

## IMPLICATION OF A HIP UNLOADER BRACE IN RECOMMENDED HIP OA MANAGEMENT: WHO, WHEN AND HOW?

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**Hip osteoarthritis (OA) imposes a significant burden on affected individuals and the community through reductions in quality of life and substantial health care costs<sup>1</sup>. Osteoarthritis has substantial impact on the quality of life in elderly patients. At the age of 85 years, the lifetime risk for hip osteoarthritis is 25% and the risk to undergo total hip replacement for end-stage hip OA is almost 10%<sup>2,3</sup>. Initial hip osteoarthritis (not associated with femoral acetabular impingement (FAI) or hip dysplasia) is normally not symptomatic and patients usually experience symptoms in later hip OA stages where osteoarthritic changes have already occurred. The goal of non-surgical hip OA management is to provide symptom relief and to improve a patient's activities and quality of daily life as long as possible. Conservative hip OA management is not indicated for end stage hip OA, and some patients with moderate hip OA need to be referred for total hip arthroplasty if conservative treatments fail.**

### GUIDELINES

Guidelines from international societies like the American College of Rheumatology (ACR) or European League Against Rheumatism (EULAR) and others mainly focus on knee osteoarthritis and transfer some of the evidence based treatments over to the hip<sup>4,5</sup> due to limited clinical data on the non-surgical management of hip osteoarthritis. Recently, the American Academy of Orthopaedic Surgeons (AAOS) published their evidence based clinical practice guidelines for the management of hip osteoarthritis. In these guidelines, they specifically reviewed the available evidence for treatment

options of hip osteoarthritis. Looking at the options for non-pharmaceutical and pharmaceutical treatment of symptomatic hip osteoarthritis, the recommendations suggest an individualized, assessment-based integrated management of care. This should consist of a core treatment and specifically selected additional treatment options based on the individual needs with regards to symptoms and joint function<sup>6</sup>.

### PATIENT EVALUATION AND INITIATION OF TREATMENT

Patients with hip pain need to be evaluated by a healthcare professional. Critical patient history, clinical examination and imaging, if necessary, are key to a successful treatment. Hip OA management should be specified to individual patients needs with regards to pathology, symptoms, activity level expectations and, if applicable, job requirements.

The patient must be informed that there is no cure from hip OA and understand that treatment includes body weight optimization (if applicable), pain coping strategies and, most importantly, that the overall goal to reduce symptoms as best as possible and that treatment may not stop or slow down disease progression.

As the care system is moving to a self-management based treatment approach, it is important to direct the patients to a solid source of information such as the Arthritis Foundation (or other group).

## ACTIVELY INVOLVE THE PATIENT IN THEIR SYMPTOM MANAGEMENT

The patient should be actively involved in the management of his or her hip OA.

- Patients should be encouraged to develop self-management strategies that reduce pain, improve sleep and function, and reduce the emotional distress that can accompany OA.
- The Arthritis Foundation offers a series of disease management classes.
- Referral to professionals trained in evidence-based, pain self-management, through cognitive-behavioral principles may be indicated for optimal outcomes.
- Within non-surgical hip OA management, it is important to manage patient's expectations. Non-surgical hip OA management addresses symptoms and not 'disease' resolution.
- Lifestyle changes and body weight management are key components to any treatment plan.

## CORE TREATMENT

Recommended core treatment includes patient information and education on the pathology of arthritis, direction of activities that may allow for an active lifestyle and especially discussion and assistance with weight loss to maintain the highest level of quality of life. The impact of therapeutic exercise may be controversial, but general expert consensus agrees that any therapeutic exercise approach should be physician or physiotherapist directed for correct form and timing of movement and muscle training rehabilitation<sup>7</sup>.

## ADDITIONAL TREATMENTS

### PHARMACOLOGICAL

Whereas paracetamol (acetaminophen) has been recommended in guidelines<sup>5</sup>, newly published meta-analysis have concluded with strong evidence the clinical effect of paracetamol is—even in the short term—insignificant<sup>8</sup>. NSAIDs should be prescribed orally to achieve pain relief. Oral NSAIDs (e.g. diclofenac or etoricoxib) have been found to provide effective pain relief in symptomatic hip osteoarthritis, but should be indicated carefully due to the potential cardiovascular, renal, and gastrointestinal side effects especially in elderly hip OA patients. Because of these risks, oral NSAIDs should only be used for short term periods<sup>8</sup>. Weak opioids can be beneficial but also have limitations due to their side effects<sup>9</sup>. Intra-articular injections of corticosteroids have a large effect size in the first week following the injection, but the effect decreases over time<sup>10</sup>. The injection of corticosteroids is recommended for patients with severe symptoms and inflammation of the joint as evidenced by the

presence of capsular effusion detected by an ultrasound examination. Image-guided (i.e. ultrasound-guided or fluoroscopic-guided) local anesthetic injections can be used to evaluate if the hip joint is itself responsible for the symptoms. The intra-articular injection of hyaluronic acid is controversial, and more clinical trials with clear injection regimens are necessary. Intra-articular platelet-rich plasma (PRP) injection may prove to be a viable treatment option but, like hyaluronic acid injections, requires more evidence<sup>11</sup>.

### BIOMECHANICAL MODIFICATION

Compared to the knee, biomechanical modifications of the hip are uncommon. The Unloader Hip (Össur, Reykjavik) attempts to replicate the optimal rotational movement of the femur. While a belt compresses the pelvis, a strap wraps from the ilium, then travels anteriorly and medially around the thigh to connect with a strap on the medial side of the knee. When tightened, this strap applies an external rotation and abduction force on the hip. Nerot and Nicholls (2016) performed a biomechanical assessment of the effects of this brace on a cohort of 14 subjects with hip OA. They showed that wearing the brace reduced adduction and internal rotation during gait. There was also a decrease in the internal abduction moment which may indicate a reduction in load through the femoral head. The authors hypothesized that these biomechanical changes were responsible for the immediate reduction in pain experienced by the majority of subjects when wearing the brace<sup>12</sup>.

The clinical benefit of the Unloader Hip brace is also supported in a recently conducted RCT. Evaluation of 45 patients with symptomatic Hip OA with a follow up of one month has shown a greater improvement of the hip function and activities of daily life in the braced group vs. the placebo group<sup>13</sup>.

**METHODOLOGY:**

We prepared an on-site meeting with OA experts from the US and Canada with a questionnaire on the current non-surgical management of symptomatic hip OA. The questionnaires laid the groundwork for in-depth discussions, and the OA experts collaborated on preliminary recommendations for the identified patient groups. We have settled on the following consensus statement.

**RECOMMENDATIONS:**

Who should get an Unloader hip brace?

Unloader Hip braces are recommended for individuals with mild to moderate hip OA alongside the recommended core treatment and for individuals suffering from moderate to severe hip pain who still have pain after initial recommended treatments.

Age and OA stage are not valid parameters to determine the right patients for an Unloader brace. Therefore, the participants recommend an Unloader Hip brace test (UHBT) initiated after selecting the brace which fits best to their individual needs and anatomy.

After the initial fitting, the brace should be tested for 5-10 minutes. Within this time, patients should walk on flat ground, ascend and descend stairs (if appropriate), and check if they are able to don and doff the brace. Some patients feel an immediate improvement in stability and/or hip pain while walking; these “responders” will most likely benefit from an Unloader Hip brace.

Close physician supervision and reassessment is recommended for patients with peripheral vascular disease, neuropathy and sensitive skin.

When to use an Unloader brace?

The Unloader Hip brace can be used during the day while active or whenever the patient feels relief of symptoms. It is helpful to start using the brace for a couple of hours daily to get used to the brace. Outcome of hip OA management should be evaluated by the physician 4-6 weeks after treatment has been initiated. With less pain, patients will increase their activities automatically – so there is no need for the prescriber to ask patients to increase their activity levels.

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

The Unloader Hip brace should be used as an additional treatment alongside the above-mentioned guideline recommended treatment options. The brace has been shown to improve activities of daily life in mild to moderate hip OA patients<sup>13</sup>.

Specific treatment recommendations for different patient groups:

The following graphs show the experts’ consensus on the management of symptomatic hip OA in the described patient groups. Please note: Co-morbidities and current medication need to be checked carefully before selecting the appropriate pharmaceutical treatment.

Precaution: Physical examination needs to be done on all patients and ideally includes at minimum: Leg length difference, flexion-adduction-internal rotation test (FADIR), passive range of motion (ROM) evaluation, flexion-abduction-external rotation test (FABER), single leg stance, single and double squat (for those who can), weakness, gait (get-up test, assess walk), supine log roll (leg raise), and palpation.

Who is the younger hip OA patient?

For the purpose of this expert recommendation, the younger hip OA patient is younger than 55 years with clinically relevant symptoms due to mild or moderate hip OA. The recommendations are made for hip OA patients but are also applicable for FAI / hip-dysplasia patients with mild to moderate hip OA.

PHASE I ACUTE		PHASE II SUB-ACUTE		ONGOING (OSTEOARTHRITIS CONFIRMED)	
		RESPONDERS	NON-RESPONDERS	RESPONDERS	NON-RESPONDERS
DIAGNOSIS	X-ray, ultrasound	Review	Diagnostic injection, MRI, repeat history, rule-out stress, rheumatoid labs (if effective)	Review	Review injection: was there improvement >4-6 weeks? Review previous imaging
TREATMENTS	Weight management, nutrition counseling	Continue with positive changes, weight-loss	If injection shows positive results, prescribe bracing, cane/crutch	Discuss what has been working well, determine next steps. Continue positive changes	Determine next steps. Time to consider surgery such as THR
	Avoid painful activity, modify activity type	Ask about function/activities	Modify/continue as tolerated		
	Optional: SYSADOA such as avacado/soy, chondroitin/glucosamine, tumeric	Continue 4-6 months	Continue 4-6 months	Stop @ 6 months & determine symptoms/effect	Stop, if after 4-6 months
	4-6 weeks therapeutic exercise and/or modalities, manual therapy and neuromuscular re-education of gait. Delay if symptoms increase	Adapt if needed, continue if funding allows, follow-up as needed	Check compliance & adapt, acupuncture	Home program, personal trainer or gym. If still doing rehab, therapeutic exercise follow-up once per month	Acupuncture & home therapy
	NSAIDs: (if effective & not contra-indicated) 2 week maximum	Reminder: stop NSAIDs (black box warning). If needed, switch to weak opioids	Review and adapt to alternative. Therapeutic injection (local/corticosteroid)	Review, stop (black box warning) Corticosteroid injection as needed (3 maximum)	Adapt injection: viscosupplementation, corticosteroid, biologics and spread 3 months apart
0-6 weeks		7-12 weeks		12-24 weeks	

Figure 1: Experts' econsensus of hip OA management in the younger patient (< 55 years). Abbreviations: Rehabilitation with physician or physiotherapist led program (PT), non-steroidal anti-inflammatory drugs (NSAIDs), magnetic resonance imaging (MRI), symptomatic slow-acting drugs (SYSADOAS), total hip replacement (THR).

Who is the active, demanding patient?

The active, demanding patient includes those that don't want to hear "no" and continue performing activities of moderate to vigorous level. This group is not age dependent. Patient history can include groin and buttocks pain, difficulty with sex, difficulty with activities of daily living, morning stiffness & pain, night pain, catching, locking, pain with activity and/or prior history of injury.

	PHASE I ACUTE	PHASE II SUB-ACUTE		ONGOING (OSTEOARTHRITIS CONFIRMED)	
		RESPONDERS	NON-RESPONDERS	RESPONDERS	NON-RESPONDERS
DIAGNOSIS	History: Groin and buttocks pain, difficulty with sex, difficulty with ADLs, AM stiffness & pain, night pain, catching, locking, pain w/ activity, prior history of injury Physical: FADIR, passive ROM, FABER, single leg stance, single & double squat, weakness, gait (get-up test, watch walk), supine log roll (leg raise), palpation X-ray (A/P, frog leg), evaluate joint above and below	History: Re-examine & reassess	Re-examine history & progress, consider advanced imaging	History: Re-examine & re-assess	Re-examine history and progress, consider advanced imaging
TREATMENTS	+/- injections	Progress rehab to functional skill work	If braced, consider injections: cortisone, viscosupplementation, PRP, stem cell	Progress rehab to functional skill work	If braced, consider injections: cortisone, viscosupplementation, PRP, stem cell
	Activity modification	Reassess activity modification and medication use	Re-evaluate rehabilitation & medication use	Reassess activity modification and medication use	If necessary, refer for brace adjustment
	Discuss occupation modification	If weight loss, provide positive feedback	If haven't considered, try bracing options	If weight loss, provide positive feedback	If not previously considered, try bracing options
	NSAIDs/acetaminophen (co-morbidities considered). If not working, try prednisone and tramadol	When applicable, continue brace use, strength training and weight loss program	If necessary, refer for brace adjustment	When applicable, continue brace use, strength training and weight loss program	Discuss weight loss, psycho-social, diet, supplement & nutrition
	Ice	If not previously considered, try bracing options	Discuss weight loss, psycho-social, diet, supplement & nutrition	If not previously considered, try bracing options	Discuss occupational modifications
	Heat		Discuss occupational modifications	Manage expectations	Re-evaluate rehabilitation & medication use
	Rehabilitation +/- modalities		Surgical discussion	Increase activity as tolerated	Surgical discussion
	Assistive device (cane, gait assistive)		Compliance w/ brace & activity adjustments	Reinforce home exercise program	Discontinue failed treatment
	Discuss bracing options		Discontinue failed treatment		Compliance w/ brace & activity adjustments
	Address and discuss weight loss, if indicated				Try what wasn't in subacute non-responders phase
	Address psychological stressors				Try radiofrequency ablation
					Pain management (referral or self)
		0-6 weeks	6-12 weeks	12+ weeks	

Figure 2: Experts' consensus of hip OA management for active, demanding patient. Abbreviations: activities of daily living (ADL), flexion-abduction-external rotation test (FABER), flexion-adduction-internal rotation test (FADIR), range of motion (ROM) and anterior/posterior (A/P).

Who is the older patient?

The older patient is considered to be older than > 55 years and wants to maintain or regain their former activity level.

	PHASE I ACUTE	PHASE II SUB-ACUTE		ONGOING (OSTEOARTHRITIS CONFIRMED)	
		RESPONDERS	NON-RESPONDERS	RESPONDERS	NON-RESPONDERS
DIAGNOSIS	X-ray, patient history, functional exam, physical exam, gait assessment, labs		MRI or diagnostic ultrasound		MRI or diagnostic ultrasound
	PHQ9/Promise Depression Scale/AAOS Questionnaire				
TREATMENTS	Therapeutic program/ home exercise	Continue effective treatment from Phase I	Therapeutic program/ home exercise	Continue effective treatment from Phase II	Biologics
	Gait aids		Diagnostic aspiration injection		Nerve block
	Modified activity		Brace		Brace
	Weight loss		Oral agents (non-narcotics)		Oral agents (non-narcotics)
	Brace		Introduction of next steps		Consider THR
	Psycho-social intervention				
Week 0		Week 7-12		Week 13-24	

Figure 3: Experts’ consensus of hip OA management for older patient. Abbreviations: rehabilitation with physician or physiotherapist led program (PT), magnetic resonance imaging (MRI), patient health questionnaire (PHQ9), total hip replacement (THR), American Academy of Orthopaedic Surgeons (AAOS)

**SUMMARY**

In most cases, conservative hip OA management is initiated when relevant osteoarthritic changes are already present. Therefore, the goal of hip OA management is to relieve symptoms and increase patient’s mobility. This needs to be communicated to the patient upfront. Interventions that enable patients to actively manage their hip osteoarthritis improve patient outcomes. The foundation for successful hip OA management is a proper diagnosis including patient medical history, clinical examination, image-guided diagnostic injections and imaging as indicated. Patients with dysplastic changes / femoro-acetabular impingement (CAM, Pincer and combined types) should be considered for surgical treatment as long as there is no-to-low grade hip OA present.

The management of hip OA consists of a non-pharmacological core treatment focused on patient information, education, psychosocial intervention, adaptation of lifestyle, exercise, use of a cane (when indicated and acceptable to the patient) and where necessary, body weight optimization. Use of oral pharmaceuticals is limited with regards to eligible patients and its duration due to the risk of potential side effects. Intra-articular injection of corticosteroids provides short term pain relief but has limitations in the treatment for the longer term. While research on the Unloader Hip is still in its infancy, results to date suggest that the brace improves patient function. Data further suggest that this improvement is mediated by alterations in hip position and loading during gait. Management of hip OA should be individualized and follow a patient-centric approach. This consensus consolidates best practice recommendations from experts in hip OA management for three different patient types: the younger, the active-demanding and the older hip OA patient in the acute, subacute and ongoing phase of hip OA.



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## PROTOCOL

Introduction of a biomechanical intervention for the treatment of hip OA. The patient gets an introduction to the Unloader Hip brace including its features, possible benefits and handling of the Unloader Hip. The brace should be fit on the patient using short leggings to ensure proper hygiene.

## TEST WALK I

Patient is asked to walk for 2 minutes on level ground with the brace on. Afterwards, the patient is asked to sit down and stand up in order to evaluate support while standing up and acceptance of the brace while sitting.

After this, the patient gets an introduction on how to don and doff the brace. If necessary, re-adjustment of the brace is done by the fitter.

## TEST WALK II (IF NECESSARY, ONLY IF ADJUSTMENTS ARE MADE)

Patient is asked again to walk for 2 minutes on level ground with the brace on.

## PATIENT HANDLING TEST

Patient is asked to remove and put on the brace by themselves in order to see if they can manage it. This can be supported by the Össur Fitting video.

## UHBT DOCUMENTATION

Patient is asked to fill in the UHBT questionnaire, consisting of 5 questions, which aids in deciding whether the selected brace is appropriate for the patient or not.

If the patient answers YES to at least 4 of the 5 questions, the brace is recommended. Improvement of 3-5 points on VAS is recommended.

# DOCUMENTATION

Name: \_\_\_\_\_ Health Insurance No.: \_\_\_\_\_

Diagnosis: \_\_\_\_\_  right  left  bilateral Hip Osteoarthritis

Date: \_\_\_\_\_

To be filled in by the patient:

1. Did you experience pain relief while using the brace?  yes  no
2. Did your hip feel more stability with the brace on?  yes  no
3. Are you comfortable with putting the brace on and taking it off by yourself?  yes  no
4. Does the brace feel comfortable while walking and sitting down?  yes  no
5. Do you think that the brace would help you with regards to your daily activities?  yes  no

Overall evaluation of the benefit:



Patient's Signature: \_\_\_\_\_ City/Date: \_\_\_\_\_