ODRA

ORTHÈSE SUR MESURE POUR LA GONARTHROSE INTERNE

EFFICACITÉ PROUVÉE SCIENTIFIQUEMENT

Plusieurs études indépendantes et reconnues internationalement ont prouvé l'efficacité de l'orthèse Odra.

Orthèse de Distraction et Rotation du genou, conçue pour soulager la douleur due à la gonarthrose interne et améliorer la qualité de vie des patients.

Odra est une genouillère articulée réalisée sur mesure, à l'efficacité sur la réduction de la douleur cliniquement prouvée. Elle est constituée de deux articulations qui combinent leurs actions pour induire une décharge sur le compartiment interne du genou :

- Articulation interne : action de Distraction lorsque la jambe est en extension, provoquant une décharge entre fémur et tibia.
- Articulation externe : action de Rotation, entraînant ainsi un recul du centre articulaire.

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Geugnon.M, Fournel.I & Al ; Effectiveness, safety, and cost-utility of a knee brace in medial knee osteoarthritis : the ERGONOMIE randomized controlled trial (DOI : 10.1016/j.joca.2020.11.009)

Objectif :

Comparer l'efficacité, la sécurité et la balance coût-utilité d'une orthèse de distraction-rotation sur-mesure (ODRA) versus une prise en charge usuelle de l'arthrose du compartiment interne du genou sur une durée d'un an.

Type d'étude : Essai médico-économique, multicentrique, contrôlé et randomisé

Matériel et Méthode :

120 patients atteints de gonarthrose du compartiment interne inclus 2 groupes :
- Orthèse Odra + prise en charge usuelle
- Prise en charge usuelle*

Patients n'ayant jamais porté d'orthèse de décharge, sans problème sévère de circulation, antécédent de thrombose profonde des membres inférieurs, valgus ou indication de mise en place d'une prothèse totale de genou.

Recommandation du port de l'orthèse : au moins 6h/j et 5j/sem ; retirer l'orthèse en période de repos.

*Prise en charge usuelle : prise en charge médicamenteuse (antidouleurs, Anti-inflammatoire non stéroïdien, injections de stéroïdes), viscosupplémentation (acide hyaluronique) et prise en charge non médicamenteuse (kinésithérapie, hydrothérapie...).

Critères d'évaluation :

Principal :
Changement de la douleur selon VAS[11] (V0-V100) entre l'inclusion (M0) et le Mois 12 (M12) avec visite de contrôle à M6.

Secondaires :
Evaluation fonctionnelle ➔ Score KOOS[4] à M0, M6 et M12 normalisé de 0 à 100.
Evaluation de la Qualité de vie ➔ Score OAKHQOL[6] à M0, M6 et M12 normalisé de 0 à 100.

Suivi téléphonique tous les 2 mois pour collecter des informations sur les critères suivants :
• Consommation médicamenteuse ➔ Carnet de suivi
• Observance ➔ Carnet de suivi ; nombre d'heures/jour et nombre de jours/semaine
• Sécurité de l'orthèse ➔ Carnet de suivi et visites de contrôle ; nombre d'évènements indésirables
• Balance coût-utilité ➔ Calcul du coût par QALY[10] basé sur le questionnaire EQ-5D-3L[2]
• Coûts directs médicaux ➔ Consommation d'actes médicaux pharmacologiques et non pharmacologiques

MCID[5] calculé pour la douleur VAS[11], la fonction en activités quotidiennes du KOOS[4], les 5 items du OAKHQOL[6].
Proportion de patient atteignant le PASS[9] pour la douleur VAS[11].

Résultats de l'étude :

- Les datas concernant le critère principal disponibles pour 54 patients du groupe prise en charge usuelle et 49 patients du groupe Odra. Groupe Odra associé à une amélioration plus importante du traitement de la douleur (différence moyenne ajustée de 11.8 lors de l'analyse primaire).
La comparaison entre M0 et M12 a montré que le Groupe Odra a un score significativement plus important que le groupe prise en charge usuelle pour tous les items KOOS[4] et les items douleur et activités physiques du score OAKHQOL[6]. Tendance à la supériorité du groupe Odra pour l'item santé mentale du score OAKHQOL[6].

- Les patients du groupe Odra avaient plus de chances d'atteindre le MCID[5] (critère d'amélioration) pour chaque item où le MCID[5] était utilisé. L'OR[7] donnant le ratio d'atteinte du MCID[5] :
• OR[7] de 2,76 pour la douleur VAS[11]
• OR[7] de 4,9 item fonction en activités quotidiennes du KOOS[4]
• OR[7] de 4,43 item Activité physique du score OAKHQOL[6]
• OR[7] de 3,56 item douleur du score OAKHQOL[6]
• OR[7] de 2,91 item santé mentale du score OAKHQOL[6]
La proportion de patients atteignant le PASS[9] (critère de satisfaction) de la douleur VAS[11] était 2,97 fois plus importante dans le groupe Odra.

- Malgré des effets secondaires classiquement liés au port d'une orthèse de genou (irritation cutanée (n=39), picotements (n=27), œdème modéré (n=15),...) déclarés pour 51 patients du groupe Odra, l'observance du groupe Odra entre M0 et M12 était proche des recommandations initiales (médiane de 5.3h/j et 6j/sem) ce qui est supérieur aux résultats rapportés dans la littérature pour d'autres orthèses.
A noter qu'un patient dans chaque groupe a déclaré une thrombose veineuse profonde lors du protocole (effet secondaire sérieux).

- Diminution significative de la consommation d'antidouleur à M12 dans le groupe Odra alors que la consommation du groupe contrôle reste stable.

- La courbe d'acceptabilité coût-utilité suggère que le groupe Odra serait effectif en terme de coût pour 85% des simulations au seuil de 45000€/QALY[10].

Conclusion :

L'étude ERGONOMIE a montré que la combinaison Odra + prise en charge usuelle est une stratégie thérapeutique prometteuse démontrant une bonne acceptation et tolérance de la part des patients atteints de gonarthrose du compartiment interne.

L'amélioration globale des items du KOOS[4] dans le groupe Odra montre que la fonction globale des patients a été améliorée après un an de port. Une claire amélioration est également notable dans 3 items du score OAKHQOL[6] pour le groupe Odra.
L'étude ERGONOMIE montre donc **une amélioration significative de la douleur et de la fonction dans le groupe Odra vs le groupe prise en charge usuelle.**
Les résultats confirment la bonne sécurité du dispositif et suggèrent le bon ratio coût-efficacité lié à son utilisation.

Malgré la déclaration de certains effets secondaires, la bonne observance du traitement à un an de port montre une bonne tolérance à moyen terme. L'estimation de 84% de patient continuant de porter l'orthèse au bout d'un an étant supérieure aux datas trouvées dans la littérature.

D'un point de vue sociétal, Odra a un ratio coût-utilité qui n'a pas été démontré pour une autre orthèse de traitement de l'arthrose du compartiment interne jusqu'à présent.
Les patients du groupe prise en charge usuelle ont reçu une proposition de test de l'orthèse à la fin de l'étude

Limites :

- Pas de condition simple ou double aveugle ➔ Pas vraiment une possibilité lorsqu'on parle de traitement orthétique.
- Pas d'utilisation d'orthèse neutre dans le groupe contrôle ➔ la présence d'une orthèse même neutre pourrait altérer la proprioception ou l'activité musculaire et ne représente donc pas un placebo strict.
- Auto-déclaration des consommations d'actes médicaux ➔ Accès à l'information via une database plus large telle que celle de la sécurité sociale n'était pas autorisé.

Biais potentiel / Conflit d'intérêt : aucun

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Clinical Trial

Effectiveness, safety, and cost–utility of a knee brace in medial knee osteoarthritis: the ERGONOMIE randomized controlled trial

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SUMMARY

Objective: This pragmatic, multicenter, open-label, randomized controlled trial (RCT) aimed to compare the effectiveness, safety, and cost–utility of a custom-made knee brace versus usual care over 1 year in medial knee osteoarthritis (OA).
Design: 120 patients with medial knee OA (VAS pain at rest >40/100), classified as Kellgren–Lawrence grade II-IV, were randomized into two groups: ODRA plus usual care (ODRA group) and usual care alone (UCA group). The primary effectiveness outcome was the change in VAS pain between M0 and M12. Secondary outcomes included changes over 1 year in KOOS (function) and OAKHQOL (quality of life) scores. Drug consumption, compliance, safety of the knee brace, and cost–utility over 1 year were also assessed.
Results: The ODRA group was associated with a higher improvement in: VAS pain (adjusted mean difference of −11.8; 95% CI: −21.1 to −2.5); all KOOS subscales (pain: +8.8; 95% CI: 1.4–16.2); other symptoms (+10.4; 95% CI: 2.7–18); function in activities of daily living (+9.2; 95% CI: 1.1–17.2); function in sports and leisure (+12.3; 95% CI: 4.3–20.3); quality of life (+9.9; 95% CI: 0.9–15.9), OAKHQOL subscales (pain: +14.8; 95% CI: 5.0–24.6); and physical activities (+8.2; 95% CI: 0.6–15.8), and with a significant decrease in analgesics consumption at M12 compared with the UCA group. Despite localized side-effects, observance was good at M12 (median: 5.3 h/day). The ODRA group had a more than 85% chance of being cost-effective for a willingness-to-pay threshold of €45 000 per QALY.

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Conclusions: The ERGONOMIE RCT demonstrated significant clinical benefits of an unloader custom-made knee brace in terms of improvements in pain, function, and some aspects of quality of life over 1 year in medial knee OA, as well as its potential cost–utility from a societal perspective.

Introduction

Knee osteoarthritis (OA) is a common degenerative joint disease, and a major cause of pain and disability in adults[1]. The medial compartment of the tibiofemoral joint is particularly exposed and sensitive to mechanical constraints, resulting in overloading of the articular cartilage and premature degeneration[2,3].

As recently outlined by the European League Against Rheumatism (EULAR), the OsteoArthritis Research Society International (OARSI), and the American College of Rheumatology (ACR), the management of knee OA includes pharmacological (use of analgesics, non-steroidal anti-inflammatory drugs (NSAIDs), and intra-articular steroid injections) and non-pharmacological treatments (aerobic exercise, muscle strength training, and health education for self-management)[4–6]. While unloader knee braces were initially recommended by OARSI, they have been withdrawn from the most recent OARSI guidelines because of inconclusive evidence regarding their symptomatic benefits[4]. Conversely, they were 'strongly recommended' in the up-to-date ACR guidelines[6], demonstrating an absence of consensus on the effect of knee braces in OA in addition to usual care.

The aim of a valgus knee brace in medial knee OA is to apply corrective forces on load distribution in order to decrease internal pressure on the medial tibiofemoral compartment. This could contribute to pain reduction and increase functional recovery[7,8]. However, in practice, these unloader knee braces are infrequently prescribed in primary care[9,10], especially because their use is often limited by localized side-effects or discomfort, potentially resulting in weak acceptability and orthosis withdrawal[10,11]. Although several controlled trials have investigated the symptomatic effects of knee bracing[12–14], a Cochrane review and systematic analysis highlighted the lack of good-quality evidence for the effects on pain and function[7,8,15]. Moreover, there is a paucity of data regarding health-related quality-of-life outcomes or medico-economic analyses, which are key outcome measures[16]. Therefore, there is a need for high-quality studies, such as randomized controlled trials (RCTs), to assess the effectiveness, safety, and medico-economic impact of orthoses on knee OA[17] in primary care.

The main objective of this multicenter, pragmatic randomized controlled trial (RCT) was to assess the effectiveness, safety, and cost–utility of a distraction-rotation, custom-made knee brace (ODRA — ®PROTEOR) used in addition to the usual care versus the usual care alone (UCA) over a period of 1 year in patients with symptomatic medial knee OA.

Methods

Study design and participants

The ERGONOMIE study was a phase-3 randomized open-label parallel-group trial conducted at seven French sites (private and public hospitals). The clinicians, assessors, and volunteers were not blinded. Patients with symptomatic medial knee OA were screened by general practitioners, rheumatologists, physical therapists, and orthopedic surgeons, and referred to one of the participating centers. None of the patients had used an unloader knee brace before inclusion, but previous use of a neoprene sleeve was tolerated.

The inclusion criteria for patients were as follows: aged >40 years old; diagnosed with medial compartment knee OA defined according to the ACR criteria (VAS pain at rest $\geq$ 40/100 in the medial compartment, with more severe pain in the medial compartment than in the lateral compartment), radiological stage II, III, or IV according to the Kellgren–Lawrence (KL) grading[18] established from X-rays taken in the previous 6 months; and no change in pharmacological treatment for at least 3 months. Patients had to be able to understand and complete the self-report questionnaires. Major exclusion criteria were: severe venous insufficiency or prior deep vein thrombosis in the lower limbs; acute inflammation of the knee; knee valgus; other significant rheumatic disease; or indication for total knee replacement according to the medical specialist consulted. All participants provided written informed consent.

The study protocol was approved by the local ethics committee and the French national agency for the safety of medical products and devices. The study was registered in May 2016 (clinical trials number NCT02765685), which was after the onset of patient enrollment in February 2015, since the systematic registration of French clinical trials only became mandatory in 2016.

Randomization

Patients were randomly assigned in a 1:1 ratio to receive the distraction-rotation knee brace in addition to usual care (ODRA group) or to receive usual care alone (UCA group). To maintain balance between groups, dynamic allocation was centrally managed using a minimization algorithm[19], relying on the following factors: center, age (<65 vs $\geq$ 65 years), sex, disease duration (<2 vs $\geq$ 2 years), body mass index (BMI; < 25 vs $\geq$ 25), past history of other osteoarticular diseases affecting the target knee (meniscus tears, ligament injuries, tendonitis, bursitis), and radiological severity at baseline (KL II or III vs KL IV).

Intervention

Patients from both groups received the usual standard care for knee OA, including pharmacological (such as NSAIDs, analgesics, steroid injections, intra-articular hyaluronic acid (IAHA) injections) and non-pharmacological treatments (physiotherapy, spa therapy, etc.).

Patients randomized to the ODRA group were fitted with an ODRA brace (®PROTEOR; Dijon, France). All orthotic adjustments were performed by a certified orthotist. Patients were told to wear the brace for at least 6 h a day, 5 days a week, and to remove it during periods of rest and when lying down. ODRA is a custom-made valgus-inducing knee brace designed with an innovative system of dynamic distraction and dynamic external rotation of the leg that shifts the center of the load towards the natural

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intercondyle position, thus limiting overload of the medial compartment[20,21] (Fig. 1; Appendix – Part A).

Follow-up assessments

Follow-up assessments were performed using self-reported instruments (VAS pain, knee injury, and osteoarthritis outcome score (KOOS), and osteoarthritis knee-and-hip quality-of-life (OAKHQOL) questionnaires[22,23]) at baseline (M0) and at each follow-up visit (M6 and M12). Patients were told that they would join the ODRA or UCA group after all assessments performed at M0 in order to limit potential disappointment bias of not receiving the brace. Moreover, patients were given the opportunity to try the ODRA brace at the end the protocol.

Clinical follow-up was completed via phone calls every 2 months for 1 year to collect compliance and safety data for the brace (in the ODRA group), and healthcare consumption (for both groups). Patients were given a diary to complete, which was then used as support for the phone calls in order to limit recall bias. During phone calls, patients were asked to complete the EuroQol 5-Dimension questionnaire (EQ-5D-3L®), a validated, standardized instrument commonly used for medico-economic evaluation[24–26].

Outcome measures

Effectiveness was defined as the benefit of the knee bracing compared with routine clinical practice[27]. The primary outcome was the change in VAS pain (0–100, min–max) between M0 and M12. Secondary effectiveness outcomes were the changes in KOOS subscale scores (pain, other symptoms, function in activities of daily living, function in sport and leisure, and knee-related quality of life)[23] and OAKHQOL domain scores (OA-specific domains covering physical activities, mental health, social support, social activities, and pain)[22,28] between M0 and M12. For both questionnaires, scores were normalized to a scale from 0 (worst) to 100 (best). At M12, the proportion of patients who experienced a clinically relevant improvement (minimal clinically important differences; MCID)[29] was calculated for VAS pain, KOOS function in activities of daily living, and the five domains of the OAKHQOL questionnaire. The proportion of patients who reached the patient-acceptable symptomatic state (PASS)[30] was computed for VAS pain. The selected MCID and PASS thresholds are shown in Table A1 (Appendix – Part B)[29,31].

The safety of the knee brace was assessed according to the potential (local and/or general) number of adverse effects of wearing the brace, compiled from phone calls and follow-up consultations. Compliance was self-reported and assessed according to the mean time the brace was worn (number of days per week and hours per day) over 1 year. Healthcare consumption types included analgesics, NSAIDs, and steroid and IAHA injection.

A cost–utility approach was used to assess the efficiency of the ODRA brace. It was specifically assessed by calculating the cost per quality-adjusted life year (QALY), based on the EQ-5D-3L (Appendix – Part C)[32]. For both groups, direct medical costs were estimated from the data obtained during each phone call from the societal perspective (including medical consultations, physiotherapy sessions, spa therapy, imagery, surgery, pharmacological treatments, and devices (including ODRA) (Appendix – Part C and Table A5).

Sample size

We assumed an absolute reduction in VAS pain of 19.9 points out of 100 for the ODRA group (based on the MCID for knee OA[33]) and no reduction (0 points out of 100) for the UCA group. Based on a previous exploratory study[21], which showed an absolute reduction in pain (25 points ± 25.3) after 12 months in 20 knee OA patients wearing the ODRA brace, we increased the expected variability by setting the standard deviation (SD) at 30 for the ODRA group and 40 for the UCA group in order to take the heterogeneity of patient management in the UCA group into account. Based on these assumptions, with an alpha risk of 5% and a power of 80%, 51 patients were required per group. We planned to enroll 60 patients in each group in case patients were lost to follow-up.

Statistical analysis

At baseline, we compared the demographic (age, sex, body mass index (BMI), social deprivation using EPICES score, education level) and disease characteristics (OA disease duration, KL grading, OA treatments) between groups using chi-square tests for qualitative variables and Student's tests or non-parametric tests for continuous variables.

The outcome measures were described for each group using mean change from baseline to follow-up with 95% confidence intervals (CI). As specified in the protocol, the primary analysis was performed on complete data, with an intention-to-treat analysis under the assumption of maximum bias[34] for patients lost to follow-up (no change in pain in the ODRA group, reduction of 20 points in the UCA group), and adjusted for unbalanced factors between groups when there were differences at baseline ($P < 0.20$). Therefore, the main analysis included all patients with no missing data for adjustment variables under the maximum bias hypothesis. This was then completed by a full-set analysis (exclusion of patients with missing data on outcome). The change in VAS pain between baseline and each follow-up was analyzed separately using linear regression. The changes in the KOOS and OAKHQOL scores were

Fig. 1 Representation of the distraction–rotation mechanism of the ODRA brace (Laroche *et al.*, 2014; with permission).

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analyzed using a mixed model adjusted for unbalanced baseline factors. Due to significant interactions between groups and time assessment, the changes in KOOS and OAKHQOL between baseline and each follow-up were analyzed separately using linear regression. The effect of ODRA vs UCA on the probability of reaching MCID for VAS pain and PASS was estimated using logistic regression models, which were run separately for M6 and M12.

Safety endpoints were described for all patients. Patients for whom compliance was available at least once in each period (M0–M6 and M6–M12) were considered for the compliance analysis. Among these patients, the median compliance with its interquartile range (IQR) was computed for the whole M0–M12 period. Healthcare consumption types were compared between groups using chi-square tests.

The cost–utility analysis was performed using the incremental cost-effectiveness ratio (ICER), calculated by dividing the incremental direct costs (difference in mean costs between the ODRA and UCA groups) by incremental QALY (difference in mean QALY). The main cost–utility analysis included patients with complete data. A complementary cost–utility analysis was performed using multiple imputation with adjustment for unbalanced baseline factors in order to take into account patients with missing data. The ICER was then compared with a reference value representing the maximum amount of investment (i.e., willingness-to-pay threshold) collectively accepted by society for one additional QALY. To our knowledge, there is no international or French consensus for the willingness-to-pay threshold for biomechanical devices in knee OA[16,35]. We therefore based our comparison on a threshold of almost €45 000 used in recent studies of other medical devices for knee OA[36,37]. We then constructed an acceptability curve based on 10,000 samples generated by a non-parametric bootstrap analysis of the differential costs and QALY observed for the two strategies (Appendix – Part C). Direct medical costs and QALY at 1 year were averaged for all patients. They were compared between groups using chi-square tests or non-parametric tests. Costs are presented in euros (€).

A two-sided *P*-value of less than 0.05 was considered significant. All analyses were performed with SAS 9.4. To facilitate understanding in the results and discussion, the results at M6 are only reported in the Appendix – Part B (Tables A2, A3, A4, and Fig.A1).

Results

Population characteristics

A total of 121 patients were enrolled between February 2015 and July 2016 (Fig. 2). One patient withdrew consent, leaving 120 knee OA patients included at baseline. Despite randomization, ODRA patients had a lower level of education, had more frequent prior history of knee surgery on the target knee, and higher VAS pain at baseline compared with UCA patients (Table I). The effectiveness results were adjusted for the following factors ($P < 0.20$): VAS pain at baseline, other osteoarticular disease affecting the target knee, prior history of surgery on the target knee, pain medication, socioprofessional category, and level of education.

Effectiveness

The main outcome was available for 54 of 60 patients (90%) in the UCA group and 49 of 60 patients (82%) in the ODRA group. The primary analysis revealed that the adjusted mean difference in VAS pain was higher in the ODRA group than in the UCA group, with an adjusted mean difference of −11.8 (95% CI: −21.1 to −2.5). Full-set analysis and the variation in VAS pain between M0 and M12 in each group are detailed in Table II.

The comparison between M0 and M12 revealed that ODRA patients exhibited significant improvements in all subscales of the KOOS, and in the pain and physical activities subscales of the OAKHQOL compared with the UCA group (Fig. 3). An interesting trend was found in the mental health domain of the OAKHQOL, suggesting an improvement in ODRA patients at M12.

MCID and PASS

Patients in the ODRA group were more likely to reach MCID at M12 for VAS pain (adjusted odds ratio (OR) = 2.76 [95% CI: 1.05–7.23]; $P = 0.04$), for KOOS function in activities of daily living (OR = 4.90 [95% CI: 1.68–14.32]; $P = 0.004$), and for three out of five domains of OAKHQOL: physical activity (OR = 4.43 [95% CI: 1.38–14.21]; $P = 0.01$), pain (OR = 3.56 [95% CI: 1.20–10.56]; $P = 0.02$), and mental health (OR = 2.91 [95% CI: 1.04–8.12]; $P = 0.04$; Table III). Likewise, the proportion of patients reaching the PASS for VAS pain was significantly higher in the ODRA group than in the UCA group (OR = 2.97 [95% CI: 1.09–8.10]; $P = 0.03$).

Compliance and safety

Between M0 and M12, the patients ($n = 47$) wore the ODRA brace for a median of 6 days per week (IQR: 5–6.75) and a median of 5.3 h per day (IQR 3.7–7).

51 patients in the ODRA group reported local side-effects, mainly skin irritation from rubbing against the brace ($n = 39$) and itching ($n = 27$). 15 patients reported moderate leg edema, and five mentioned the appearance or worsening of varicose veins. These side-effects led to 26 provisional and eight definitive withdrawals of the brace (16%), as well as adjustments of the brace by the local orthotist. One serious side-effect (deep vein thrombosis) potentially related to the orthosis was identified. One patient in the UCA group also had deep vein thrombosis during follow-up.

Healthcare consumption

Between M0 and M12, 28.3% of patients in the ODRA group had at least one acid hyaluronic injection, compared with 41.7% in the UCA group ($P = 0.13$). The proportion of patients using pharmacological treatments did not differ significantly between groups (Table IV). However, the median reduction in the number of analgesics used in the week preceding the consultation between M0 and M12 was −6.5 (IQR: 15–0) in the ODRA group vs 0 (IQR: −4 to 7) in the UCA group ($P < 0.001$). Non-pharmacological treatment (physiotherapy sessions or spa therapy) did not differ significantly between groups during follow-up. Otherwise, four patients (two in each group) underwent surgery for total knee replacement over the study period.

Cost–utility

The main cost–utility analysis was performed on 90 patients (40 from the ODRA group) because of missing data. The cumulative direct difference in cost over 1 year was €1335 (95% CI: 620–2049), with higher costs in the ODRA group than in the UCA group (€2116 vs €781, respectively; $P = 0.0002$), mainly due to the cost of the orthosis itself (€1200). The mean difference in QALY was 0.08 (95% CI: −0.003 to 0.16) (29 days) in favour of the ODRA group (QALY 0.70 vs 0.62; $P = 0.07$). The calculated ICER was €16 683 per additional QALY (95% CI: −32,929 to 42,808]. A cost–utility acceptability curve suggested that ODRA could be cost-effective for 85% of the simulation at a threshold of €45 000 per QALY gained (Fig. 4).

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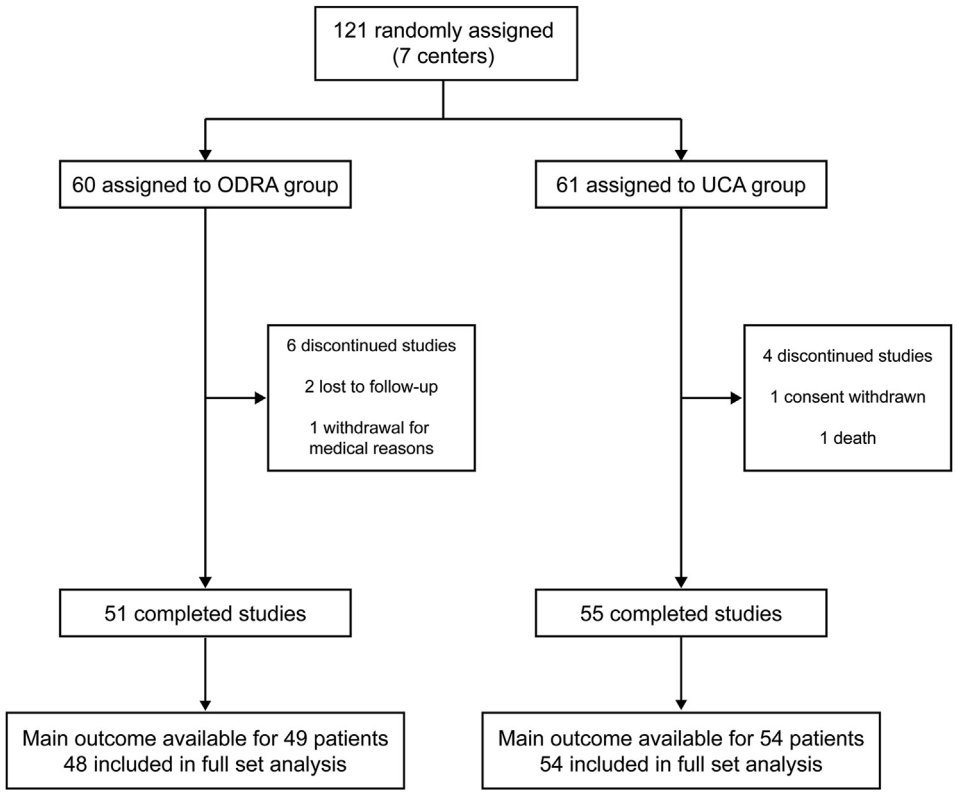

Fig. 2 Flow chart of the ERGONOMIE RCT.

The results of the complementary cost–utility analysis revealed a slight increase in the ICER (ICER = €25 225; 95% CI: 23,129–45,331); Appendix – Table A6).

Discussion

To our knowledge, this is the first randomized controlled OA trial investigating the medium-term benefits of an unloader knee brace in terms of both clinical and economic outcomes, in a regular healthcare setting, with high external validity due to the relatively unselected patients and multidisciplinary screening. Thus, ERGONOMIE will be helpful in answering the question of whether this custom-made orthosis has additional value in real life. Our results demonstrated that the combination of an ODRA brace and usual care is statistically associated with improvements in pain, function, and some aspects of OA health-related quality of life at 1 year in comparison with usual care alone. They also confirmed the good safety profile of the unloader knee brace. Finally, the ODRA brace seems to be cost-effective, as suggested by the cost–utility analysis.

The main result of ERGONOMIE is the significant improvement in pain and function observed in the ODRA group when compared with the UCA group. These results are consistent with previous RCTs suggesting that additional treatment with an unloader knee brace improves pain and physical function[14,38,39] compared with usual care. In a study by Moyer *et al.*[11], these effects appeared smaller, but were still present when compared with a control orthosis group. In addition, dichotomous variables such as MCID and PASS are useful for algo-functional outcome measures, since they specify the proportion of patients who 'feel better' and 'feel well', respectively[40]. In our study, the difference was clinically relevant because patients in the ODRA group 'felt better' in terms of mental health (OAKHQOL), function in activities of daily living (KOOS), and VAS pain, and 'felt well' for VAS pain, compared with patients in the UCA group.

Recently, Thoumie *et al.*[38] observed a similar improvement in short-term pain (−26/100 on VAS) with another valgus-inducing knee brace (three-point pressure) after a 6-week treatment period, showing that the knee brace provided immediate pain relief thanks to its biomechanical effect. Our results suggest that this positive effect, which is associated with significantly improved function and quality of life, could be extended to the medium-term without a decrease in symptomatic effects. In a comparable RCT including 130 knee OA patients, Brouwer *et al.*[12] observed no difference in pain, function (evaluated using the Hospital for Special Surgery score – HSS), or quality of life (evaluated by EQ-5D®) at 1 year. However, the HSS score is not as effective as the KOOS for assessing global function, as indicated by OARSI[41]. The KOOS includes the WOMAC (Western Ontario and McMaster Universities Arthritis Index) plus others items related to function in leisure and sport activities, and is therefore a better indicator of overall function in knee OA[23]. In our study, a significant improvement in all KOOS subscales was observed in the ODRA group, showing that global function had improved after 1 year. Ostrander *et al.*[42] observed a similar improvement in the KOOS scores of patients with an unloader brace over a shorter period. Furthermore, the EQ-5D® questionnaire used by Brouwer *et al.* is a

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	ODRA group ($n = 60$)	UCA group ($n = 60$)	*P*-value
Socio-demographic characteristics			
Age (years; mean ± SD)	65 ± 11,8	62.2 ± 11,1	0.44
Women	34 (56.7%)	34 (56.7%)	1
BMI (kg/m^2; mean ± SD)	29.4 ± 5.2	29.8 ± 5.9	0.65
Education level			**0.01***
less than high school diploma degree	25 (44.6%)	13 (23.6%)	
High school diploma degree	16 (28.6%)	13 (23.6%)	
More than 2 years after high school diploma degree	15 (26.8%)	29 (52.7%)	
Type of occupation before retirement			0.14
Skilled	15 (25.4%)	22 (37.9%)	
Unskilled	34 (57.6%)	32 (55.2%)	
Unemployed	10 (17%)	4 (6.9%)	
Social deprivation (EPICES score ≥ 30)	19 (32.2%)	14 (24.1%)	0.33
Disease characteristics			
VAS pain 0–100 (mean ± SD)	61.8 ± 17.4	54.8 ± 50.1	**0.03***
Disease duration (years; median, IQR)	3.1 (1.2–9.8)	4.3 (1.0–6.7)	0.78
Radiological Kellgren–Lawrence grading			0.73
II	18 (30%)	15 (25%)	
III	31 (51.7%)	31 (51.7%)	
IV	11 (18.3%)	14 (23.3%)	
History of surgery on the target knee	26 (43.3%)	15 (25%)	**0.03***
Other osteoarticular disease affecting the target knee	2 (3.3%)	8 (13.3%)	**0.05***
OA treatment			
Within the previous 6 months			
Physiotherapy	18 (30%)	21 (35%)	0.56
Hyaluronic acid injection	21 (35%)	21 (35%)	1
Intra-articular steroid injection	17 (28.3%)	18 (30%)	0.84
Within the previous week			
Analgesics	46 (76.7%)	38 (63.3%)	0.11
NSAIDs	12 (20%)	14 (23.3%)	0.66

Data are *n* and % unless indicated.
SD: standard deviation.
NSAIDs: nonsteroidal anti-inflammatory drugs.
* Statistical difference between groups was observed ($P < 0.05$).

Table I Baseline population characteristics (ERGONOMIE RCT)

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	Unadjusted mean change from baseline (95% CI)		*Adjusted between group difference (95% CI)	
	Full set analysis ($n = 103$)	**Maximal bias analysis ($n = 120$)**	**Full set analysis ($n = 101$)**	**Maximal bias analysis ($n = 109$)**
UCA	−9.4 (−16.4 to −2.4)	−10.4 (−16.8 to −4.1)	Reference	Reference
ODRA	−21.2 (−28.2 to −14,1)	−17.3 (−23.4 to −11.2)	−13.0 (−22.6 to −3.3)	−11.8 (−21.1 to −2.5)

For changes within group, a negative value indicates improvement.
For changes between groups, negative values favor ODRA.
Primary effectiveness analysis corresponds to maximal bias analysis.
UCA: usual care alone; CI: confidence interval.
* Adjusted for VAS pain at baseline, other osteoarticular disease affecting the target knee, prior history of surgery on the target knee, pain medication, socio-professional category and level of education.

Table II Mean reduction in VAS pain between M0 and M12 (ERGONOMIE RCT)

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more generic instrument for measuring quality of life in terms of preferences associated with an individual's health state than OAKHQOL, which is a disease-specific instrument for OA of the lower limbs[22,23]. Specifically, our results showed that three OAKHQOL domains were clearly improved in the ODRA group (pain, physical activities, and mental health). The two other OAKHQOL domains (social support and social activities) might not be improved in the ODRA group because these domains are less sensitive to change[43] and rely more on the patient's environment than on a potential effect of the biomechanical device.

Patients in the ODRA group did report side-effects, including skin irritation or swelling[11]. However, given the good results in terms of

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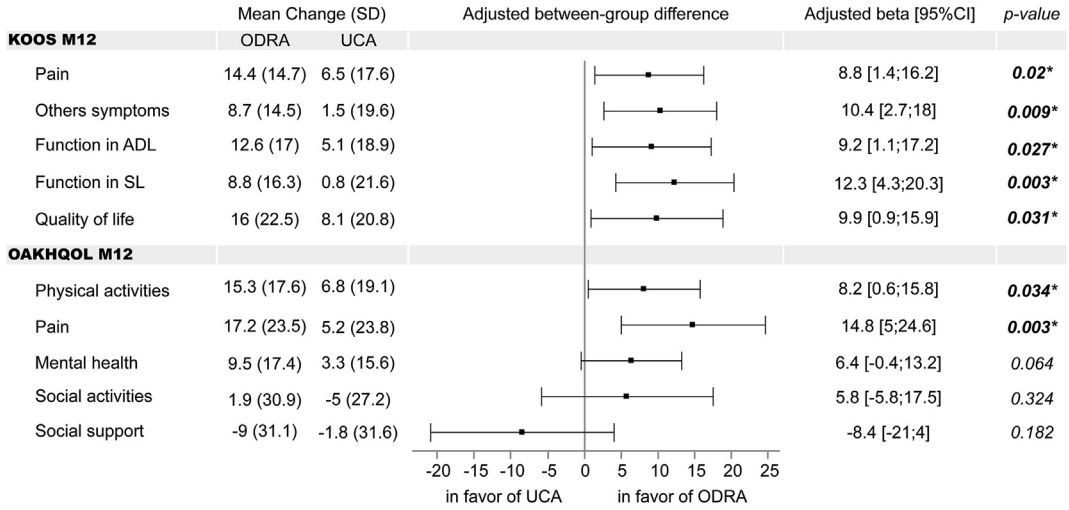

Fig. 3 Evolution of KOOS and OAKHQOL scores between M0 and M12 in the ODRA group compared with the UCA group (ERGONOMIE RCT).

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	% of patients reaching MCID		Multivariate analysis (reference = UCA)	
	ODRA	UCA	ORa (95% CI)	*P*-value
VAS pain				
Pain reduction > 19.9 points	46.9	27.8	2.76 (1.05–7.23)	**0.04***
KOOS				
Functional improvement in activities of daily living ≥ 9 points	58.1	29.2	4.90 (1.68–14.32)	**0.004***
OAKHQOL				
Physical activity improvement ≥ 19 points	35.3	13.2	4.43 (1.38–14.21)	**0.01***
Pain improvement ≥ 21.4 points	35.3	17	3.56 (1.20–10.56)	**0.02***
Mental health improvement ≥ 11.7 points	39.2	18.9	2.91 (1.04–8.12)	**0.04***
Social activity improvement ≥ 5.8 points	35.3	34	0.95 (0.37–2.44)	0.91
Social support reduction ≥ 18.2 points	11.8	20.8	0.53 (0.15–1.85)	0.32

MCID: minimal clinically important difference.
UCA: usual care alone.
VAS: visual analog scale.
KOOS: knee injury and the osteoarthritis outcome score.
OAKHQOL: osteoarthritis knee-and-hip quality-of-life questionnaire.
ORa: Odds ratio adjusted for VAS pain at baseline, other osteoarticular disease affecting the target knee, prior history of surgery on the target knee, pain medication, socio-professional category, and level of education.
* Statistical difference between groups was observed ($P < 0.05$).

Table III Proportion of patients who experienced significant relevant improvement (MCID) in effectiveness criteria between M0 and M12 in the ODRA group compared with the UCA group (ERGONOMIE RCT)

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acceptability and compliance, patients (even elderly ones) seemed to tolerate the ODRA brace well in the medium term. Indeed, the estimated percentage of patients who continued to use the ODRA brace daily at 1 year was particularly high (84%) compared with other studies[12,44,45]. This could be partly associated with the good clinical results of our study compared with the literature. In addition to its effectiveness, the ODRA is custom made and less bulky than the three-point orthosis currently prescribed for medial knee OA, which may improve tolerance and acceptability.

Our analysis of the consumption of analgesics and NSAIDs revealed some differences between the groups at M12. There was a significant decrease in the use of analgesics in the ODRA group, whereas NSAID consumption remained stable in the UCA group. There is almost no literature that focuses on this potential analgesic-sparing effect; only one previous RCT reported lower analgesic consumption at 6 weeks, but this was not statistically significant[38]. There was no significant reduction in the use of intra-

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	ALL	ODRA	UCA	*P*-value
ANALGESICS				
N and % of patients using analgesics within the previous 7 days at M0	84 (70%)	46 (76.7%)	38 (63.3%)	0.11
N and % of patients using analgesics during the study period	98 (81.7%)	48 (80%)	50 (83.3%)	0.64
NSAIDs				
N and % of patients using NSAID within the previous 7 days at M0	27 (22.5%)	13 (21.7%)	14 (23.3%)	0.83
N and % of patients using NSAID during the study period	73 (60.8%)	35 (58.3%)	38 (63.3%)	0.57
HYALURONIC ACID INJECTION (targeted knee)				
N and % of patients with hyaluronic acid injection within the 6 months preceding M0	42 (35%)	21 (35%)	21 (35%)	1
N and % of patients with hyaluronic acid injection during the study period	42 (35%)	17 (28.3%)	25 (41%)	0.13
STEROID INJECTION (targeted knee)				
N and % of patients with steroid injection within the 6 months preceding M0	35 (29.2%)	17 (28.3%)	18 (30%)	0.84
N and % of patients with steroid injection during the study period	16 (13.3%)	10 (16.7%)	6 (10.1%)	0.28

NSAID: non-steroidal anti-inflammatory drug.

Table IV Comparison of symptomatic pharmacological treatment between groups at M0 and M12 (ERGONOMIE RCT)

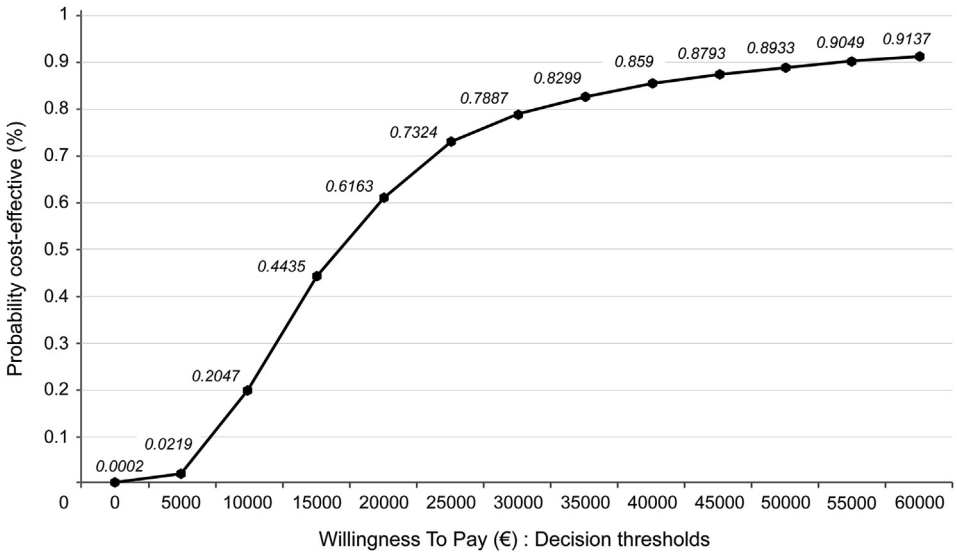

Fig. 4 Acceptability curve for the choice of strategy (ERGONOMIE RCT). This curve makes it possible to evaluate the probability that the ODRA strategy will be cost-effective according to several willingness-to-pay thresholds. It is based on the 10,000 samples generated by the bootstrap analysis. At each value of the willingness-to-pay threshold (***x***-axis), the curve gives the proportion of samples for which the ICER ratio is below this WTP value. This proportion (***y***-axis) reflects the probability for which the ODRA strategy is more efficient than the UCA strategy at the WTP value. To our knowledge, there is no consensus regarding thresholds for biomechanical devices in knee OA in France, unlike in other countries[16,34].

articular symptomatic treatments (steroid or IAHA injection) at M12 despite significant improvements in pain and quality of life.

Finally, the cost–utility analysis showed an annual direct cost of €781 per year for the UCA group. This is comparable to estimated costs in previous French studies on knee OA[37,46,47], keeping in mind that the extra costs in the ODRA group are mainly attributable to the price of the brace. The extra costs associated with one additional QALY gained with the ODRA brace varied between €16 683 and €25 225, which is comparable with the ICER previously reported for the treatment of knee OA (from €4000 to €57 550 and from €240 to €53 225 for disease-modifying osteoarthritis drugs (DMOADs) and IAHA, respectively[36]). When we compare our ICER to the willingness-to-pay threshold of €45,000 suggested in the literature, the likelihood that the ODRA brace would be cost-effective is more than 85% compared with usual care alone. Concerning QALY, the incremental effectiveness of the ODRA (mean difference in QALY) is comparable with the literature (from 0.01 to 0.025 for DMOADS, and from 0.024 to 0.115 for IAHA[36]). Taken together, these results suggest that, from a societal perspective, the

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ODRA would have a cost–utility that has not been demonstrated so far for a brace in knee OA.

We recognize that this pragmatic RCT had some limitations. Neither the investigators nor the participants were blinded to the treatment group. In trials evaluating knee braces, it is difficult to guarantee both the blinding of patients and of medical investigators[48]. The absence of a neutral orthosis as control group was also a limitation. However, a knee brace that does not realign may nonetheless have therapeutic effect by altering proprioceptive input, or muscle coactivation or recruitment, and may limit injurious joint motion, and thus not constitute a pure placebo. In RCTs focused on OA, a placebo response is not necessarily equivalent to the improvement of symptoms because this improvement could be related to natural variation of disease activity, regression to the mean, additional undeclared treatments, response bias, or the Hawthorne effect[49]. However, a placebo effect cannot be fully excluded. Moreover, as a reflection of the real-world setting and despite randomization, significant differences between groups were observed at baseline. Indeed, at the time of randomization, for some patients ($n = 3$) the investigators erroneously reported osteoarticular disease affecting the target knee, which was used in the minimization algorithm. The values were then corrected, but this may explain some imbalance between groups. However, these differences were at least partially balanced because we adjusted comparisons for these factors.

Another limitation was the declarative collection of healthcare consumption and direct medical costs, even if this was crossed with different sources (self-reported diary, follow-up visits, phone calls). This method was required because access to data via larger national medical databases, such as the French national health insurance inter-regime information system, was not authorized.

In conclusion, the ERGONOMIE study has shown that combining the ODRA brace with usual care is a promising therapeutic strategy, which demonstrates good acceptability and tolerance in patients with medial knee OA. Further research is needed to confirm the cost–utility of this expensive custom orthotic device, and to investigate the predictive factors of patient response, which would help clinicians to identify the best candidates for an ODRA brace. Longer-term studies over 2–5 years are also warranted to check long-term improvement, and to confirm the good safety profile and the OA-related real-life habits of patients fitted with this device. The potential impact of the ODRA on disease progression, cartilage damage, or knee-replacement surgery must also be considered because of its medico-economic and societal costs.

Conflicts of interest

All authors declare no conflict of interests and disclose no financial or personal relationships with other people or organizations that could inappropriately influence (bias) this work. The PROTEOR group had no role in the study design or performance, writing of the manuscript, or decision to publish.

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Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.joca.2020.11.009.

Author contributions

MG, CM, PO, and IF contributed to the design of the study. AD, EB, CB, AC, TC, DL, JMC, AR, JFM, KM, MT, and DW participated in the acquisition and inclusion of data. MG drafted the first version of the manuscript, contributed to the interpretation and discussion of the results, and coordinated the manuscript writing. IF and ALS performed the statistical analysis, and participated in the interpretation analysis and discussion of this paper. CBi and CM revised the manuscript and contributed to its improvement. PO coordinated the manuscript writing and contributed to the interpretation and discussion of this paper.All authors read and approved the final manuscript.

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2020

Robert-Lachaine.X & Al, Three-month efficacy of three knee braces in the treatment of medial knee osteoarthritis in a randomized crossover trial (DOI : 10.1002/jor.24634)

Objectif :

Déterminer les effets d'un traitement de 3 mois avec une orthèse 3 points valgisante (V3P), une orthèse Odra (VER) et une orthèse stabilisatrice (utilisée après lésion ligamentaire) sur l'activité quotidienne, le confort, la douleur et le KAM[3].

Type d'étude : Essai Crossover randomisé

Matériel et Méthode :

24 patients inclus ➔ 21 patients ont réalisé l'étude jusqu'au bout.

Les patients ont tous porté 3 types d'orthèse (dans un ordre aléatoire), à chaque fois pendant 3 mois :
• Une orthèse sur-mesure Odra (« VER-Brace » dans l'étude)
• Une orthèse de série PAO[8] de type 3 points (« V3P-Brace »)
• Une orthèse de stabilisation de série PAO[8] utilisée généralement après des problèmes de ligaments.
Période de Wash out de 15 jours sans orthèse entre chaque type d'orthèse.

AQM[1] avant et après chaque période de 3 mois ➔ 6 examens AQM[1] par patient.
Instruction au patient de porter les orthèses autant que possible.

Critères d'évaluation :

Principaux :
Douleur et confort de l'orthèse ➔ Echelle VAS[11]
AQM[1] Selon deux conditions (avec et sans orthèse) ➔ KAM[3]
Suivi du Temps de port ➔ Carnet de suivi, choix par intervalles 0 ; 1 à 3h ; 4 à 5h ; 6h et plus
Suivi des consommations médicamenteuse ➔ Carnet de suivi
Score évaluant la fonction selon 5 items ➔ Test KOOS[4]
Score fonctionnel ➔ Test WOMAC[12]

Résultats de l'étude :

- Efficacité des 3 types d'orthèse sur la diminution de la douleur
- Orthèse 3 points moins portée que les autres orthèses lors des dernières semaines
- Amélioration des scores fonctionnels KOOS[4] et WOMAC[12] avec les 3 orthèses
- L'orthèses Odra s'est démarquée comme étant plus confortable que les deux autres orthèses
- **A la fin de l'étude, + de 75% des patients ont décidé de garder l'Odra parmi les 3**. Les raisons : amélioration de la qualité de vie, plus de confort, la taille, la facilité de mise en place. Globalement, il y a une meilleure observance.
- L'Odra réduit davantage le KAM[3] (knee adduction moment)

Conclusion :

Une amélioration de la douleur, de l'état fonctionnel, de la raideur et de la qualité de vie a été notée pour les 3 orthèses.
L'orthèse sur-mesure Odra a montré un confort plus important, une meilleure observance et une réduction plus importante du KAM[3] comparé aux deux autres types d'orthèse.

Limitation :

Auto-déclaration de l'observance.
Taille d'échantillon assez faible ➔ Puissance statistique suffisante pour les critères d'évaluation.
Certains patients étaient en obésité ce qui peut augmenter les artefacts dus aux tissus mous ➔ Patients atteints de gonarthrose sont souvent en surpoids, les intégrer était pertinent.
Pas d'évaluation du niveau d'atteinte du compartiment médial ➔ Chaque patient a utilisé les 3 orthèses.

Biais potentiel / Conflit d'intérêt : aucun

PROTEOR

Abstract

Three-month efficacy of three knee braces in the treatment of medial knee osteoarthritis in a randomized crossover trial

Xavier Robert-Lachaine Yoann Dessery Étienne L. Belzile Sylvie Turmel Philippe Corbeil

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Abstract

Immediate biomechanical and functional effects of knee braces are often reported, however, the duration and type of knee brace treatment for knee osteoarthritis (KOA) remain unclear. The objective was to evaluate usage, comfort, pain, and knee adduction moment (KAM) of three knee braces each worn 3 months by patients. Twenty-four patients with KOA were assigned in a randomized crossover trial a valgus three-point bending system brace (V3P-brace), an unloader brace with valgus and external rotation functions (VER-brace) and a stabilizing brace used after ligament injuries (ACL-brace). Functional questionnaires and gait assessment were carried out before and after each brace wear period of 3 months. A Friedman test was applied between brace wear diary recordings. Repeated measures analyses of variance contrasted the factors brace type (ACL, V3P, and VER), time (pre and post) and wear (without and with) on comfort, pain, function, and KAM. Brace usage was similar, but the V3P-brace was slightly less worn. Discomfort was significantly lowered with the VER-brace. All knee braces relieved pain and symptoms from 10% to 40%. KAM angular impulse was reduced with the three braces, but the VER-brace obtained the lowest relative reduction of 9%. The interaction between time and wear indicated that part of the KAM reduction with brace wear was maintained post treatment. All three knee braces have great benefits for pain and function among the medial KOA population. The VER-brace offers additional advantages on daily use, comfort and KAM, which could improve compliance to brace treatment.

2015

Ornetti P & Al, Clinical effectiveness and safety of a distraction-rotation knee brace for medial knee osteoarthritis, Annals of Physical and Rehabilitation Medicine (DOI : 10.1016/j.rehab.2015.03.004)

Objectif :

Evaluer l'efficacité clinique et la sécurité d'un nouveau type d'orthèse sur-mesure (Odra) dans le cadre du traitement de la douleur induite par l'arthrose du compartiment interne du genou.
Evaluer l'effet de l'orthèse sur la douleur après 6 semaines et à un an de port.

Type d'étude : Prospective, Interventionnelle, monocentrique

Matériel et méthode :

20 Patients inclus ➔ 18 patients ayant été au bout de l'étude
Instruction au patient de porter l'orthèse au moins 6h/j et 5j/sem.

Critères d'évaluation :

Principal :
Niveau de douleur à inclusion et à 6 semaines et 1 an ➔ Echelle VAS[11] de 0 à 100

Secondaires :
Niveau de douleur à 1an ➔ Echelle VAS[11] de 0 à 100
AQM[1] à l'inclusion et à 6 semaines ➔Paramètres spatio-temporels
Score évaluant la fonction selon 5 items ➔ Test KOOS[4]
Evaluation de la consommation médicamenteuse (anti-douleur et anti-inflammatoire non stéroïdiens) ➔ Carnet de suivi, auto-déclarations
Tolérance et observance ➔ Carnet de suivi, auto-déclarations

Résultats de l'étude :

- **Diminution des symptômes douloureux du genou après 6 semaines. Cette condition se maintient au-delà de 52 semaines ;**
- Amélioration fonctionnelle notable pour chaque item après 6 semaines. Cette amélioration reste notable après un an de port ;
- Diminution significative de la consommation médicamenteuse après 6 et 52 semaines ;
- **2 patients sur les 3 en arrêt de travail en raison de leur genou lors de l'inclusion dans l'étude ont pu reprendre leur activité professionnelle ;**
- Les 9 patients qui avaient arrêté une pratique sportive de loisir du fait de la douleur ont pu reprendre ;
- Bonne adhésion au traitement comparativement aux autres orthèses de genou, déclaration d'un temps de port moyen de 6h/j et 4.8j/sem après un an de port ;
- **Augmentation moyenne de 10% de la vitesse de marche après 6 semaines de port, augmentation de la longueur et de la fréquence de pas**.

Conclusion :

Les résultats de cette étude montrent une efficacité de l'orthèse sur-mesure Odra à court et moyen terme dans le cadre de la réduction de la douleur et de l'amélioration fonctionnelle.
L'orthèse Odra semble avoir un ratio Bénéfice/Risque plus avantageux que ceux des orthèses de référence (décharge, 3 points...).

Limitations :

Recrutement dans un hôpital universitaire.
Petite taille d'échantillon ➔ Puissance statistique atteinte pour cette étude préliminaire.
Absence d'évaluation de l'effet placébo ➔ la présence d'une orthèse même neutre pourrait altérer la proprioception ou l'activité musculaire et ne représente donc pas un placebo strict.

Biais potentiel / Conflit d'intérêt : aucun

PROTEOR

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Original article

Clinical effectiveness and safety of a distraction-rotation knee brace for medial knee osteoarthritis

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ABSTRACT

Objective: Evaluation of the clinical effectiveness and safety of a new custom-made valgus knee brace (OdrA) in medial knee osteoarthritis (OA) in terms of pain and secondary symptoms.
Methods: Open-label prospective study of patients with symptomatic medial knee OA with clinical evaluation at 6 and 52 weeks (W6, W52). We systematically assessed pain on a visual analog scale (VAS), Knee injury and Osteoarthritis Outcome Score (KOOS), spatio-temporal gait variables, use of nonsteroidal anti-inflammatory drugs (NSAIDs) and analgesic-sparing effects of the brace and tolerance. Mean scores were compared at baseline, W6 and W52 and the effect size (ES) and 95% confidence intervals (95% CIs) were calculated.
Results: We included 20 patients with knee OA (mean age 64.2 ± 10.2 years, mean body mass index 27.2 ± 5.4 kg/m^2). VAS pain and KOOS were improved at W6 and W52: pain (ES = 0.9 at 1 year), amelioration of other symptoms (ES = 0.4), and function in activities of daily living (ES = 1.1), sports and leisure (ES = 1.5), quality of life (ES = 0.9) and gait speed (ES = 0.41). In total, 76% of patients showed clinical improvement at 1 year. Analgesic and NSAIDs consumption was significantly decreased at W6 and W52. One serious adverse effect noted was lower-limb varices, and observance was deemed satisfactory at 1 year.
Conclusion: This new unloader brace appeared to have good effect on medial knee OA, with an acceptable safety profile and good patient compliance.

1. Introduction

Knee osteoarthritis (OA) is a chronic disabling joint disease that causes increasingly severe functional impairment in everyday activities. The medial compartment is the most frequently affected, given the physiological high loading on this zone. The condition is frequently aggravated by constitutional or acquired bow-leggedness [1,2]. To limit pain in medial-compartment knee OA, conservative medical management combining pharmacological and nonpharmacological treatment is recommended [3–5]. The use of medical devices such as foot pronation orthotics [6,7] or articulated valgus knee braces is advocated [8–10]. Although the beneficial effect of these devices on symptoms are related to their proprioceptive properties [11,12] or muscle activation [13–15], the principal effect stems from their ability to unload the medial compartment, where the pain originates [1,2,8,16–18].

The improvement in functional capacities is better with unloader knee braces than knee sleeves or neutral articulated braces [8,16,19,20]. However, the efficacy of the braces is still debated [10,21,22], and tolerance to the braces is poor because they irritate the skin, impair venous return, can cause oedema and are bulky, which can hamper certain movements in everyday life [23]. In clinical practice, this type of orthotic device is rarely prescribed by physicians specialized in degenerative joint diseases of the knee because they prefer pharmacological treatments and/or rehabilitation [8].

Recently, the PROTEOR group developed a new custom-made brace, the OdrA system (Fig. 1). The brace features an innovative system to unload the medial compartment by distraction and

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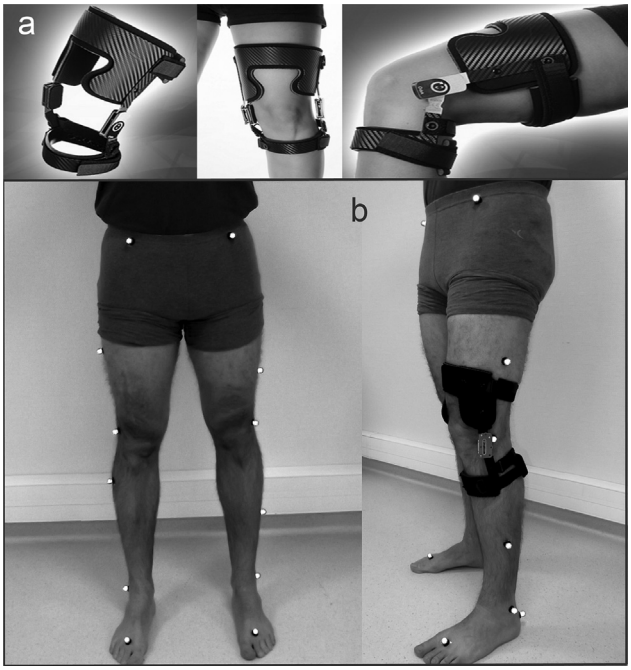

Fig. 1. Knee brace with the OdrA system (PROTEOR, France).

external rotation. This mechanism allows for shifting the vertical axis of the ground reaction force vector backwards and medially toward the center of the knee joint, which reduces the knee adduction moment during the propulsion phase but disappears in the swing phase or at rest, with the knee bent. The new system, which was recently validated biomechanically in terms of kinetic and kinematic dimensions [24], is also less cumbersome because it is custom-made, with few voluminous tibial and femoral straps. This dynamic unloader brace, with no effect at rest with the knee bent, is equipped with a rack and pinion system that plays a dual role in weight-bearing positions: distraction and external rotation of the leg. The effect is to shift the centre of the load toward the natural inter-condyle position and thus to limit overloading of the medial compartment [24], which is often aggravated in patients with bow-leggedness or with medial meniscus degeneration.

In terms of the current overall re-evaluation of treatments in knee OA, the beneficial effects of this device on symptoms by unloading the medial compartment as well as tolerance and compliance could lead to its use in clinical practice. However, in addition to data needed from validated algo-functional questionnaires, spatio-temporal gait data are needed to provide an objective evaluation of the functional benefits of this dynamic knee brace on gait [18,25,26]. These investigations are in response to recent requests from accreditation organisations responsible for authorising the commercialisation of these medical devices: the French health authority requires a high level of scientific evidence for these orthotic devices, with high-quality therapeutic trials, on which marketing approval for these expensive and not risk-free devices depends [27].

The primary objective of this interventional prospective single-centre study was to evaluate the efficacy of the new valgus knee brace with the OdrA system for medial-compartment knee OA on pain at week 6 (W6). Secondary objectives were to evaluate the effect of the brace on other symptoms in the short-term (W6) and medium-term (W52) and to provide data on tolerance and compliance in clinical practice.

2. Materials and methods

2.1. Patients

Patients consulting at the Department of Rheumatology and Physical Medicine of Dijon University Hospital over six months were recruited consecutively. We included patients 40 to 80 years old who had unilateral medial-compartment knee OA according to ACR criteria [28] (medial compartment pain at rest $>$ 4 on a 0–10 visual analog scale [VAS]), radiological stage II, III or IV according to the Kellgren and Lawrence classification [29] determined by radiography performed in the previous six months, with no change in pharmacological treatment in the previous six months and no injections of hyaluronic acid or corticosteroids during this period. Exclusion criteria were presence of a disease that could interfere with gait analysis or inflammatory or rapidly destructive knee OA. Patients with an indication for surgery according to the medical specialist consulted, a valgus morphotype or another disease likely to cause knee pain or modify gait were also excluded. After inclusion and custom-moulding of the OdrA brace, patients were instructed to wear the brace for at least 6 h/day, 5 days/week.

The study was conducted in accordance with good clinical practices and the Declaration of Helsinki (ClinicalTrials.gov identifier: NCT01884883) and was approved by the local ethics committee. Patients gave informed consent to be in the trial.

2.2. Gait protocol

At inclusion and at W6 after wearing the brace, patients underwent a standard protocol for quantified gait analysis (VICON system, Oxford, UK). This gait protocol has been described elsewhere for the biomechanical validation of the OdrA device [24]. Briefly, reflective markers, detected by eight infrared cameras, were placed on the pelvis and lower limbs of patients, who were instructed to walk up and down a 10-m path 12 times. The spatio-temporal gait variables were recorded over the 6 m in the middle of the track to avoid acceleration and deceleration phenomena. The patients were told to walk at their usual comfortable speed.

2.3. Data collection

At inclusion, the following clinical data were collected: age, sex, body mass index (kg/m^2), disease duration, and radiological stage by the Kellgren and Lawrence classification [29].

Judgement criteria were collected at inclusion and at 6 and 52 weeks (W6, W52). For the principal outcome criteria (improvement in pain at W6 compared with inclusion), pain was measured at rest by a VAS (0–100).

The following secondary outcomes were evaluated. Improvement in pain at W52 compared with at inclusion was measured at rest by a VAS (0–100). Overall self-evaluation of disease severity was measured by a VAS (0–100). Function was measured by the Knee injury and Osteoarthritis Outcome Score (KOOS) consisting of 42 questions covering 5 domains, each scored from 0 (worst) to 100 (best) [30]: pain, other symptoms, function in activities of daily living (ADL), function in sports and leisure (SL) activities and quality of life (QoL). This internationally validated score includes all of the domains of Western Ontario and McMaster Universities Arthritis Index (WOMAC; pain, stiffness, function) and adds more demanding activities and important aspects of QoL. The KOOS can be represented in the form of a graph, with a line linking the different domains [31]. Consumption of nonsteroidal anti-inflammatory drugs (NSAIDs) and analgesics was evaluated by the number of days per week each class of drug was taken. Disease severity at W6 and W52 was measured by a semi-quantitative

Likert scale: 1, severely worsened; 2, worsened; 3, stable; 4, improved; 5, much improved. Tolerance to the brace and compliance was evaluated by recording adverse effects in a patient diary and by mean time the brace was worn (number of hours per day and number of days per week). The following spatio-temporal gait variables were collected at W0 and W6 [24]: walking speed (m/s), stride length (m), stride width (m), stride frequency (Hz), single and double support time (% of gait cycle) and step dephasing (% of gait cycle).

2.4. Statistical analysis

The principal analysis was intent-to-treat (ITT), with last observation carried forward (LOCF) used for missing data. Data are described with mean ± SD for clinical and gait spatio-temporal variables. Scores at different times were compared with those at inclusion by Wilcoxon matched pairs test. $P < 0.05$ was considered statistically significant. The amplitude of the therapeutic effect of the brace for each judgement criterion was evaluated by the effect size (ES) with the following interpretation: 0 to 0.5, weak effect; 0.5 to 0.8, moderate effect; > 0.8, major effect [32]. For ES values (clinical and spatio-temporal parameters), 95% confidence intervals (95% CIs) were calculated by the non-parametric bootstrap method.

According to data in the literature from similar clinical studies, improvement in pain on a VAS at W6 (principal criterion) should be at least 20%. With an alpha risk of 0.05 and power of 80%, a minimum of 15 subjects was necessary. Taking into account the possibility of patients leaving the trial, we needed to include 20 patients for 1 year of follow-up. Statistical analysis involved use of Statistica v10.2 (Statsoft Inc., Tulsa, USA).

3. Results

We included 20 patients in the study (16 females; mean age 64.2 ± 10.2 years; mean body mass index 27.2 ± 5.4 kg/m^2) (Table 1). Pain, disease severity and functional disability at inclusion were high, with no indication for surgery according to the treating rheumatologist. In total, 16 patients (80%) were taking level I or II analgesics and 6 (30%) NSAIDs. At W6, clinical and gait analysis data were analyzed for 19 patients because one patient had to stop wearing the brace due to venous intolerance and at W52, 18 of the 19 patients were re-evaluated (one patient lost to follow-up).

Table 1
Characteristics of the 20 patients wearing the OdrA brace for knee osteoarthritis (OA) at inclusion.

Characteristics	
Age (years)	64.2 ± 10.2
Sex ratio (F/M), no. of patients	16/4
BMI (kg/m^2)	27.2 ± 5.4
Disease duration (years)	6.4 ± 4.7
Pain, VAS (0–100)	63.1 ± 12.8
Disease severity, VAS (0–100)	64.2 ± 16.5
WOMAC function (0–100)	56.7 ± 12.8
Symptomatic treatments (% patients)	
Analgesics	80
NSAIDs	30
SYSADOAs	35
Radiographic stage of knee OA	
Kellgren and Lawrence classification, no. of patients	
II	5
III	9
IV	6

Data are mean ± SD unless indicated.
BMI: body mass index; VAS: visual analog scale; WOMAC: Western Ontario and McMaster University Osteoarthritis Index; NSAIDs: nonsteroidal anti-inflammatory drugs; SYSADOAs: symptomatic slow-acting drugs.

At W6, mean pain score had decreased by more than 50% from inclusion (63.1 ± 12.8 to 29.8 ± 14.2, $P < 0.001$) (Table 2; Fig. 1). The ES at W6 was 2.6 (95% CI 1.6–2.6); the mean pain score was 38.1 ± 17.4 at W52 (ES 2.1 [1.0–2.8]). A significant benefit was also seen for functional repercussions at W6 ($P < 0.01$, ES > 1), whatever the KOOS domain: pain (ES 1.9 [1.5–2.5]); other symptoms (ES 1.2 [0.4–2.0]); function ADL (ES 1.8 [1.4–2.2]); function SL (ES 1.7 [1.2–2.2]); and QoL (ES 1.1 [0.3–1.9]). At W52, this benefit on symptoms remained significant as compared with at inclusion for all domains (Fig. 2).

However, the domains of pain, symptoms and function ADL were significantly decreased between W6 and W52. At W6, 85% of patients thought that their state with regard to knee OA had "improved" or "much improved" as compared with 76% at W52.

The consumption of NSAIDs and analgesics had decreased significantly at W6 and W52 ($P < 0.05$). At W52, the consumption of analgesics had decreased to a mean of 1.3 days per week as compared with 4.5 at inclusion, and one third of patients had stopped analgesics completely. For NSAIDs, of the six patients who were taking these at least once a week, only one continued to take them regularly at W52. Concerning professional activities, for those who had not retired (40% of professionally active patients at inclusion), two of the three patients on sick leave because of knee OA were able to go back to work part- or full-time at W52.

Concerning the gait analysis (Table 3), between inclusion and W6, walking speed increased because of a concomitant increase in stride length and frequency. Walking speed had increased by a mean of 10% between inclusion and final evaluations (ES 0.41 [95% CI 0.06–0.75], $P < 0.05$) and exceeded 1 m/s, considered appropriate for people in this age group. Stride length increased to a lesser degree (ES 0.25 [0.09–0.51]). In contrast, stride width, step dephasing and single and double support time were not significantly modified by wearing the brace. The ES for objective gait variables (0.16–0.45) was smaller than that for subjective clinical parameters.

Concerning device tolerance, one female patient had to stop the study early because of aggravation of lower-limb varicose veins, although Doppler ultrasonography revealed no deep vein thrombosis. Six patients reported one or several superficial adverse effects concerning the skin: local heat ($n = 2$), moderate irritation ($n = 4$), and zone of excessive weight bearing at the front of the tibia ($n = 5$). The patients wore the knee brace for a mean of >8 h/day and > 6 days/week at W6, with a decrease to a mean of 6 h/day and 4.7 days/week at W52. Most patients reported no particular difficulties in putting on and taking off the brace, but some reported difficulties in getting dressed ($n = 5$) because of the lateral hinges.

4. Discussion

The results of this clinical evaluation of a new valgus knee brace, the OdrA, for which the biomechanical properties have already been validated [24], show that the brace effectively reduced symptoms of medial-compartment knee OA, in both the short-term (ES at W6 from 1.1 [95% CI 0.3–1.9] to 2.6 [1.6–2.6]) and the medium-term (ES at W52 from 0.9 [0.3–1.5] to 1.9 [1.0–2.8]) according to KOOS scores. These results are better than those reported in the literature (ES 0.2–0.7) for unloader braces used by other patients with symptomatic knee OA [16,26,33–35]. This improvement is superior to the minimal clinically important difference (MCID) reported for the KOOS (37). However, this threshold (MCID 9/100), which depends on patient characteristics, is recognized only for the KOOS QoL [36] and function in ADL [37] and is equivalent to the MCID for the WOMAC function subscale in knee OA [38].

Table 2
Clinical scores at inclusion (W0), 6 weeks (W6) and 1 year (W52) after wearing the OdrA knee brace and magnitude of the therapeutic effect (effect size).

Clinical variables	W0 $n=20$	W6 $n=19$	W52 $n=18$	ES (95% CI)	
				W6	W52
Pain, VAS (0–100)	63.1 ± 12.8	29.8 ± 14.2*	38.1 ± 17.4*§	2.6 (1.6–3.6)	1.9 (1.0–2.8)
Disease severity, VAS (0-100)	64.2 ± 16.5	34.1 ± 16.8*	36.9 ± 15.9*§	1.9 (1.1–2.7)	1.7 (1.0–2.4)
KOOS (0–100)					
Pain	42.6 ± 12.5	66.0 ± 13.6*	54.3 ± 13.2*§	1.9 (1.4–2.4)	0.9 (0.5–1.3)
Symptoms	54.4 ± 17.3	75.7 ± 17.5*	60.2 ± 16.2*§	1.2 (0.4–2.0)	0.4 (0.05–0.9)
ADL	44.5 ± 12.6	67.8 ± 11.9*	58.5 ± 12.7*§	1.8 (1.4–2.2)	1.1 (0.6–1.6)
SL	14.5 ± 13.4	37.3 ± 12.9*	34.0 ± 12.4*	1.7 (1.2–2.2)	1.5 (0.7–2.2)
QoL	28.6 ± 17.4	45.9 ± 23.3*	45.7 ± 16.5*	1.0 (0.3–1.7)	0.9 (0.3–1.5)

Data are mean ± SD unless indicated.
KOOS: Knee injury and Osteoarthritis Outcome Score (0–100, 0, worst, to 100, best); ADL: activities of daily living; SL: sport and leisure activities; QoL: quality of life; ES: effect size; 95% CI: 95% confidence interval.
*$P < 0.05$ comparing W6 vs W0 and W52 vs W0.
§$P < 0.05$ comparing W6 vs W52.

Tolerance of the brace seemed to be good, except for one patient with lower-limb varicose veins, which may be a contraindication for this type of semi-rigid knee support. The brace seems to be relatively easy to use in everyday life, even in older patients, and thus has few of the constraints frequently reported with this type of apparatus concerning putting it on or the bulkiness [23].

Our study contains some limitations. The recruitment at a teaching hospital implies bias in the selection of patients with symptomatic knee OA. As well, the study had a small sample size, which could have hidden significant differences and did not allow us to identify predictors of a good response by multivariate analysis for defining the profile of patients. Therefore, the results need to be confirmed in larger studies. The possible placebo effect, which is well known in OA [39], also needs to be considered in this evaluation of benefits of the brace for symptoms. The results were still positive at one year and compliance was good, which suggests that the effect on symptoms was substantial; rates of pain relief with these medical devices often decrease quickly in the medium-term [40]. Only a randomised study comparing a neutral placebo brace could estimate the part of pain relief related to the placebo effect. A comparative randomised study comparing a reference articulated unloader knee brace already on the market could have been proposed to overcome this weakness, but such an analysis could not be realized in this preliminary study.

Pain and function were substantially improved with the brace, as shown by the ES (>0.8) and the high rate of satisfaction among patients (>75% at one year). The reduced consumption of drugs achieved by wearing the brace is important; this judgement criterion is rarely reported for these braces (one negative study for NSAIDs and analgesics and two positive studies [19,20,41]). This latter point is of clinical relevance for this disease, with disability implications for everyday life activities, and for OA patients, who are often older and taking a large number of drugs. Concerning the clinical follow-up at one year, two of the three patients on sick leave at inclusion were able to return to work and nine patients who had stopped physical activities (sport and/or leisure) were able to resume them. Wearing the brace was accompanied by improved QoL, as was previously reported with this type of apparatus [34], and underlines the importance of taking this pertinent judgement criterion into account. It also justifies choosing the KOOS rather than the Lequesne or WOMAC assessment, because this recently validated international score evaluates more demanding activities (running, squatting) and addresses interesting aspects of QoL [30]. In the literature, only one study used the KOOS [42] but did not show the benefits of an articulated valgus brace compared with a brace in a neutral position. In our sample, the efficacy of the brace seemed to wane with time, especially for everyday symptoms, which could have been due to a deterioration in the arthritis or to the less frequent use of the brace after one year, as shown by patient diaries, or perhaps premature wear of the unloader brace, which will have to be proven. Indeed, this type of custom-made device may need

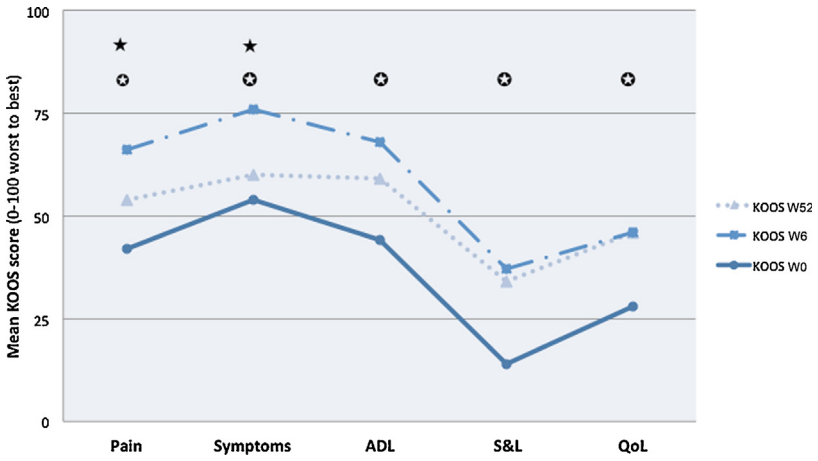

Fig. 2. Knee injury and Osteoarthritis Outcome Score (KOOS) profile for patients wearing the OdrA knee brace at inclusion (W0, $n = 20$) and week 6 (W6, $n = 19$) and week 52 (W52, $n = 18$). ADL: activities of daily living; SL: sports and leisure activities; QoL: quality of life. *$P < 0.05$ for W6 vs W0 and W52 vs W0. ✪ $P < 0.05$ for W6 vs W52.

Table 3
Spatio-temporal gait variables at inclusion (W0) and 6 weeks (W6) after wearing the OdrA knee brace and magnitude of the therapeutic effect (effect size).

Gait variables	W0 $n=20$	W6 $n=19$	ES (95% CI)
Walking speed ($m.s^{-1}$)	0.98 ± 0.24	$1.08 \pm 0.26^*$	0.41 (0.06–0.75)
Stride length (m)	1.08 ± 0.20	$1.13 \pm 0.21^*$	0.25 (0.09–0.51)
Frequency ($cycle/min^{-1}$)	53.4 ± 6.6	$56.4 \pm 7.2^*$	0.45 (0.13–0.77)
Single-support time (% gait cycle)	66.3 ± 2.5	65.9 ± 2.7	0.16 (0.12–0.20)
Double-support time (% gait cycle)	15.3 ± 2.5	14.8 ± 1.6	0.20 (0.02–0.38)
Step dephasing (% gait cycle)	51 ± 0.6	51.1 ± 0.6	0.16 (0.13–0.19)
Stride width (m)	0.28 ± 0.05	0.29 ± 0.06	0.20 (0.08–0.32)

Data are mean ± SD unless indicated.
ES, effect size; 95% CI, 95% confidence interval.
$^*P < 0.05$ comparing W6 and W0.

readjustments, particularly in cases of modified musculature of the patient (three patients in our series). Thus, to achieve its biomechanical effect properly, the custom-made brace must fit the contours of the limb perfectly.

Several studies have used the WOMAC (included in the KOOS) to assess the effect of a valgus knee brace. Most reported a significant improvement in symptoms, although with an ES < 0.8 in the most recent review of the literature [18]. Nonetheless, these data are difficult to compare because the populations were heterogeneous and the articulated braces did not all have the same degree of valgisation or the same unloader mechanism. For example, none used the dynamic external rotation effect of the OdrA system [24]. Therefore, the exact place of valgus braces and the characteristics of the population that could benefit from them have yet to be established in medial knee OA, despite the recent scientific interest in these devices [3,10]. We now need well-conducted studies with reference follow-up criteria, such as validated questionnaires [20] and/or the analysis of reference quantified gait parameters [43,44] in knee OA.

Most of our spatio-temporal gait variables showed significantly improvement but to a lower degree than for pain and function variables. This lower ES (0.16–0.45, depending on the variable) for objective criteria compared with subjective patient-reported outcomes may be explained in part by a greater inter-subject variability in these biomechanical criteria. The findings also raise the possibility of a placebo effect induced by wearing the brace. We found a fast (in six weeks) and significant increase (>10%) in speed, which corroborates certain results with other articulated knee braces, for example, for the absence of any effect on stride width [12,18]. Several hypotheses could explain this more efficient gait, the first being a postural gain due to the improved proprioception with the custom-made knee brace [11,45] but above all, the unloader effect on the medial compartment of the affected side, which is inversely associated with walking-related pain in knee OA [2,8,14,42].

Altogether, the new valgus brace with the OdrA system appears to have a benefit/risk ratio that is better than those reported so far with the reference unloader braces, or three-point braces. These results will be re-evaluated in the near future in a French multicentre randomized real-life study, conducted at the request of the French Health Authority, with both algo-functional and medico-economics criteria (cost-utility analysis). This study will allow for better determining the place of this new medical device in the therapeutic management of knee OA [5,10]. These preliminary results confirm the place of valgus braces in medial-compartment knee OA [46], as underlined by the new OARSI recommendations [4].

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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2014

Dessery.Y & Al, Comparison of three knee braces in the treatment of medial knee osteoarthritis, Knee (DOI : 10.1016/j.knee.2014.07.024.)

Objectif :

Comparer l'effet immédiat du port de différentes orthèses (3 points valgisante, Odra et stabilisatrice) sur la douleur, le confort, et la charge du genou en médial chez des patients atteints d'arthrose du compartiment interne.

Type d'étude : Essai Crossover randomisé monocentrique

Matériel et méthode :

24 patients inclus ➔ 21 patients ont réalisé l'étude jusqu'au bout.
Les patients ont tous porté 3 types d'orthèse (dans un ordre aléatoire), à chaque fois pendant 3 mois :
- **Une orthèse Odra (« VER-Brace » dans l'étude)**
- **Une orthèse PAO[8] de type 3 points (« V3P-Brace »)**
- **Une orthèse de stabilisation PAO[8] utilisée généralement après des problèmes de ligaments.**

Période de Wash out de 15 jours sans orthèse entre chaque type d'orthèse.
AQM[1] avant chaque période de 3 mois

Critère d'évaluation :

Principaux :
Douleur et confort ➔ Echelle VAS[11]
AQM[1] ➔ Analyse du KAM[3]

Résultats de l'étude :

- Diminution de la douleur pour les 3 types d'orthèse.
- L'orthèse Odra diminue le plus le KAM[3].
- Odra augmente la rotation externe de cheville et de genou.
- Odra est l'orthèse de genou la plus confortable parmi les trois orthèses testées (notamment grâce à sa petite taille).
- **Le design des sangles de l'Odra évite les points de pression sur certains points anatomiques, améliorant ainsi le confort.**

Conclusion :

- **Diminution de la charge mécanique sur l'articulation du genou ;**
- **Diminution immédiate de la douleur conséquente au port de l'orthèse ;**
- **Meilleur confort d'Odra par rapport aux deux autres orthèses.**

Limitations :

Absence de groupe contrôle pour évaluation de l'effet placebo.

Biais potentiel / Conflit d'intérêt : aucun

PROTEOR

Abstract

Comparison of three knee braces in the treatment of medial knee osteoarthritis

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Affiliations expand

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Abstract

Background: Conservative orthotic treatments rely on different mechanisms, such as three-point bending systems or hinges forcing external rotation of the leg and knee stabilization, to alter the biomechanics of the lower limbs and thus reduce knee loading on the affected compartment in patients with knee osteoarthritis (KOA). No previous study had compared the effects of these mechanisms on external loading and leg kinematics in patients with KOA.

Methods: Twenty-four patients with medial KOA (Kellgren-Lawrence grade II or III) wore three custom knee braces: a valgus brace with a three-point bending system (V3P-brace), an unloader brace with valgus and external rotation functions (VER-brace) and a functional knee brace used in ligament injuries (ACL-brace). Pain relief, comfort, lower extremity kinematics and kinetics during walking were compared with and without each knee brace.

Results: Knee pain was alleviated with all three braces ($p<0.01$). The VER- and ACL-braces allowed a significant reduction in peak knee adduction moment (KAM) during terminal stance from 0.313 to 0.280 Nm/Bw x Ht ($p<0.001$) and 0.293 to 0.268 ($p<0.05$), respectively, while no significant reduction was observed with the V3P-brace ($p=0.52$). Reduced knee adduction and lower ankle and knee external rotation were observed with the V3P-brace but not with the VER-brace. The ACL-brace did not modify lower limb kinematics.

Conclusions: No difference between the knee braces was found for pain reduction, discomfort or KAM. The VER-brace was slightly more comfortable, which could ensure better compliance with treatment over the long term.

Keywords: External rotation; Knee adduction moment; Knee brace; Pain; Valgus.

2014

Laroche.D & Al, Biomechanical effectiveness of a distraction–rotation knee brace in medial knee osteoarthritis:Preliminary results, Knee (DOI : 10.1016/j.knee.2014.02.015)

En plus de l'effet valgisant (de distraction), il est possible de réduire le moment d'adduction en augmentant la rotation externe de la jambe et du pied. La rotation externe autorise un déplacement de l'axe verticale de la force de réaction au sol vers l'arrière et le centre du genou ce qui réduit le moment d'adduction.

Objectif :

Quantifier les bénéfices d'un nouveau type d'orthèse à double fonction de distraction et de rotation (Odra) chez des patients souffrant d'arthrose du compartiment interne.

Type d'étude : Essai en ouvert, étude interventionnelle prospective monocentrique

Matériel et Méthode :

20 Patients
5 semaines de port continu, recommandation d'un port de 6h/j et de 5j/sem
AQM[1] selon deux conditions (avec et sans orthèse) à W0 et à +5 semaines (W5)

Critères d'évaluation :

Principaux :
Evaluation de la douleur ➔ Echelle VAS[11]
Score fonctionnel ➔ Test WOMAC[12]
AQM1 ➔ paramètres spatio-temporels, paramètres cinétiques

Résultats de l'étude :

-Score WOMAC[12] de douleur, fonction et raideur ont diminué de 30% entre W0 et W5.
-Diminution de la douleur de 50% sur l'échelle VAS[11] entre W0 et W5.
-17 patients sur 20 se considéraient « satisfait » des effets de l'orthèse sur les symptômes de la vie quotidienne à la fin de l'étude.
-Différence d'angle de progression du pied notable entre W0 et W5, elle est notable également entre les deux conditions de port (avec et sans orthèse).
-Diminution immédiate du KAM[3] en fin de phase d'appui perdurant à W5 et après ablation de l'orthèse.
-Augmentation de la vitesse de marche à W5 avec et sans orthèse.

Conclusion :

Port de l'orthèse de distraction-rotation (Odra) a permis une amélioration significative de l'état fonctionnel et de la marche à court terme (inférieur à 2 mois).
L'étude ajoute des preuves objectives à l'argumentaire soutenant l'utilité des orthèses pour améliorer la marche et traiter l'arthrose du compartiment interne.

Limitations :

Absence de groupe contrôle pour évaluation de l'effet placebo.
Recrutement dans un hôpital universitaire.
Petite taille d'échantillon ➔ Puissance statistique atteinte pour cette étude préliminaire.

Biais potentiel / Conflit d'intérêt : aucun

PROTEOR

Abstract

Biomechanical effectiveness of a distraction-rotation knee brace in medial knee osteoarthritis: preliminary results

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Abstract

Background: Non-pharmacological therapies are recommended for the care of knee osteoarthritis patients. Unloader knee braces provide an interesting functional approach, which aims to modulate mechanical stress on the symptomatic joint compartment. We aimed to confirm the biomechanical effects and evaluate functional benefits of a new knee brace that combines a valgus effect with knee and tibial external rotation during gait in medial osteoarthritis patients.

Methods: Twenty patients with unilateral symptomatic medial knee osteoarthritis were included and they performed two test sessions of 3D gait analysis with and without the brace at the initial evaluation (W0) and after 5weeks (W5) of wearing the brace. VAS-pain, satisfaction scores, WOMAC scores, spatio-temporal gait parameters (gait speed, stride length, stance and double stance phases, step width), and biomechanical data of the ipsilateral lower limb (hip, knee, ankle and foot progression angles) were recorded at each session.

Results: VAS-pain and WOMAC significantly decreased at W5. Walking speed was not significantly modified by knee bracing at W0, but increased significantly at W5. Knee adduction moments and foot progression angles significantly decreased in the terminal stance and push off, respectively, with bracing at W0 and W5. Lower-limb joint angles, moments and powers were significantly modified by wearing the brace at W0 and W5.

Conclusion: This new knee brace with distraction-rotation effects significantly alters knee adduction moments and foot progression angles during gait, which might lead to significant functional gait improvements and have carry-over effects on pain at the short term in osteoarthritis patients (<2 months).

Level of evidence: level IV.

Keywords: Biomechanics; Knee brace; Knee osteoarthritis; Locomotion.

GLOSSAIRE

AQM[1] : Analyse quantifiée du mouvement/de la marche
Analyse cinétique et cinématique permettant d'identifier d'éventuels défauts dans les mouvements cycliques de la marche, et ce par comparaison à une marche supposée « normale ».

EQ-5D-3L[2] : EuroQoL 5 Dimensons Questionnaire
Le questionnaire EQ-5D-3L est un outil auto-administré composé d'un système descriptif de la qualité de vie des patients et d'une échelle visuelle analogique. Le système descriptif prend en compte 5 dimensions de l'état de santé (mobilité, soins personnels, activités de la vie quotidienne, douleurs, et anxiété). Ce questionnaire permet d'évaluer l'impact de l'état de santé sur la qualité de vie.

KAM[3] : Knee Adduction Moment
Lors de la phase d'appui du cycle de marche, la direction de la réaction du sol sur le sujet passe en dedans du genou entrainant un moment articulaire externe d'adduction. Le KAM ou Moment externe d'adduction (MEA) en français étant corrélé à la charge sur le compartiment médial, il est considéré comme un paramètre caractéristique de la gonarthrose fémoro-tibiale médiale.

KOOS[4] : Knee injury and osteoarthritis outcome score
Questionnaire auto-administré utilisé pour évaluer chez les patients les changements induits par un traitement. Ce questionnaire évaluant les conséquences tant à court terme qu'à long terme de la gonarthrose permet d'obtenir l'opinion du patient sur son genou et les problèmes y étant associés. Evaluation selon 5 catégories : douleur, autres symptômes, fonction en activités quotidiennes, fonction en activités sportives et de loisirs, qualité de vie relative au genou.

MCID[5] : Minimal clinically important difference
La différence minimale cliniquement importante est le plus petit changement dans un score/résultat évalué considéré par le patient comme étant révélateur d'une amélioration ou d'une aggravation de sa prise en charge.

OAKHQOL[6] : Osteoarthritis knee and hip quality of life
Également appelé AMIQUAL, cet outil spécifique à l'atteinte arthrosique de la hanche et du genou couvre les items suivants : Activités Physiques, Douleur, Santé Mental, Activités Sociales et Soutien Social.

OR[7] : Odd Ratio
L' « Odds Ratio » pouvant être appelé rapport de cotes en Français, est définit comme le rapport de la cote d'un événement arrivant à un groupe A d'individus, par rapport au même événement arrivant à un groupe B d'individus.
< 1 signifie que l'événement est moins fréquent dans le groupe A que dans le groupe B ;
= 1 signifie que l'événement est aussi fréquent dans les deux groupes ;
> 1 signifie que l'événement est plus fréquent dans le groupe A que dans le groupe B

PAO[8] : Petit appareillage orthopédique
Le petit appareillage orthopédique peut être standard fabriqué en série (petites attelles, colliers cervicaux...) et vendu dans les pharmacies et magasins d'aides techniques.

PASS[9] : Patient acceptable symptomatic state
Niveau symptomatique en-deçà duquel le patient considère son état de santé comme acceptable et se rapproche du concept de faible niveau de maladie. Il peut se définir comme le niveau de « je vais bien », comme un critère de satisfaction.

QALY[10] : Quality-adjusted life year
est un indicateur économique visant à estimer la valeur de la vie. Le QALY peut être utilisé, en médecine, pour déterminer la valeur pécuniaire d'une intervention ou d'un traitement. Une année en bonne santé correspond à un QALY de 1 ; une intervention causant la mort correspond à un QALY de 0 ; une année au cours de laquelle l'intervention thérapeutique permet de prolonger l'espérance de vie effective mais affecte les conditions de vie (par exemple, en évitant le décès au prix d'un handicap) sera comptée entre 0 et 1.

VAS[11] : Visual analogue scale (0-100) :
L'échelle visuelle analogique (EVA) en français est une échelle d'auto-évaluation de la douleur ressentie. Lors du test une réglette a curseur est présentée au patient qui positionne le curseur au niveau de sa douleur.

WOMAC[12] : Western Ontario and McMaster University Osteoarthritis Scale
Index de sévérité symptomatique de l'arthrose des membres inférieurs, cet indice permet de réaliser une évaluation de l'état fonctionnel lié une coxarthrose ou gonarthrose et donc de la qualité de vie du patient.

PROTEOR

Notes

ODRA

ORTHÈSE SUR MESURE POUR LA GONARTHROSE INTERNE

• Mode d'action unique breveté
Le double effet de distraction et rotation induit une décharge du compartiment interne du genou.

• NOUVEAU
Garnissage interne soigneusement sélectionné pour un bon maintien de l'orthèse.

• Orthèse dynamique
Agit exclusivement lorsque le genou est en extension : aucune contrainte sur le genou en flexion.

• Observance bonne
Plusieurs études dont l'étude ERGONOMIE ont montré une bonne observance de la part des utilisateurs.

• Morphologique
Réalisée sur moulage ou prise d'empreinte numérique par un orthoprothésiste.

• Efficacité prouvée
L'étude ERGONOMIE a prouvé une réduction de la douleur et une amélioration de la qualité de vie des patients.

• NOUVEAU
Fermeture par Quicky clips pour une mise en place facile et rapide.

• Indications
Douleur du compartiment interne supérieure à 40 mm sur l'échelle EVA, quel que soit le stade radiographique.

• Contre-indications
Problèmes veineux superficiels, atteinte du compartiment externe supérieure au compartiment interne traité, recurvatum très prononcé.

En France, l'orthèse Odra est prise en charge en grand appareillage.
Les médecins spécialistes en médecine physique et réadaptation fonctionnelle, les médecins spécialistes en orthopédie ou en rhumatologie peuvent prescrire cette orthèse sur un Cerfa 12042*02.

• Prescription type :
Faire sur moulage une orthèse pour gonarthrose du compartiment interne en utilisant les articulations à crémaillère Odra.
A préciser :
- Côté droit ou gauche
- Cotation de la douleur >40 sur l'échelle EVA

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L'articulation Odra est un dispositif médical de classe I, fabriqué par la société PROTEOR. Il est destiné à la fabrication d'orthèse de genou. L'orthèse fabriquée avec une articulation Odra pour la gonarthrose du compartiment interne, est prise en charge par les organismes d'assurance maladie dans certaines situations : consultez ameli.fr. 02/2021- LPPR : 2736596