Special print from:
ORTHOPÄDIE TECHNIK 08/17 –
Verlag Orthopädie-Technik
Dortmund, Germany

Orthotics

M. Benning, R. Schneider-Nieskens

Superiority of a Knee Relief Orthosis in the Treatment of Knee Osteoarthritis

A Prospective Randomised Controlled Trial

The results of this randomised controlled trial on patient-related clinical endpoints show a high medical benefit of wearing the "Genu OA" orthosis compared with standard treatment in patients with osteoarthritis of the knee. In addition to the considerably longer pain-free walking distance, the high degree of comfort and ease of use contribute to acceptance of the orthosis and thus to the success of treatment. This study shows the need for further high-quality clinical studies on the long-term clinical benefit of knee ortheses that apply a valgus/varus torque.

Key words: osteoarthritis of the knee, osteoarthritis, knee, randomised controlled trial, knee orthosis

Introduction

Osteoarthritis of the knee is one of the most common diseases among the elderly. It affects around 34% of women and 24% of men over age 60 around the world [1]. According to data from the Federal Statistical Office, osteoarthritis of the knee is the main reason for the indication for knee replacement surgery [2]. In 2015, total knee replacements were number 18 of the 50 most common operations in hospitals [3]. Elderly patients in particular are affected by increased risks due to total knee replacement surgery such as complications during anaesthesia, revision surgery or bacterial infections of the knee prosthesis that can lead to sepsis and heart attack [2, 4, 5].

The medial knee compartment is affected by osteoarthritic changes more often than the lateral knee compartment [6]. This is due to axis deviation [7]. An important treatment approach thus involves shifting the load to the intact compartment [8, 9]. The use of an unloader knee brace that encompasses the knee has proven to be a safe, cost-efficient treatment option for reducing pain and improving function. It can even delay the need for surgery [10]. Both clinical and biomechanical studies have confirmed the effectiveness of knee orthoses, however they were only rarely based on randomised comparative study designs. In addition, the long-term benefit of valgus/varus orthoses must be proven in additional clinical studies. The evidence of a benefit also depends on patient acceptance with respect to wearing the orthosis and on the progression of osteoarthritis [10, 11]. The objective of this prospective randomised study with a parallel group design on the use of the „Genu OA" knee orthosis was thus to document the following aspects:

a) The medical benefit in the sense of effect on pain, walking distance and range of movement and these results from the patient's perspective
b) The suitability of the orthosis in outpatient care
c) Handling and acceptance by patients with osteoarthritis of the knee.

Methods

Study design

The study is a post-market clinical follow-up study according to the European MEDDEV 2.12/2 rev.2 [2012-01] guideline. In this randomised, prospective, interventional, single-centre study with a dual-arm parallel group design, a group of patients with osteoarthritis of the knee was treated with the „Genu OA" knee orthosis for a period of two months and compared with a control group that received a standard intervention.

Patients

Patients were recruited from an orthopaedic centre for the study. The patients were assigned to one of the two groups based on a randomisation list prepared in advance. The study included patients with medial or lateral femorotibial osteoarthritis grade 2 or 3 according to the Kellgren-Lawrence system. The exclusion criteria included inability to walk or dependence on a wheelchair and diseases that did not allow participation in the study for a period of two months. Additional exclusion criteria were concomitant ipsilateral patellofemoral osteoarthritis grade 3 or 4, ipsilateral osteoarthritis of the hip grade 2 to 4, each according to the Kellgren-Lawrence system, a body-mass index over 30, cortisone injections within the last four weeks before the start of the study and inability to communicate in German.

Intervention

In the study, the treatment of patients with the „Genu OA“ knee orthosis (Fig. 1) from Thuasne was compared with the standard intervention for a period of two months. The orthosis consists of an elastic textile material. One side of the orthosis has a removable joint bar that supports physiological joint alignment. Extension and flexion limitation can be set using stops. The unloader system consisting of non-elastic tension elements acts on the contralateral side. The tension system is based on a 3-point unloading system and ensures the necessary relief for the affected knee compartment. It consists of two crossover straps. To make it easier for the patient to open and close the orthosis, the straps have an automatic magnet closure on the front. The orthosis design allows it to be used for either medial or lateral unloading.

All patients in the orthosis group were trained in the handling of the orthosis and the risks of a circulatory disorder and swelling of the lower leg due to too tight straps were explained. Two groups of patients, one with and one without an orthosis, were observed for a pre-defined period of two months. The standard treatment given up to then (oral and local analgesics, physiotherapy, buffer heel, lateral wedge or use of a walking cane) was continued. The two groups were then compared with respect to previously determined parameters.

Parameters

All parameters for the results of the study were determined in advance. The main parameter was extension of the pain-free walking distance after using the orthosis for two months. The following secondary parameters were recorded:

- The Lequesne index was used to register changes in: pain, walking distance and physical functions as a useful complement to the clinical findings. It allows the patient‘s individual health status to be measured and the results from the patient‘s perspective to be assessed [12].
- Pain on loading was measured on the numerical rating scale (NRS) after a thirty-minute walk.
- Pain at rest was also recorded based on the NRS.
- The use of analgesics at the end of the study was compared with the baseline amount at the start of the study. Discontinuing the pain medication was equivalent to a reduction of 100%. The medication itself was not changed. Data from patients who did not take any analgesics at the start of the study were not included in the reduction.
- The subjective range of movement was assessed qualitatively by having patients rate it as „clearly improved“, „improved“, „unchanged“, „deteriorated“ or „clearly deteriorated“.
- The objective improvement of range of movement was measured in degrees.
- Pressure and unpleasant sweating in the orthosis were also assessed qualitatively as reported by patients. The patients indicated whether wearing the orthosis was bothersome and whether the pressure was perceived to be „annoying“, „unpleasant“, „painful“ or „tolerable“ and whether any permanent pressure points or unpleasant sweating occurred.
- Handling of the orthosis was measured qualitatively by asking both the patient and the medical specialists about problems with care or use (fitting, adjusting, adapting) as well as how easy the user information was to understand. Wearing comfort was also assessed by asking qualitative questions about the following aspects: presence of pressure points, individual adjustability, constrictions, skin irritation, unpleasant sweating and heat build-up.

Statistics

With a statistical power of 80%, a sample size of 16 patients per group was calculated to be necessary for the study to prove a change in the walking distance from 1.0 (± 0.8) to 0.3 (± 0.4) in an independent two-sample t-test with a level of significance of 0.05. A drop-out rate of 5% was assumed when calculating the number of cases. The randomisation list was generated with the „randomizR“ program. Mean values and standard deviations, absolute frequencies and percentages are used to describe the data. T-tests were used to calculate the differences between the groups with respect to „pain at rest“ and „objective range of movement“. The group differences in analgesic use were examined using F tests, subjective range of movement using Cochran-Armitage tests. A linear mixed-effects model with the variable of influence „Treatment“ and the covariable „Previous value“ was adapted to fit the data on change of the Lequesne index, the walking distance and pain on loading. The statistical analyses were conducted using the „SAS 9.4“ program (SAS Institute Inc., Cary, NC, USA; Windows 10, 64 bit).

Results

The follow-up period was two months long, from 12 December 2016 to 28 February 2017. A total of 32 suitable patients were randomised to the two groups: 15 patients were assigned to the control group and 17 to the orthosis group (see the flowchart in Fig. 2). All 32 patients were available to follow-up after the study.

There were no statistically significant differences in the characteristics between the two groups at the start of the study (Tab. 1). Nine patients in the orthosis group (52.9%) and nine patients in the control group (60%) had grade 3 osteoarthritis of the knee; eight patients (47.1%) in the orthosis group and six patients (40.0%) in the control group had grade 2 osteoarthritis of the knee. The pain-free walking distance in the orthosis group was 2.71 (± 1.39) km and in the control group 2.87 (± 1.55) km at the start of the study. The average level of pain at the end of a 30-minute walk was indicated to be 4.71 (± 0.99) on the NRS in the orthosis group at the start of the study; in the control group, this value was 4.20 (± 0.56). At the start of the study, the average Lequesne index was reported to be 7.62 (± 3.24) in the orthosis group and 8.43 (± 3.58) in the control group. Some 13 patients in

Fig. 1 „Genu OA“ orthosis.

the orthosis group and 11 in the control group took analgesics at the start of the study. The objective range of movement was between 104 degrees in the control group and 105 degrees in the orthosis group.

Table 2 presents the primary and secondary endpoints of the study. The change in the pain-free walking distance was significantly increased in the orthosis group compared with the control group ($F = 20.23$, ndf 1, ddf 29, $p = 0.0001$). While the increase in the pain-free walking distance was 1.29 in the orthosis group after treatment, the difference on the control group was barely measurable. Figure 3 shows the changes in the pain-free walking distance over the two months of treatment.

The average intensity of pain at the end of a maximum 30-minute walk was reduced in the orthosis group by 1.06 (± 0.66) points on the numerical rating scale; this value was hardly changed in the control group during the study (-0.1 ± 0.35). The change in pain under loading was significantly increased in the orthosis group compared with the control group ($F = 22.13$, ndf 1, ddf 29, $p < 0.0001$). Figure 4 shows this change in the groups over a period of two months.

With respect to pain at rest, no changes were observed over the course of the study. Only one study participant reported a value lower by one unit on the NRS after two months. The resting pain was reduced only in the orthosis group from 1.59 (± 1.00) to 1.53 (± 0.94) and did not change in the control group. There was no difference between the groups at the end of the two-month treatment period with respect to the average values of resting pain ($t = 1.42$, df 29.64, $p = 0.1654$).

The Lequesne index dropped in the control group by an average of 0.17 (± 0.36) to 8.27 (± 3.48), while in the orthosis group, it was reduced by 0.68 (± 0.71) to 6.94 (± 2.86). The change in the Lequesne index was significantly higher in the orthosis group compared with the control group ($F = 10.08$, ndf 1, ddf 29, $p = 0.0035$). Figure 5 shows this change during the study period of two months.

A reduction of 17.3% in the use of analgesics was observed in the orthosis group; the reduction in the control group was 3.1%. However, this difference was not statistically significant ($F = 3.40$, ndf 1, ddf 22, $p = 0.0785$).

Despite wearing the orthosis, 35% of the patients reported that their range of movement was „improved“ and 65% said it was „unchanged“. In the comparison group, two patients rated their range of movement as „improved“ and the remaining patients „unchanged“. There was no significant difference in the change in subjective range of movement between the treatment groups (Cochran-Armitage test, $p = 0.1522$).

The objective range of movement was improved in the orthosis group by 2.35 (± 4.37) degrees and in the comparison group by 0.67 (± 2.58) degrees. The difference between the groups was not significant ($F = 1.61$, ndf 1, ddf 21, $p = 0.2142$).

The patients in the orthosis group reported that they perceived wearing the orthosis to be unpleasant: The pressure of the corrective straps was described as „annoying“ and „uncomfortable“ but not „painful“ or „intolerable“. No persistent pressure points developed, also no unpleasant sweating. Five patients came outside of the scheduled follow-up appointments to have the orthosis readjusted.

During the entire application and observation period, no adverse side effects occurred that might have been related to the use of the orthosis. In five patients, the metal bar of the orthosis had to be readjusted due to insufficient unloading of the osteoarthritic compartment. No patients fitted with the orthosis had difficulty handling or caring for the orthosis.

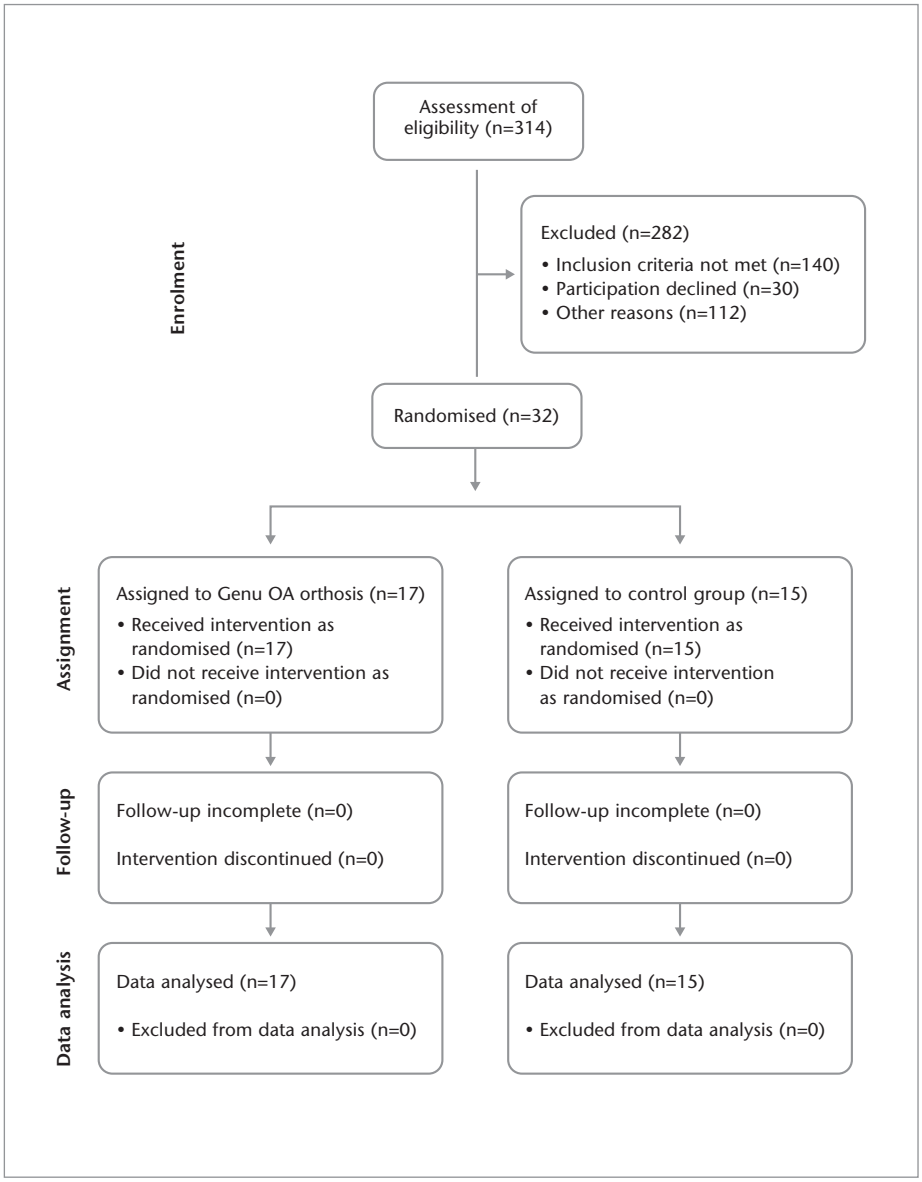

Fig. 2 *Flowchart of patient inclusion and follow-up examinations.*

Discussion

In this prospective randomised comparative study, the pain-free walking distances were extended significantly in patients with osteoarthritis of the knee by wearing the „Genu OA“ orthosis; the pain on loading was also reduced considerably compared with standard treatment. The significant reduction of the Lequesne index confirmed the positive effect on pain, walking distance, and physical functions in the orthosis group from the patients‘ perspective as well. Handling was found to be easy and wearing comfort was good. The orthosis thus meets the technical and medical requirements for products of the type „Knee orthoses for unloading and alignment“ and according to the results of this study, is suitable for use in patients with osteoarthritis of the knee, both in outpatient care and at home.

This study contributes to the requirement for evidence of efficacy for clinical trials with a randomised comparative study design [11]. The power of the study was appropriate for detecting differences between the groups. All patients included were available to follow-up and their results could be analysed at the end of the study. In addition, the selection criteria were based on radiological criteria for the classification of osteoarthritis of the knee as used in clinical practice [13], which allows the results of the study to be transferred to practice. The relevance of the results for fitting practice was increased by including the patient perspective. This is important with respect to acceptance of the orthosis and thus of the treatment success. Overall, no change in resting pain was observed, which could be due to the short treatment period of just two months. The results suggest a need for further high-quality clinical trials on the sustained benefit of valgus/varus orthoses.

Although no change in the treatment regimen took place in the control group, the pain-free walking distance was increased. What is called a response bias may be responsible for this. A bias of this kind may be attributed to the study participants, to changed (response) behaviour in a study situation, to the design of the questions or of the questionnaire, or to an interviewer effect.

Based on the Lequesne index, wearing the orthosis had a greater positive

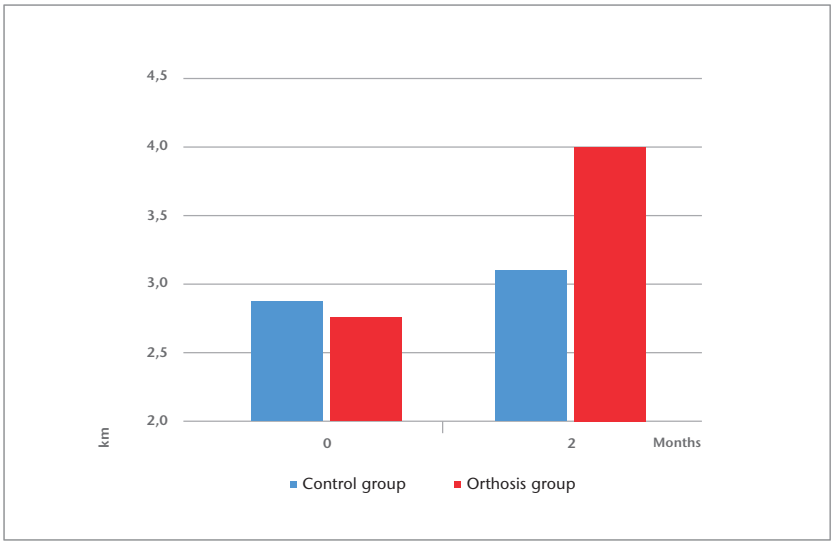

Fig. 3 *Change in the pain-free walking distance.*

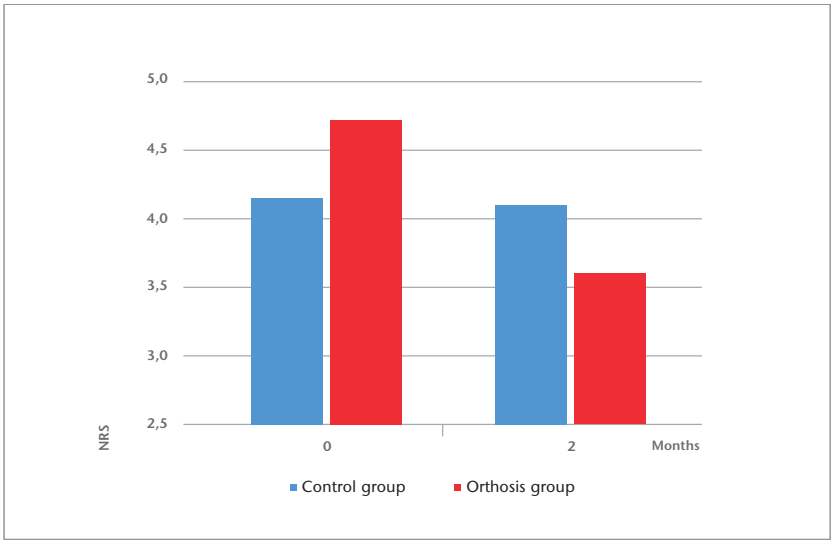

Fig. 4 *Change in loading pain.*

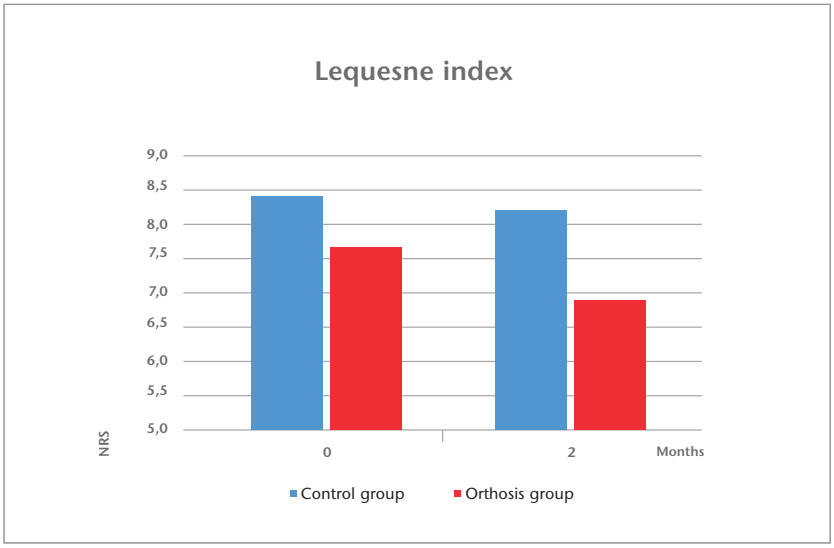

Fig. 5 *Change in the Lequesne index.*

Characteristic	Orthosis group	Control group
Female (%)	12 (70.6)	10 (66.7)
Age, mean (±)	69.53 (9.91)	70.07 (12.26)
BMI, mean (±)	26.82 (1.83)	26.48 (2.01)
Left knee affected (%)	7 (41.25)	9 (66.0)
Lateral osteoarthritis of the left knee grade 3 (%)	2 (11.8)	0
Lateral osteoarthritis of the right knee grade 3 (%)	0	1 (6.7)
Lateral osteoarthritis of the left knee grade 2 (%)	0	1 (6.7)
Lateral osteoarthritis of the right knee grade 2 (%)	2 (11.8)	2 (13.3)
Medial osteoarthritis of the left knee grade 3 (%)	3 (17.6)	7 (46.7)
Medial osteoarthritis of the right knee grade 3 (%)	4 (23.5)	1 (6.7)
Medial osteoarthritis of the left knee grade 2 (%)	2 (11.8)	1 (6.7)
Medial osteoarthritis of the right knee grade 2 (%)	4 (23.5)	2 (13.3)
Pain-free walking distance,mean (±)	2.71 (1.39)	2.87 (1.55)
Pain on loading (30-min. walk, NRS), mean (±)	4.71 (0.99)	4.20 (0.56)
Pain at rest (NRS), mean (±)	1.59 (1.0)	2.0 (0.93)
Lequesne index, mean (±)	7.62 (3.24)	8.43 (3.58)
Use of analgesics, N (%)	13 (76.47)	11 (73.34)
Objective range of movement, degree (±)	105.29 (11.25)	104.0 (11.83)

Tab. 1 *Basic characteristics.*

Result	Orthosis group	Control group
Change in the pain-free walking distance, mean (±)	1.29 (0.90)*	0.20 (0.37)
Change in pain on loading (30-min. walk, NRS), mean (±)	-1.06 (0.66)*	-0.13 (0.35)
Change in pain at rest (NRS), mean (±)	-0.06 (0,24)	0 (0)
Change in the Lequesne index, mean (±)	-0.68 (0.71)*	-0.17 (0.36)
Change in use of analgesics, mean (±)	-17.31 (23,68)	-3.09 (10.25)
Improvement in subjective range of movement, N (%)	6 (35.3)	2 (13.3)
Improvement in objective range of movement, degree (%)	2.35 (4.37)	0.67 (2.58)

Tab. 2 *Primary and secondary endpoints.*

*p=0.0001

effect on pain, walking distance and physical functions than the standard treatment from the patient perspective as well. The Lequesne index allowed the individual health status and the patient's view of the treatment results to be assessed [12]. This index is widely used around the world and is recommended by the World Health Organization (WHO) to measure outcomes of knee diseases [14]. Since the Lequesne index measures the duration, but not the intensity of pain, and measures walking distances only up to one kilometre, pain was assessed in this study using the numerical rating scale and the walking distance was measured separately.

Although the improvement in the range of movement was not the primary goal of the orthosis, the increase in mobility appeared at least subjectively to improve the range of movement as well. Due to the gradual increase in unloading of the osteoarthritic compartment during follow-up, the patients learned to estimate the correlation between pain relief, the pain-free walking distance and corrective compression of the tension straps. Providing comprehensive information to the patient and readjusting the orthosis were basic requirements for acceptance of the orthosis.

The results of this method were that it ensured easy, correct and safe use of the orthosis. No intolerable pressure from the metal bar occurred in any of the patients that they could not correct themselves immediately. There was no constriction at the back of the knee or skin irritation where the orthosis came into contact with the patient's skin.

Conclusion

Wearing the „Genu OA" orthosis had a significantly superior effect on pain, walking distance and physical functions compared with standard treatment and thus on aspects that ultimately have a positive effect on the quality of life and independence of patients. In addition to a good corrective effect, the orthosis is also comfortable to wear, is easy to handle, can be applied quickly and can be worn under clothing or for sports. In addition, it can be individually adjusted. The orthosis is thus suitable for independent use by the intended users in a domestic setting.

This randomised comparative study suggests a need for further high-quality clinical trials over a longer observation period to prove evidence of the long-term benefit of valgus/varus orthoses.

For the authors:
Dr. med. Michael Benning
Friedrich-Wilhelm-Platz 5/6
52062 Aachen, Germany
m.benning@exinmo.de

Reviewed paper

Literatur:

[1] Pereira D, Peleteiro B, Araujo J, et al. The effect of osteoarthritis definition on prevalence and incindence estimates: a systematic review. Osteoarthritis Cartilage, 19 (11): 1270–1285
[2] RKI – Robert Koch-Institut (Hrsg.) Arthrose. Gesundheitsberichterstattung des Bundes, Heft 54. Berlin: RKI, 2013
[3] Statistisches Bundesamt. Fallpauschalenbezogene Krankenhausstatistik (DRG-Statistik). Diagnosen, Prozeduren, Fallpauschalen und Case Mix der vollstationären Patientinnen und Patienten in Krankenhäusern, 2015. https://www.destatis.de/DE/Publikationen/Thematisch/Gesundheit/Krankenhaeuser/FallpauschalenKrankenhaus2120640157004.pdf?__blob=publicationFile (Zugriff am 23.05.2017)
[4] Deutsche Gesellschaft für Unfallchirurgie (DGU) in Zusammenarbeit mit der Österreichischen Gesellschaft für Unfallchirurgie (ÖGU) (Hrsg.). S1-Leitlinie Endoprothese bei Gonarthrose (AWMF-Leitlinienregister Nr. 012-008). Stand: 01.06.2009 (in Überarbeitung), gültig bis 30.06.2014. http://www.awmf.org/uploads/tx_szleitlinien/012-008_S1_Endoprothese_bei_Gonarthrose_2009_abgelaufen.pdf (Zugriff am 23.05.2017)
[5] Lalmohamed A, Vestergaard P, Klop C, Lerkevang Grove E, de Boer A, Leufkens HGM, van Staa TP, de Vries F. Timing of Acute Myocardial Infarction in Patients Undergoing Total Hip or Knee Replacement. Arch Intern Med, 2012; 172 (16): 1229–1235
[6] Hernborg JS, Nilsson BE. The natural course of untreated osteoarthritis of the knee. Clin Orthop Relat Res, 1977; (123): 130–137
[7] Cerejo R, Dunlop DD, et al. The influence of alignment on risk of knee osteoarthritis progression according to baseline stage of disease. Arthritis Rheum, 2002; 46 (10): 2632–2636
[8] Greitemann B. Konservative Therapie der Arthrose – Hilfsmittelversorgung. Arthroskop, 2009; 222: 176–182
[9] Waller C, Hayes D, et al. Unload it: the key to the treatment of knee osteoarthritis. Knee Surg Sports Traumatol Arthroscop, 2011; 19 (11): 1823–1829
[10] Lorbach O, Mosser P, et al. Sense or nonsense of unloader braces. Orthopäde, 2014; 43 (11): 984–987
[11] Moyer R, Birmingham T, et al. A systematic review and meta-analysis of biomechanical and clinical effects of valgus knee bracing. Osteoarthitis Cartilage, 2014; 22: 457
[12] Grimmig H, Melzer C et al. Der routinemäßige Einsatz des Lequesne-Index zur Ergebnismessung in der orthopädischen Rehabilitation bei Hüft- und Knieerkrankungen. Using the Lequesne questionnaires for patients with hip and knee disabilities in daily routine to reflect the quality of outcome in rehabilitation. Z Orthop Unfall, 2002; 140 (4): 452–459
[13] Deutsche Gesellschaft für Orthopädie und Orthopädische Chirurgie und Berufsverband der Ärzte für Orthopädie (Hrsg.). Leitlinien der Orthopädie. 2. Auflage. Köln: Deutscher Ärzte-Verlag, 2002
[14] Ludwig FJ, Melzer C et al. Kulturelle Adaptation des Lequesne-Index für Hüft- und Kniegelenkserkrankungen im deutschen Sprachraum. Cross Cultural Adaptation of the Lequesne Algofunctional Indices for German Speaking Patients with Osteoarthritis of the Hip and the Knee. Rehabilitation, 2002; 41 (4): 249–257