide lower amount of unloading, unloader braces provide higher amounts of unloading. Some braces also allow adjustable unloading by the patient (i.e. Unloader One or Unloader FIT).

In case of synovitis and effusion, corticosteroid injections are recommended in all patient groups. Viscosupplementation and PRP may be considered in patients in the subacute phase or if they have responded to this treatment options in the past.

It is important to mention, that the patient should be actively involved in the management of knee OA. To the extent that pain and limitations in function are experienced, patients can be encouraged to develop self-management strategies that reduce pain, improve sleep and function, and reduce the emotional distress that can accompany OA. National Arthritis Foundation usually offers a series of disease management classes. For other patients, referral to professionals trained in evidence-based pain self-management, based on cognitive-behavioral principals, may be indicated for optimal outcomes.

Specific treatment recommendations for different patient groups:
The following graphs show the experts' consensus on the management of symptomatic knee OA in the described patient groups. Please note: Co-morbidities and current medication need to be checked carefully in order to select the appropriate pharmaceutical treatment.

Treatment recommendation for the younger knee OA patient

Who is the younger knee OA patient?
For this expert recommendation, the younger knee OA patient is considered to be younger than 65 years and may have knee OA as a result of previous surgeries. The recommendations are made for patients without any type of knee surgery in the last twelve months.

ACUTE PHASE	SUBACUTE PHASE		CHRONIC PHASE	
WEEK 0–6	RESPONDERS WEEK 7–12	NON-RESPONDERS WEEK 7-12	RESPONDERS > 3 MONTH ONGOING	NON-RESPONDERS > 3 MONTH ONGOING
Check patient history, clinical exam X-ray Education Modify activities Physical therapy Weight management Ice NSAIDs Corticosteroid injection *(if appropriate)* Unloader brace Insole Shock absorber Acupuncture TENS	Check patient history, clinical exam Education Weight management Activity ↑ Strength training Home exercise Ice, if needed NSAIDs Unloader brace Insoles	Check patient history, clinical exam MRI Cognitive behavioral therapy NSAIDs Injections: Corticosteroid, HA, PRP Modified activity Weight management Ice., as needed Unloader brace Insoles *Discontinue failed treatment*	Check patient history, clinical exam Education Weight management Management of expectations Activity ↑ Strength training Home exercise (NSAIDs as needed) Unloader brace Cognitive behavioral therapy	Check patient history, clinical exam MRI (if not done yet) Check on co-morbidities (not including psych-social factors) Injections: Corticosteroid, HA, PRP (if not done yet) Check compliance Consider surgery consult Cognitive behavioral therapy

Figure 1: Expert´s consensus of knee OA management in the younger patient (< 65 years + post-traumatic knee OA)

Abbreviations:

HA: Hyaluronic acid

NSAIDs: Nonsteroidal anti-inflammatory drugs

MRI: Magnetic resonance imaging

PRP: Platelet-rich plasma

TENS: Transcutaneous electrical nerve stimulation

Treatment recommendation for the active and demanding knee OA patient

Who is the active demanding patient?
The active demanding patient is considered to perform activities of moderate to vigorous level, competitive athlete. Belonging into this patient group is not age dependent.

ACUTE PHASE	SUBACUTE PHASE		CHRONIC PHASE	
WEEK 0–4	RESPONDERS WEEK 5–6	NON-RESPONDERS WEEK 5-6	RESPONDERS	NON-RESPONDERS
X-rays (all views, Rosenberg, Merchant) NSAIDs Education Supplements (Glucosamine, Chondroitin) Physical therapy, home exercise program Weight management, exercise and diet (may refer to dietician) Unloader brace (may have PFD or PFOA-check in physical therapy)	Education, continue home exercise program Activity modification and education Continue weight management Gradually increase activity Gait analysis NSAIDs (as needed) and topical Unloader brace	Refer to non-op sports med/musculoskeletal physician Mechanical symptoms: Reconfirm diagnosis: depends with exam---MRI, if SONK---bone scan Cognitive behavioral therapy If swollen + pain: Corticosteroid If pain, no swelling: IA visco Consider another NSAID or topical If not already, offer brace Continue maintaining weight Change physical therapy/exercise If not doing TENS, STEM or isometrics, water aerobics, Pilates, manipulations	Discontinue physical therapy Home exercise program only Sport specific activity Gait analysis, if runner Continue weight management Discontinue oral (NSAIDs: keep for flares) or topical only Activity education Chronicity education If not above, self-mgmt. IA steroid or IA visco Cognitive behavioral therapy	Visco, if worked If doing injections, continue PRP, stem cells (self-pay) Consider physical therapy in case-by-case basis Alternative therapy such as acupuncture Ortho surgery consult, HTO Cognitive behavioral therapy

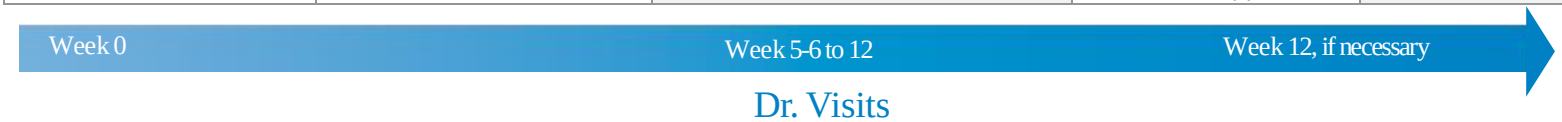

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Figure 2: Expert´s consensus of knee OA management for active and demanding patient

Abbreviations:

HTO: High tibial osteotomy

IA: Intra-articular

NSAIDs: Nonsteroidal anti-inflammatory drugs

MRI: Magnetic resonance imaging

PRP: Platelet-rich plasma

SONK: Spontaneous osteonecrosis of the knee

STEM: Electrical stimulation

TENS: Transcutaneous electrical nerve stimulation

Treatment recommendation for the older knee OA patient

Who is the older patient?

The older patient is considered to be older than > 65 years- wanting to maintain / regain their former activity level.

ACUTE PHASE I	CHRONIC PHASE	NON-RESPONDERS
Follow up 6 to 8 weeks – treatment plan	Follow up every 3 to 6 months based on symptoms	If no response to Phase I and II
Clinical exam X-Ray Biomechanical analysis Patient reported outcomes including patient expectations and goals Activity modification Physical therapy Weight management Education/Nutritional counseling/Handout Oral & topical analgesics NSAIDs, if appropriate Cortisone injection (if warranted) Knee sleeve/Wedges Fall prevention- canes	Cognitive behavioral therapy HA Unloader brace Reinforce/Re-assess: Physical therapy Weight management Activity modification Opioids (low dose/low risk population) Consider biologics	Referral for surgical management: TKR Unicompartmental knee replacement Referral for Chronic Pain Management for the non-surgical candidate Re-assess all from Phase I and II Manage expectations Biologics Unloader brace Cognitive behavioral therapy

Week 0-8 | Week 12-24 | Week 25-72

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Figure 3: Expert´s consensus of knee OA management for older patients

Genicular radio-frequency ablative therapy and/or percutaneous nerve stimulation can be considered in elderly patients with ongoing/chronic OA related pain not responding to non-invasive treatment options. This can be either pre-operatively or post-operatively if patients have persistent pain syndromes.

Abbreviations:

HA: Hyaluronic acid

TKR: Total knee replacement

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