ethylene damage can be variable and is not always a single value. Distribution of the pressure based on the prosthesis geometry should be evaluated to see whether the load in deep flexion is excessive. However, a small contact area in flexion will increase the contact stress and surely increases the risk for mechanical failure. The mechanical loads used in the previous contact stress analyses were less than the loads calculated in the present study. This may lead to underestimation of the contact stress on the prosthesis. In a joint with contact area less than 200 mm^2, the stress during both kneeling and full squat may exceed the yield point of polyethylene (Figure 4). Considering the joint contact force in high flexion, the design protocol for the knee prosthesis should include providing a larger contact area in any flexion range. On this point, we recommend a contact area of more than 200 mm^2 to safely sustain loads during deep flexion.

As discussed in the above sections, published contact areas were used in our contact stress simulation and the average contact stress was calculated. Using this approach, it is not possible to indicate peak contact stress or stress distribution at the joint. A 2-D knee model in this study has a generic joint anatomy and does not consider anatomical variations among the subjects. Modification of the model (i.e., a subject-specific model) or using a different modeling approach (i.e., finite element model) will be helpful to clear these limitations. Our analysis involved knees with normal function and range of motion. This fact limits the application of our results to TKA patients. Usually, patients following TKA have limitation in the extensor muscle force and range of motion. In many cases, it is not possible to perform the deep flexion described in this study. However, current improvements in surgical technique and prosthesis design have been providing better postoperative function and range of motion for patients. Many patients should be able to acquire knee function close to normal in the near future. Our data will be useful for deriving design criteria for a prosthesis that is capable for full flexion.

Acknowledgments

The authors would like to acknowledge the contributions of Chris O. Dyrby, Eng., and Eugene J. Alexander, Ph.D., for helping with the acquisition and processing of the data. The authors also appreciate Ms. Mayumi Oshidari for her help in this study. The research materials in this study were partially supported by a grant from Zimmer.

References

Barbour, P.S., Barton, D.C., & Fisher, J. (1997). The influence of stress conditions on the wear of UHMWPE for total joint replacements. *Journal of Materials Science. Materials in Medicine, 8*, 603-611.

Chapman-Sheath, P.J., Bruce, W.J.M., Chung W.K., Morberg, P., Gillies, R.M., & Walsh, W.R. (2003). In vitro assessment of proximal polyethylene contact surface areas and stresses in mobile bearing knees. *Medical Engineering & Physics, 25*, 437-443.

Clements, K.M., Bee, Z.C., Crossingham, G.V., Adams, M.A., & Sharif, M. (2001).How severe must repetitive loading be to kill chondrocytes in articular cartilage? *Osteoarthritis Cartilage, 9*, 499-507.

Coggon, D., Croft, P., Kellingray, S., Barrett, D., Mclaren, M., & Cooper, C. (2000). Occupational physical activities and osteoarthritis of the knee. *Arthritis and Rheumatism, 43*, 1443-1449.

Dahlkvist, N.J., Mayo, P., and Seedhom, B.B. (1982). Forces during squatting and rising from a deep squat. *Engineering in Medicine, 11*, 69-76.

Ellis, M.I., Seedhom, B.B., & Wright, V. (1979). Forces in the knee joint whilst rising from a seated position. *Engineering in Medicine, 6*, 33-40.

Escamilla, R.F., Fleisig, G.S., Zheng, N., Barretine, S.W., & Andrews, J.R. (1998). Biomechanics of the knee during closed kinetic chain and open kinetic chain exercises. *Medicine and Science in Sports and Exercise, 30*, 556-569.

Felson, D.T., Hannan, M.T., Naimark, A., Berkeley, J., Gordon, G., Wilson, P.W.F., & Anderson, J. (1991). Occupational physical demands, knee bending, and knee osteoarthritis: results from the Framingham Study. *Journal of Rheumatology, 18*, 1587-1592.

Fukubayashi, T., & Kurosawa, H. (1980) The contact area and pressure distribution pattern of the knee. *Acta Orthopaedica Scandinavica, 51*, 871-879.

Harris, M.L., Morberg, P., Bruce, W.J.M., & Walsh, W.R. (1999) An improved method for measuring tibiofemoral contact areas in total knee arthroplasty: A comparison of K-scan sensor and Fuji film. *Journal of Biomechanics, 32*, 951-958.

Kettelkamp, D.B., & Jacobs, A.W. (1972). Tibiofemoral contact area-determination and implications. *Journal of Bone and Joint Surgery, 54-A*, 349-356.

Kuster, M.S., Wood, G.A., Stachowiak, G.W., & Gachter, A. (1997). Joint load considerations in total knee replacement. *Journal of Bone and Joint Surgery, 79-B*, 109-113.

Lacote, M., Chevalier, A., Miranda, A. (1987). *Clinical Evaluation of Muscle Function*. New York: JB Churchill Livingstone.

Li, G., Most, E., Sultan, P.G., Schule, S., Zayontz, S., Park, S.E., & Rubash, H.E. (2004). Knee kinematics with a high-flexion posterior stabilized total knee prosthesis:

An in vitro robotic experimental investigation. *Journal of Bone and Joint Surgery*, 86-A, 1721-1729.

Lu, T.W., O'Connor, J.J., Taylor, S.J., & Walker, P.S. (1998). Validation of a lower limb model with in vivo femoral forces telemetered from two subjects. *Journal of Biomechanics, 31*, 63-69.

Lutz, G.E., Palmitier, R.A., An, K.N., & Chao, E.Y.S. (1993). Comparison of tibiofemoral joint forces during open-kinetic-chain and closed-kinetic-chain exercises. *Journal of Bone and Joint Surgery, 75-A*, 732-739.

Maquet, P.G., Van de Berg, A.J., & Simonet, J.C. (1975). Femorotibial weight-bearing areas. Experimental determination. *Journal of Bone and Joint Surgery, 57-A*, 766-771.

Morrison, J.B. (1970). The mechanics of the knee joint in relating to normal walking. *Journal of Biomechanics, 3*, 51-61.

Nakagawa, S., Kadoya, Y., Todo, S., Kobayashi, A., Sakamoto, H., Freeman, M.A.R., & Yamano, Y. (2000). Tibiofemoral movement 3: Full flexion in the living knee studied by MRI. *Journal of Bone and Joint Surgery, 82-B*, 1199-1200.

Nakayama, K., Matsuda, S., Miura, H., Higaki, H., Otsuka, K., & Iwamoto Y. (2005). Contact stress at the post-cam mechanism in posterior stabilized total knee arthroplasty. *Journal of Bone and Joint Surgery, 87-B*, 483-488.

Nagura, T., Dyrby, C.O., Alexander, E.J., & Andriacchi T.P. (2002). Mechanical loads at the knee joint during deep flexion. *Journal of Orthopaedic Research, 20*, 881-886.

Pena, E., Calvo, B., Martnez, M.A., Palanca, D., & Doblare, M. (2005). Finite element analysis of the effect of meniscal tears and meniscectomies on human knee biomechanics. *Clinical Biomechanics, 20*, 498-507.

Schipplein, O.D., & Andriacchi, T.P. (1991). Interaction between active and passive knee stabilizers during level walking. *Journal of Orthopaedic Research, 9*, 113-119.

Stukenborg-Colsman, C., Ostermeier, S., Hurschler, C., & Wirth, C.J. (2002). Tibiofemoral contact stress after total knee arthroplasty: Comparison of fixed and mobile-bearing inlay designs. *Acta Orthopaedica Scandinavica, 73*, 638-646.

Taylor, W.R., Heller, M.O., Bergmann, G., & Duda, G.N. (2004). Tibio-femoral loading during human gait and stair climbing. *Journal of Orthopaedic Research, 22*, 625-632.

Thambyah, A., Goh, J.C.H., & De, S.D. (2005). Contact stress in the knee joint in deep flexion. *Medical Engineering & Physics, 27*, 329-335.

Toutoungi, D.E., Lu, T.W., Leardini, A., Catani, F., & O'Connor, J.J. (2000). Cruciate ligament forces in the human knee during rehabilitation exercises. *Clinical Biomechanics, 15*, 176-187.

Weiss, J.M., Noble, P.C., Conditt, M.A. Kohl, H.W., Roberts, S., Cook, K.F., Gordon, M.J., & Mathis, K.B. (2002). What functional activities are important to patients with knee replacements? *Clinical Orthopaedics, 404*, 172-188.

Wilk, K.E., Escamilla, R.F., Fleisig, G.S., Barrentine, S.W., Andrews, J.R., & Boyd, M.L. (1996). A comparison of tibiofemoral joint forces and electromyographic activity during open and closed kinetic chain exercises. *American Journal of Sports Medicine, 24*, 518-527.

Wilson, W., van Rietbergen, B., van Donkelaar, C.C., & Huikes, R. (2003). Pathways of load-induced cartilage damage causing cartilage degeneration in the knee after meniscectomy. *Journal of Biomechanics, 36*, 845-851.

Zhang, Y., Hunter, D.J., Nevitt, M.C., Xu, L., Niu, J., Lui, L., Yu, W., Aliabadi, P., & Felson, D.T. (2004). Association of squatting with increased prevalence of radiographic tibiofemoral knee osteoarthritis: The Beijing Osteoarthritis Study. *Arthritis & Rheumatism, 50*, 1187-1192 .

OsteoArthritis and Cartilage (2007) 15, 932–936

doi:10.1016/j.joca.2007.02.004

Osteoarthritis and Cartilage

ICRS International Cartilage Repair Society

OARSI OSTEOARTHRITIS RESEARCH SOCIETY INTERNATIONAL

The lateral wedged insole with subtalar strapping significantly reduces dynamic knee load in the medial compartment

Gait analysis on patients with medial knee osteoarthritis

Y. Kuroyanagi M.D.*, T. Nagura M.D., Ph.D., H. Matsumoto M.D., Ph.D., T. Otani M.D., Ph.D., Y. Suda M.D., Ph.D., T. Nakamura M.D., Ph.D. and Y. Toyama M.D., Ph.D.
Department of Orthopaedic Surgery, School of Medicine, Keio University, Tokyo, Japan

Summary

Objective: Two lateral wedged insoles were compared: one with, and the other without, subtalar strapping.

Methods: Twenty-one patients (age 58–83, mean 72) with medial knee osteoarthritis (OA) were enrolled. Thirty-seven knees in the patients were divided into three groups based on the Kellgren and Lawrence OA grading system; grades 2 (cases = 20), 3 (cases = 11), and 4 (cases = 6). The subjects were tested during walking barefoot and during walking with a silicon rubber lateral wedged insole with elevation of 10 mm attached to a barefoot. Gait analysis was performed on a 10 m walkway for each subject under three different walking conditions; barefoot, wearing a conventional insole, and a subtalar strapping insole. Peak knee varus moment during gait was measured under each condition, and compared between the three conditions and between the OA grades.

Results: On the whole (cases = 37), the peak varus moment was significantly reduced by wearing either of the insoles, compared to walking barefoot. The reduction was more obvious with the strapping insole (−13%, $P < 0.01$), compared with the conventional insole (−8%, $P < 0.05$). In moderate OA patients (grades 2 and 3), the moments were significantly lower with the strapping insole, compared with the conventional insole ($P = 0.0048$ and 0.005, respectively). However, no significant difference was detected in severe OA patients (grade 4) between the two types of insoles ($P = 0.4$).

Conclusions: Both lateral wedged insoles significantly reduced the peak medial compartment load during gait. The subtalar strapping insole had a greater effect than the conventional insole, particularly in patients with moderate medial knee OA.

Key words: Osteoarthritis, Knee, Biomechanics, Gait, Orthosis.

Introduction

Knee osteoarthritis (OA) occurs in approximately 11% of the population at 65 years or older, and is thought to cause more damage to mobility in the elderly than any other disease[1]. Patients with knee OA usually demonstrate major involvement in one compartment. The medial compartment is involved nearly 10 times as often as the lateral compartment[2]. During walking, the mechanical load which is transferred through the medial compartment is nearly 2.5 times greater than that transferred through the lateral compartment for a group of normal subjects, and the medial load becomes 3.3 times greater for a group of patients with an average varus deformity of 9°[3]. It has been shown that cartilage damage progresses due to high joint load in the medial compartment and that pain increases as the deterioration increases[4]. Therefore, reducing the joint load in the medial compartment of the knee acts to improve the disease or to relieve pain.

There are several treatments to manage varus knee deformity. In every case, the primary goal of the treatment is to correct the mechanical axis of the limb. For moderate or severe varus OA, surgical treatment, such as high tibial osteotomy and total knee arthroplasty (TKA) have been performed. Although this type of surgery has provided successful clinical results, it is often costly for the patients and it forces them to get over complications[5,6]. In particular, more than 500,000 cases of TKA are annually performed in the US, and approximately three billion dollars are spent on TKA. Alternatives to surgical treatment are required to lighten the patient's burden and the medical costs.

The lateral wedged insole has been recommended as an efficacious non-invasive method for managing medial knee OA[7]. This orthosis was firstly reported by Sasaki and Yasuda[8,9] and was aimed to alter the mechanical alignment of the lower leg to reduce loading in the medial compartment of the knee by correcting the valgus inclination at the calcaneus. Wolfe and Brueckman[10] reported that 82% of their patients had at least some improvement in pain with a lateral wedged insole. Keating *et al.*[11] reported that 61% of medial OA knees had improved pain scores with the insole. Both Crenshow *et al.*[12] and Kerrigan *et al.*[13] showed that 5° or 10° laterally wedged insoles significantly reduced the knee varus torque in medial knee OA patients during the stance period of walking compared to barefoot or when wearing flat-heeled shoes. These studies showed that the lateral wedged insole effectively reduced the load at the medial compartment of the knee.

*Address correspondence and reprint requests to: Yuji Kuroyanagi, M.D., Department of Orthopaedic Surgery, School of Medicine, Keio University, 35 Shinanomachi, Shinjuku-ku, Tokyo 160-8582, Japan. Tel: 81-3-5363-3812; Fax: 81-3-3353-6597; E-mail: yuji-kuro@nifty.com

Received 16 October 2006; revision accepted 4 February 2007.

According to Toda *et al.*[14], the lateral wedged insoles with elastic strapping of the subtalar and ankle joints (strapping insole) changed the femorotibial angles (FTAs) and talar tilt angles in medial knee OA patients. They also reported that the strapping insole corrected the FTA by 3° on weight bearing radiographs, and it had better clinical effects, compared with the conventional lateral wedged insole alone[14–17]. However, their evaluation was analyzed under static conditions, and no study has been quantified to indicate the dynamic biomechanical effect of the strapping insole.

The purpose of the current study was to describe the changes in the joint load during gait using two types of lateral wedged insoles (a lateral wedged insole alone and a lateral wedged insole with an elastic strapping band) in medial knee OA patients. We hypothesized that the dynamic joint load in the medial compartment is reduced more by the strapping insole than by the commonly used lateral wedged insole.

Material and methods

STUDY DESIGN

This study was accomplished through a prospective case control study of patients with medial compartment knee OA. The patients were recruited from the general orthopedic outpatients clinic of a university hospital. Before the study was initiated, the Institutional Review Board approved the study and informed consent was obtained from all of the subjects.

INCLUSION/EXCLUSION CRITERIA

Subjects were diagnosed as having medial compartment knee OA according to the American College of Rheumatology criteria for the diagnosis of knee OA, medial knee pain, and radiographic osteophyte at the medial joint space of the knee and at least one of the following items: age greater than 50 years, morning stiffness lasting more than 30 min, or crepitus on motion[18]. Patients who were currently using a wedged insole or other custom-made orthosis in their shoes on a regular basis were excluded. Those who had rheumatoid arthritis, other systematic inflammatory arthritis or peripheral or central nervous system diseases were also excluded. In addition, we confirmed that none of the patients had any previous surgical treatments or concurrent clinically active arthritis at any other joints in the lower extremities. Patients who were not able to walk without a cane or walker were also excluded[13]. According to the above inclusion and exclusion criteria, 37 knees in 21 patients were included in this study.

DESCRIPTION OF THE INSOLES

A silicon rubber 10 mm lateral wedge (Nakamura brace, Tokyo, Japan) was used for both types of insoles (Fig. 1). This silicon rubber has a 10 mm lateral elevation and a 75 mm width, which has an approximately 7.6° inclination. This silicon rubber material is usually used for cosmetic remodeling and has a natural form-fit to the skin. The 75 mm width silicon rubber was scaphoid shaped and it was suitable for attachment to a barefoot of all of the subjects. The rational for using this inclination was that 7.6° was approximately the median between 5° and 10°, based on a study by Kerrigan *et al.*[13], which showed that 5° or 10° laterally wedged insoles significantly reduced the knee varus moment.

GAIT ANALYSIS

All subjects performed the trials, 10 m level walking at a comfortable walking speed, in a gait laboratory. They walked under three different conditions; barefoot, wearing the insole attached to a barefoot (conventional insole) and wearing the insole with subtalar strapping added to a barefoot (strapping insole) on both sides. The order of testing of each condition was randomized and blinded to the patients. Each condition was measured twice.

Six retro-reflective markers were placed at the superior iliac spine, the greater trochanter, the lateral joint line of the knee, the lateral malleolus, the lateral aspects of the calcaneus, and the head of the fifth metatarsal bone[19]. The three dimensional positions of the six markers were captured using a four-camera system fixed in the gait laboratory (120 frames/s; Pro-reflex, Qualysis, Sweden). During the gait, ground reaction force was also measured using a force plate fixed on the floor in the gait laboratory (sample frequency 120 Hz; AM6110, Bertec, Columbus, OH, USA). The three-dimensional knee kinetics were then assessed by an inverse dynamics approach[20]. Knee varus moment in the coronal plane was also analyzed in this study.

DATA ANALYSIS

The gait data were automatically processed using original software, in which the patients' names and testing

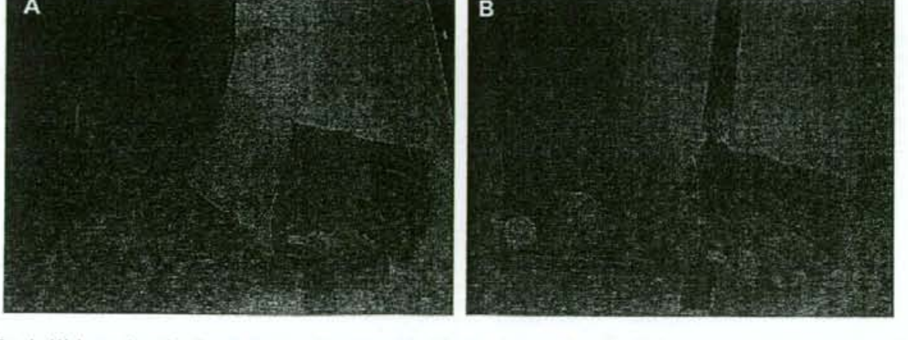


Fig. 1. (A) Lateral wedge insole (conventional insole); (B) lateral wedge insole with the strapping (strapping insole).

conditions were encoded and blinded. An average value of two trials for each condition was used. The maximum knee varus moment in the stance phase and walking speed were calculated from the data under each condition. The difference between the three conditions (i.e., barefoot, wearing the conventional insole, and wearing the strapping insole) and that between the OA grades was analyzed.

STATISTICAL ANALYSIS

The data were evaluated by Wilcoxon's signed-ranks test. The statistical significance level was set at $P = 0.05$.

Results

CHARACTERISTICS OF THE SUBJECTS

The patients were 58–83 (mean 72) years old and had radiographic OA of at least grade 2 severity according to the Kellgren–Lawrence scale[21]; 20 knees were classified into grade 2, 11 knees were grade 3 and 6 knees were grade 4. The subjects had an average weight of 50 ± 5 kg and an average height of 1.52 ± 0.04 m, an average Hospital for Special Surgery (HSS) score, which is a knee rating system, consists of pain, knee walking function, range of motion, muscle strength, flexion deformity, and instability (full score: 100 points) of 77.4 (grade 2: 83.7, grade 3: 74.6, grade 4: 66.5), an average FTA, the angle formed by the axes of the femur and the tibia on standing radiographs, of 186.1 (grade 2: 182.6, grade 3: 188.2, grade 4: 194.0).

GAIT ANALYSIS

There were no patients who complained of any adverse effects or stopped using the wedged insole during the gait analysis.

Overall, peak knee varus moment during walking barefoot, while wearing the conventional insole and while wearing the strapping insole were 4.2 ± 1.8, 3.9 ± 1.5, 3.7 ± 1.4 (%BW*Ht), respectively (Fig. 2). The peak varus moment was significantly reduced by wearing the conventional insole or the strapping insole compared to the barefoot condition. The reduction was more obvious with the subtalar strapping insole (−13%, $P < 0.01$) than with the insole alone (−8%, $P < 0.05$).

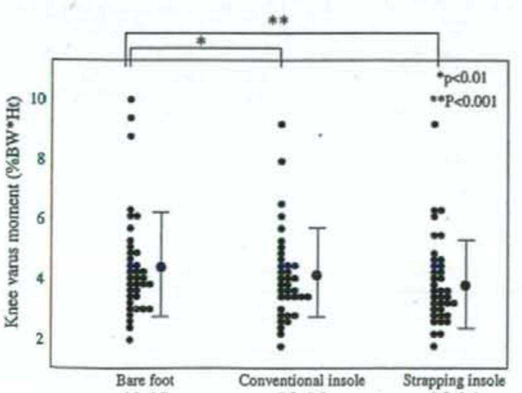


Fig. 2. Peak knee varus moment with each condition ($N = 37$).

In moderate OA patients (grades 2 and 3), the moments were significantly lower in the group wearing the subtalar strapping insole than in the group wearing the insole alone ($P = 0.0048$ and 0.005, respectively, Table I). However, no significant difference was detected in the severe OA patients (grade 4) between the two types of insoles ($P = 0.40$). The walking speeds in the barefoot condition, with the conventional insole and with the strapping insole were 0.73 ± 0.23, 0.76 ± 0.26, 0.74 ± 0.26 (m/s), respectively (Table II). There were no statistical differences between the three conditions.

Discussion

The results of this study support our hypothesis that the lateral wedged insole significantly reduces the knee varus moment during walking compared to the barefoot condition with no insole. In particular, the strapping insole reduces the varus moment more than the lateral wedged insole alone in moderate OA (grades 2 and 3). However, in cases with grade 4 knees, the strapping insole had little effect in regard to the reduction of the joint load.

The reduction in the varus moment due to wearing an insole ranged from 6% to 8% in previous biomechanical studies, which compared the knee varus moments in subjects wearing shoes and when inserting wedges into the shoes[12,13]. The current study was limited in that it did not clarify the influence of combining the subtalar strapping insole and shoes.

Kerrigan *et al.*[22] reported that knee varus moment wearing women's dress shoes with heels of just 3.8 cm height (moderate high-heeled shoes) increased 9% compared with that wearing control shoes without any additional heel in 20 healthy elderly adult women. Shakoor and Block[23] performed gait analyses on 75 subjects with knee OA while they were wearing their everyday walking shoes and while they were walking barefoot. Their results showed that peak joint loads significantly decreased when walking barefoot, with an 11.9% reduction noted in the knee varus moment. In the current study, the varus moment was reduced 11% due to wearing the subtalar strapping insole added to a barefoot, compared with walking barefoot for patients with moderate OA.

From the above reports[22,23] and the current study, we inferred that the difference in the varus moment between wearing the strapping insole added to a barefoot and wearing moderate high-heeled shoes alone might be more obvious than that between wearing the moderate high-heeled shoes alone and when inserting wedges into the shoes. Therefore, future studies should include an evaluation of varus moment when wearing moderate high-heeled shoes alone and when wearing a subtalar strapping insole combined with the shoes.

Table I
Peak knee varus moment during gait with each OA grade

OA grade	N	Barefoot (%BW*Ht)	Conventional insole (%BW*Ht)	Strapping insole (%BW*Ht)	P value[a,b]	
2	20	3.9 ± 1.6	3.6 ± 1.3	3.4 ± 0.9	*0.024	**0.048
3	11	4.5 ± 1.5	4.1 ± 1.2	3.9 ± 1.2	*0.019	**0.0050
4	6	4.8 ± 2.6	4.5 ± 2.6	4.7 ± 2.5	*0.046	0.40

P value; (a) barefoot vs conventional insole; (b) barefoot vs strapping insole. $^*P < 0.05$; $^{**}P < 0.01$.

Table II
Walking speed with each OA grade

OA grade	N	Barefoot (m/s)	Conventional insole (m/s)	Strapping insole (m/s)	P value[a,b]	
2	20	0.80 ± 0.27	0.82 ± 0.30	0.83 ± 0.30	0.88	0.10
3	11	0.66 ± 0.17	0.68 ± 0.18	0.65 ± 0.17	0.36	0.54
4	6	0.70 ± 0.21	0.72 ± 0.22	0.66 ± 0.22	0.28	0.08
Total	37	0.73 ± 0.23	0.76 ± 0.26	0.74 ± 0.26	0.06	0.19

P value; (a) barefoot vs conventional insole; (b) barefoot vs strapping insole.

Surgery can correct the mechanical axis of the lower limb and decrease the knee varus moment as well as knee pain and disease progression[24,25]. It has been reported that the high tibial osteotomy changed the knee varus moment from 5.7 ± 1.4 (%BW*Ht) to 4.6 ± 0.6 (%BW*Ht) at 6 years postoperatively[26]. The reduction in the varus moment due to surgery (19%) was almost similar to the reduction demonstrated by the strapping insole (13%) in this study, and this supports the strategy to treat medial knee OA using the insole[14].

The knee varus moment is also influenced by walking speed[27]. In our study, there was no difference in walking speed among the three conditions (barefoot, while wearing the conventional insole, and while wearing the strapping insole). Therefore, the use of insoles successfully reduced the knee loads without changing the walking speed.

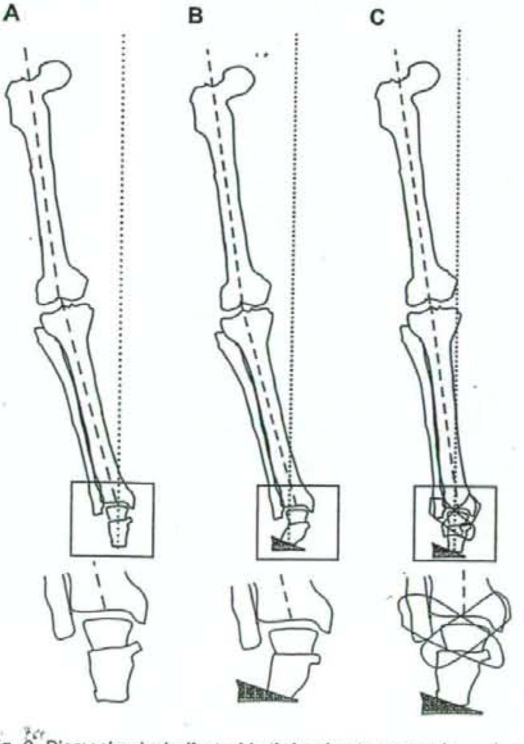


Fig. 3. Biomechanical effect of both insoles to correct lower leg alignment. (A) Barefoot; (B) wearing conventional insole; (C) wearing strapping insole. Conventional insoles move the weight bearing axis and reduce knee joint load in the medial compartment, but do not change FTA. Strapping insoles can change FTA and shift the weight bearing axis more and make the greater effect to reduce the joint load.

The walking speeds reported in Table II (0.65–0.83 m/s) are lower than those reported for patients with moderate and medial compartment knee OA (0.9–1.1 m/s)[12,13]. The possible reasons for this are that the patients in this study walked barefoot and they had a lower average height and a shorter average step length compared to other studies.

The lateral wedged insole itself should change the mechanical axis but it was not able to correct the lower limb alignment, while the strapping insole was able to correct the FTA in patients with genu varum. This difference in changing the limb alignment can be explained by the effect of subtalar strapping. The varus deformity of the knee will not be changed by the conventional insole because the lateral wedge effect is thought to be canceled in the subtalar joint. On the other hand, the elastic strap would fix the subtalar and ankle joints, and cause valgus angulation both in talus and tibia. The strapping of the joints would result in correction of varus alignment of the lower limb in patients with varus knee OA (Fig. 3). More details on the effect of subtalar strapping and related radiographic analysis were well described by Toda *et al.*[14,28,29].

The conventional insoles were effective for all of the OA grades, while the strapping insoles had less effect in knees with an advanced grade. In a knee with severe OA, the knee becomes rigid and has three-dimensional deformities, such as medial torsion of the tibia[30]. Therefore, the strapping insole, supposed to fix the ankle and subtalar joints and to correct varus deformity, will not have enough effect to change the mechanical axis in a limb with rigid deformity. On the other hand, the conventional insole will change the calcaneus angle, and successfully shift the mechanical axis. Thus, in advanced cases, choosing conventional insoles is quite plausible, compared with choosing the strapping insoles.

Another possible limitation of this study was these biomechanical effects were obtained in a 10 m walkway and the gait data were not acquired after a period of getting accustomed to the subtalar strapping insole. Although we believe that these biomechanical effects are sustained with long-term use of the insoles, it will be necessary to continue the study with long-term endpoints in order to assess both biomechanical (gait analysis) and joint-structural (OA disease progression) effects.

In conclusion, our data suggest that the use of a conventional insole has a mild effect on the knee at any OA grade, and a greater effect can be achieved through the use of the strapping insole, compared with the conventional insole, on knees without any severe deformity, such as K–L grade 4. The use of the strapping insole provides a reasonable biomechanical effect to reduce the medial compartment load and it can be recommended as a cost-effective treatment for moderate knee OA.

Acknowledgment

The authors would like to thank Yoshimori Kiriyama, Ph.D., for his valuable help with this study.

References

1. Guccione AA, Felson D, Anderson JJ. Defining arthritis and measuring functional status in elders: methodological

issues in the study of disease and physical disability. Am J Public Health 1990;80:945–9.
2. Ahlback S. Osteoarthritis of the knee: a radiographic investigation. Acta Radiol 1968;277(Suppl.):70–2.
3. Schipplein OD, Andriacchi TP. Interaction between active and passive knee stabilizers during level walking. J Orthop Res 1991;9:113–9.
4. Spector TD, Hart DJ. How serious is the knee osteoarthritis? Ann Rheum Dis 1992;51:1105–6.
5. Greismer RP. Current concepts review. Unicompartmental osteoarthritis of the knee. J Bone Joint Surg 1995;77A:278–92.
6. Maquet P. The treatment of choice in osteoarthritis of the knee. Clin Orthop 1985;192:108–12.
7. Altman RD, Hochberg MC, Moskowitz RW, Schitzer TJ. Recommendation for medical management of osteoarthritis of the hip and knee. Arthritis Rheum 2000; 43:1905–15.
8. Sasaki T, Yasuda K. Clinical evaluation of the treatment of osteoarthritic knees using a newly designed wedged insole. Clin Orthop 1987;215:181–7.
9. Yasuda K, Sasaki T. The mechanics of treatment of the osteoarthritic knee with a wedged insole. Clin Orthop 1987;215:162–72.
10. Wolfe SA, Brueckman FR. Conservative management of genu valgus and varum with medial/lateral heel wedge. Indiana Med 1991;84:614–5.
11. Keating EM, Faris PM, Ritter MA, Kane J. Use of lateral heel and sole wedges in the treatment of medial osteoarthritis of the knee. Orthop Rev 1993;22:921–4.
12. Crenshow SJ, Pollo FE, Calton EF. Effects on lateral-wedged insole on kinetics at the knee. Clin Orthop 2000;375:185–92.
13. Kerrigan DC, Jennifer LL, Goggins J, Merriman GJ. Effectiveness of a lateral-wedged insole on knee varus torque in patients with knee osteoarthritis. Arch Phys Med Rehabil 2002;83:889–93.
14. Toda Y, Segal N, Kato A, Yamamoto S, Irie M. Effect of a novel insole on the subtalar joint of patients with medial compartment osteoarthritis of the knee. J Rheumatol 2001;28:2705–10.
15. Toda Y, Segal N. Usefulness of an insole with subtalar strapping for analgesia in patients with medial compartment osteoarthritis of the knee. Arthritis Rheum 2002;47:468–73.
16. Toda Y, Tsukimura N, Kato A. The effect of different elevations of lateral wedged insoles with subtalar strapping on medial compartment osteoarthritis of the knee. Arch Phys Med Rehabil 2004;85:673–7.
17. Toda Y, Tsukimura N. A six-month followup of a randomized trial comparing the efficacy of a lateral-wedge insole with subtalar strapping and an in-shoe lateral-wedge insole in patients with varus deformity osteoarthritis of the knee. Arthritis Rheum 2004;50:3129–36.
18. Hochberg MC, Altman RD, Brandt KD, Clark BM, Dieppe PA, Griffin MR, *et al.* Guidelines for the medical management of osteoarthritis. Part II. Osteoarthritis of the knee. Arthritis Rheum 1995;38:1541–6.
19. Nagura T, Dyrby CO, Alexander EJ, Andriacchi TP. Mechanical loads at the knee joint during deep flexion. J Orthop Res 2002;20:881–6.
20. Andriacchi TP, Galante JO, Fermier RW. The influence of total knee-replacement design on walking and stair-climbing. J Bone Joint Surg Am 1982;64:1328–35.
21. Kellgren LH, Lawrence JS. Radiological assessment of osteoarthritis. Ann Rheum Dis 1957;16:494–502.
22. Kerrigan DC, Johansson JL, Bryant MG, Boxer JA, Della Croce U, Riley PO. Moderate-heeled shoes and knee joint torques relevant to the development and progression of knee osteoarthritis. Arch Phys Med Rehabil 2005;86:871–5.
23. Shakoor N, Block JA. Walking barefoot decreases loading on the lower extremity joints in knee osteoarthritis. Arthritis Rheum 2006;54:2923–7.
24. Wang JW, Kuo KN, Andriacchi TP. The influence of walking mechanics and time on the results of proximal tibial osteotomy. J Bone Joint Surg 1990;72-A:905–9.
25. Prodromos CC, Andriacchi TP, Galante JO. A relationship between gait and clinical changes following high tibial osteotomy. J Bone Joint Surg 1985; 67-A:1188–94.
26. Wada M, Imura S, Nagatani K. Relationship between gait and clinical results after high tibial osteotomy. Clin Orthop 1998;354:180–8.
27. Mundermann A, Dyrby CO, Hurwitz DE, Sharma L, Andriacchi TP. Potential strategies to reduce medial compartment loading in patients with knee osteoarthritis of varying severity: reduced walking speed. Arthritis Rheum 2004;50:1172–8.
28. Toda Y, Tsukimura N, Segal N. An optimal duration of daily wear for an insoke with subtalar strapping in patients with varus deformity osteoarthritis of the knee. Osteoarthritis Cartilage 2005;13:353–60.
29. Toda Y, Tsukimura N. A 2-year follow-up of a study to compare the efficacy of lateral wedged insoles with subtalar strapping and in-shoe lateral wedged insoles in patients with varus deformity osteoarthritis of the knee. Osteoarthritis Cartilage 2006;14:231–7.
30. Nagamine R, Miyanishi K, Miura H, Urabe K, Matsuda S, Iwamoto Y. Medial torsion of the tibia in Japanese patients with osteoarthritis of the knee. Clin Orthop 2003;408:218–24.

分担研究報告書

2.　動作解析装置を用いた歩行障害・ADL 障害の解明に関する研究

国立身体障害者リハビリテーションセンター病院

病院長　赤居正美

運動機能系障害研究部　部長　中澤公孝

厚生労働科学研究費補助金（長寿科学総合研究事業）
分担研究報告書

動作解析装置を用いた歩行障害・ADL障害の解明に関する研究

研究分担者　　赤居　正美　　国立障害者リハビリテーションセンター病院　院長

研究要旨

高齢者が要支援となる主な原因疾患である変形性膝関節症を対象に、動作計測を行い日常生活動作における力学的負荷と臨床症状の関連を検証し、疾患の病態を反映する新しい評価指標を提唱することを目的とする。

膝関節外科・生体医工学・生理学・リハビリテーション医学の専門医からなる班構成により、各施設が単発的に行ってきた臨床・基礎研究のノウハウを統合することで、疾患評価のための統一的な計測手法を確立し、的確な診断のための簡便な指標を提唱する。これまでの静的X線評価にかわり患者の動的評価をすることで、新たな客観的指標を確立しようとすることが本研究の独創的な点である。個々の患者の状態について定量的・客観的評価が可能となることで、臨床現場における要支援・要介護のあいまいな判定の防止につながると同時に、予防・治療を行った際の効果判定基準ともなり、介護医療全体における不要なコストの削減に貢献することが期待される。さらには日常生活動作の負荷を評価することで、変形性膝関節症の重症化を予防するための適切な装具治療・生活指導指針を明示できる。

A．研究目的

変形性関節症は高齢者が要支援となる疾患の第1位を占め、高齢化社会を迎える日本の医療においてその適切な診断・治療に対するニーズは大きい。中でも変形性膝関節症は頻度が高く、病状の進行により歩行能力が低下しADLを大きく障害する。変形性膝関節症の診断には通常X線を用いるが、患者が症状を訴えるのは実際の動作中であり、静的評価であるX線では実際の病態を反映しないことも多い。本研究では、X線に変わる新たな評価方法として、動作解析装置による関節負荷の計測を行い、臨床症状・重症度・ADL障害との関連を検討する。最終的には、疾患の病態を反映する客観的指標の提唱を行う。

B．研究方法

初年度、当施設ではPoint Cluster Technique (Andriacchi 1998)によって、変形性膝関節症患者における膝関節の微細運動の特性を明らかにすることを目指した。

大腿，下腿の部位マーカーより，各部位の計算上の軸(慣性主軸)を求め、膝関節角度(6自由度：内/外転、内/外旋、伸/屈、前/後、上/下、内/外側)を算出した。マーカー配置は、骨指標マーカー 8個、部位マーカー 16個（大腿10，下腿6）とし、各マーカーのノイズを受けず、骨運動に近い微細な計測を可能とした。

被験者は若年健常者（YS群，N=19）と膝OA患者（OA群，N=50）とし、両群間での比較を行った。合わせて患者群では、Kellgren & Lawrence 分類を用いたサブグループでの比較を行った。日常生活動作などに注目した調査票による臨床評価も行った。

（倫理面への配慮）

研究対象者に対する人権擁護上の配慮、研究方法による研究対象者に対する不利益、危険性の排除や説明と理解（インフォームドコンセント）に関わる状況に関して十分に配慮する。

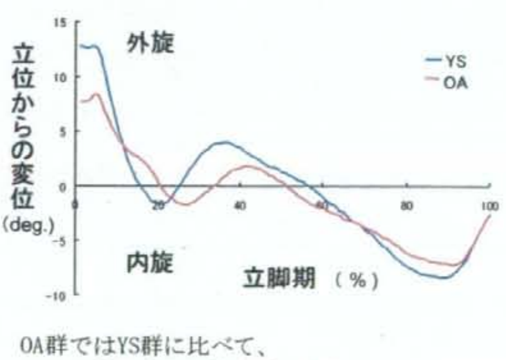
C．研究結果

レントゲン撮像による病期分類ではGrade 1から4までが、各々4例、9例、17例、19例となった。

検討1：膝関節内・外旋角度の群間分析

YS群では、

- 接地時：大きく外旋
- 立脚20%まで：急激な内旋
- 一様なパターンを示す

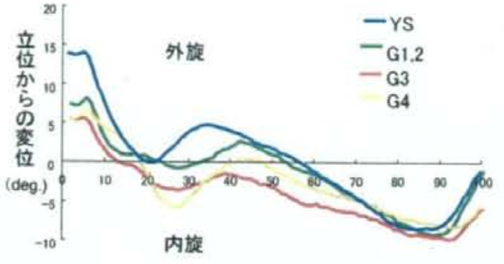


OA群ではYS群に比べて、

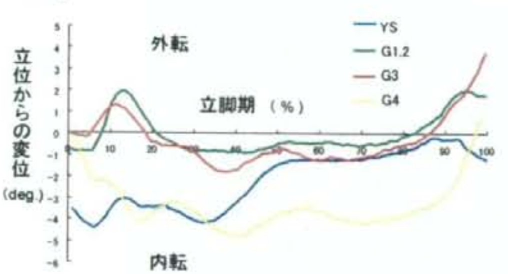
- 接地時の外旋角度が少ない

・　回旋変化量が少ない
・　パターンに個人差が大きい

検討2：膝関節内・外旋角度の病期別分析
Grade 1,Grade 2の比較的軽症者でも回旋変化量においてYS群との差が見られた。変形の初期段階からの膝回旋運動の阻害があった。



検討3：膝関節内・外転角度の病期別分析
Grade 1、2、3に共通して、立脚初期の外転→内転の急激な角度変化が見られ、Grade 4に特異的な立脚期全般を通した著しい内転位での歩行があった。



以上より、初期OAの特性として
立脚初期の生理的な回旋運動の阻害
立脚初期の急激な内外転（側方動揺性）の発生
重度OAの特性として
立脚期全般（特に中期以降）の著しい内転
が確認された。

D．考察
これまで変形性膝関節症の重要な関節負荷指標として、歩行中の膝内反トルク(Knee varus torque)が提唱され、病態・予後との関連が研究されてきた。しかしこれら欧米のデータは体格や膝の形態が異なり、わが国の患者評価のための指標とはなりにくい。日本人の変形性膝関節症患者に対する関節負荷についてはほとんどデータがなく、病態・予後との関連も不明である。
介護予防推進にむけた運動器疾患対策の一環として、要介護の重要な原因疾患である変形性膝関節症がどのようにADL障害を引き起こすかを追究することは重要で、特に本研究では実際の歩行・ADL動作を計測するため、より患者の全身状態・病態を反映した新たな指標を確立できると考えている。
客観的な指標は、要支援・要介護の適切な判定基準となり、臨床現場におけるあいまいな判定の防止につながり、しいては介護医療全体における不要なコスト削減に貢献する。また動作解析データは予防・治療を行った際の効果判定基準ともなるため、変形性膝関節症の重症化を予防するための適切な装具治療・生活指導指針を提示することが可能となり、自立喪失の高齢者数の減少に寄与することが期待される。

E．結論
初期OAの特性として
・立脚初期の生理的な回旋運動の阻害
・立脚初期の急激な内外転（側方動揺性）の発生が確認されたので、これらの運動特性が、動作から見たスクリーニングや治療介入効果判定の有効な資料となる事が期待できる。
次年度には現在の診断スクリーニングとして用いられている片脚起立などについても計測を行い、これらの手法と実際の関節負荷との関連を検討し、的確な診断のための簡便な指標に結びつけたい。

F．健康危険情報

G．研究発表

1.　論文発表

・ Nagano Y, Sakagami M, Ida H, Akai M, Fukubayashi T. Statistical modeling of knee valgus during a continuous jump test. Sports Biomechanics 7(3):342-350,2008
・ Nakajima K, Kakihana W, Nakagawa T, Mitomi H, Hikita A, Suzuki R, Akai M, Iwaya T, Nakamura K, Fukui N. Addition of an arch support improves the biomechanical effect of a laterally wedged insole. Gait and Posture 29(2)：208-13,2009
・ Nagano Y, Ida H, Akai M, Fukubayashi T. Biomechanical characteristics of the knee joint in female athletes during tasks associated with anterior cruciate ligament injury. Knee. 16(2):153-8,2009

2.　学会発表

・永野康治，内藤健二，深野真子，井田博史，赤居正美，福林徹．多点皮膚マーカー計測法の膝OA患者における歩行解析への応用 Part I -膝OA患者歩行における解析法の違い-．第20回日本運動器リハビリテーション学会，東京，2008-07．抄録集，2008，p.108.

・内藤健二, 永野康治, 深野真子, 井田博文, 中澤公孝, 赤居正美, 福林徹. 多点皮膚マーカー計測法の膝OA患者における歩行解析への応用PartⅡ －膝OA患者と若年健常者との比較－. 第20回日本運動器リハビリテーション学会学術集会. 東京, 2008-07. 抄録集, 2008, p.109.

・Naito K, Nagano Y, Fukano M, Ida H, Torii S, Nakazawa K, Akai M, Fukubayashi T. The comparison of in vivo knee kinematics between knee osteoarthritis patients and young healthy subjects during normal gait. -Application of point cluster technique-. International symposium on ligament and tendon IX, Las Vegas, 2009-02, Absturucts, 2009, p.58.

H. 知的財産権の出願・登録状況
（予定を含む。）

1. 特許取得
特になし
2. 実用新案登録
特になし
3. その他

分担研究報告書

3. 動作解析装置を用いた歩行障害・ADL障害の解明に関する研究

新潟大学超越域研究機構整形外科　　　　教授　大森　豪

厚生労働科学研究費補助金（長寿科学総合研究事業）
（総括・分担）研究報告書

動作解析装置を用いた歩行障害・ADL傷害の解明に関する研究

（主任又は分担）研究者　大森　豪　新潟大学超域研究機構　教授

研究要旨
　変形性膝関節症の発症・進行に伴う膝関節運動や歩行の変化を高精度動作解析装置を用いて解析し、日常生活動作への影響を検討評価した。その結果、歩行や立ち上がりなどの日常動作における膝関節への荷重状態が本症の発症、進行に大きく影響し、中でも立脚歩行初期におけるスラスト運動が重要である可能性が強く示唆された。

分担研究者氏名・所属機関名及び所属機関における職名

（分担研究報告書の場合は、省略）

A．研究目的
　変形性膝関節症（以下膝OA）の発症、進行に伴う膝関節運動や歩行の変化を解析し、日常生活動作への影響を評価する。さらに、本症の予防、治療に役立つ方法を運動学的観点から策定する

B．研究方法
　高精度3次元運動解析システムを用いて、健常人および膝OAの各グレードの男女を対象に肥厚運動解析を行った。
（倫理面への配慮）
事前に研究の目的、内容について説明を行い同意書を取得した上で実施した。

C．研究結果
　10名の測定結果では、膝OAの進行に伴い内反モーメントおよび、スラストの出現率が増大していた。また、膝関節の3次元荷重線は内側後方へ変位していた。また、健常人においてもスラスト用の運動が見られる例があった。

D．考察
　今回の研究の結果、膝OAの発症と進行に歩行時のスラスト運動が関与している可能性が示唆された。我々の行った疫学調査からもスラスト運動と膝OA発症の関係が明らかとなっており、今後、スラストと下肢筋力の関係を解明することが必要と考えられる。

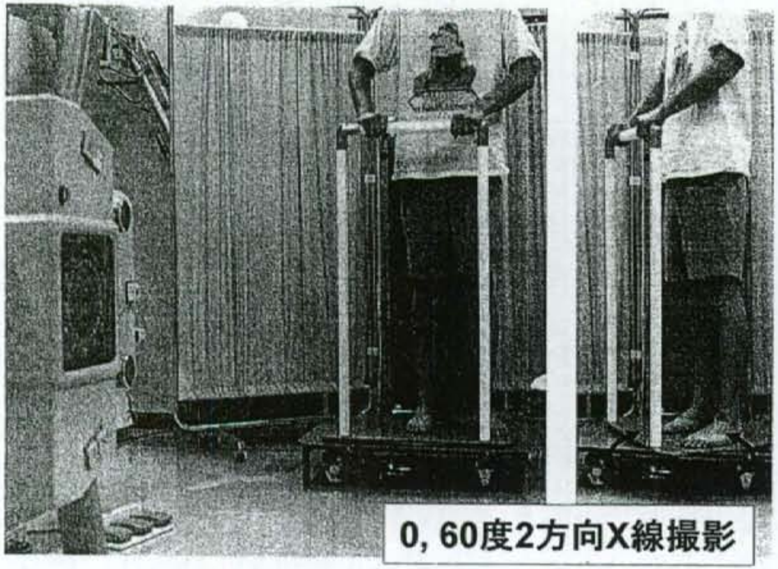
E．結論
　膝OAの発症、進行には歩行時におけるスラスト運動が影響している可能性が明らかとなった。今後、スラストを抑制する目的での下肢筋力との関連性を検討する必要があると考えられる。

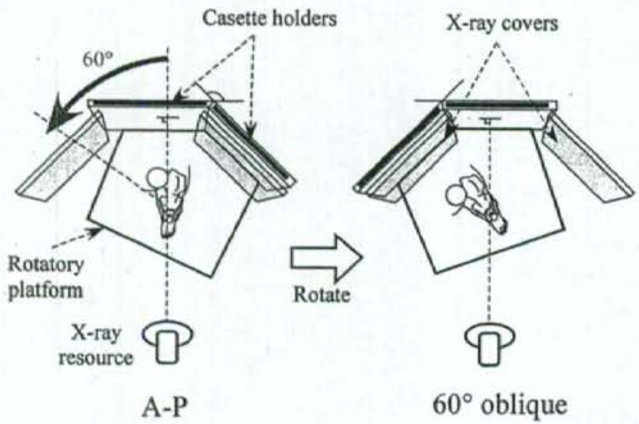
F．健康危険情報
　特記すべき事項の発生無し
（分担研究報告書には記入せずに、総括研究報告書にまとめて記入）

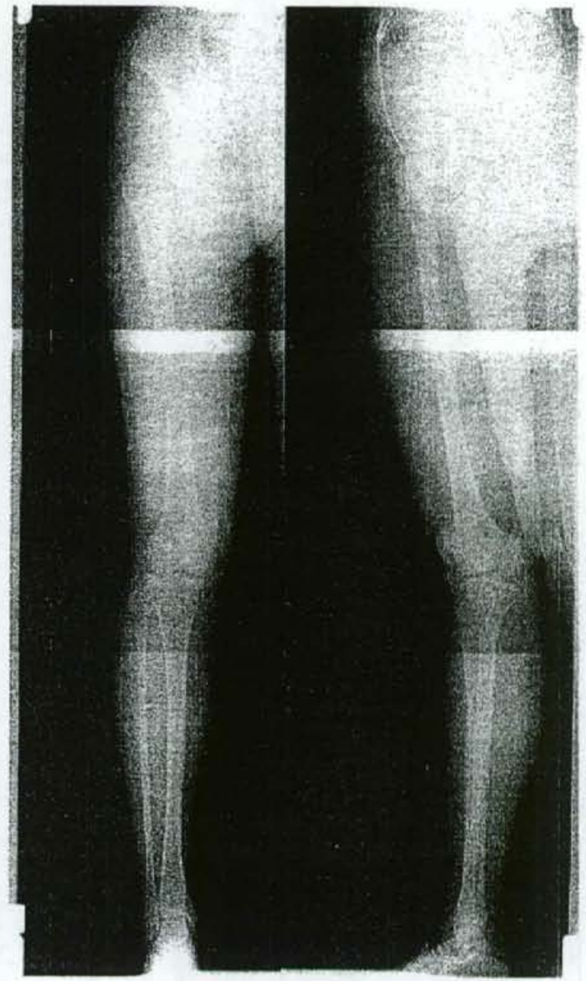
G．研究発表
1.　論文発表
　別紙記載
2.　学会発表
・第81回日本整形外科学会
・9^{th} Tri-city Scientific Meeting
・第35回日本臨床バイオメカニクス学会
・第39回日本人工関節学会
（発表誌名巻号・頁・発行年等も記入）

H．知的財産権の出願・登録状況
　（予定を含む。）
1. 特許取得
　無し
2. 実用新案登録
　無し
3. その他
　特記事項無し

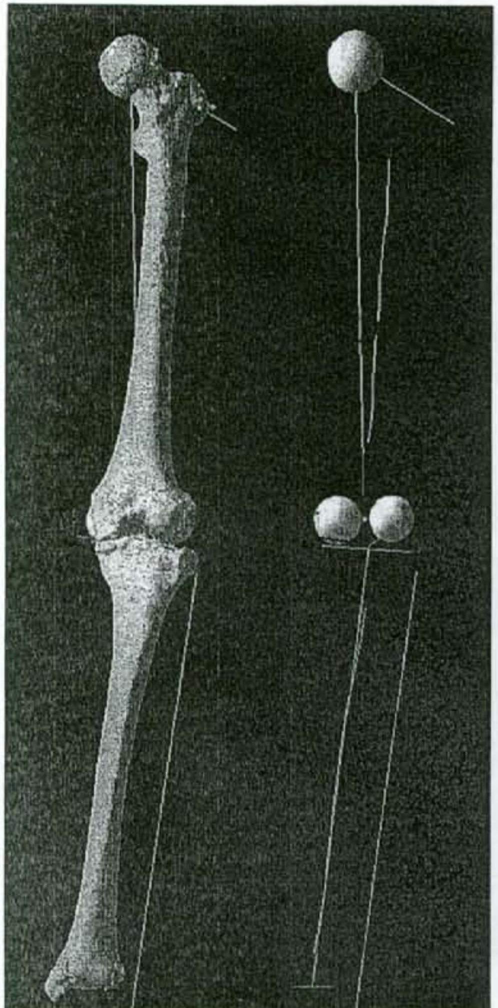
3次元下肢アライメント評価システム(Knee CAS) (LEXI社)







正面像　60度斜角像



実際のアライメントを
再現した3次元骨モデル

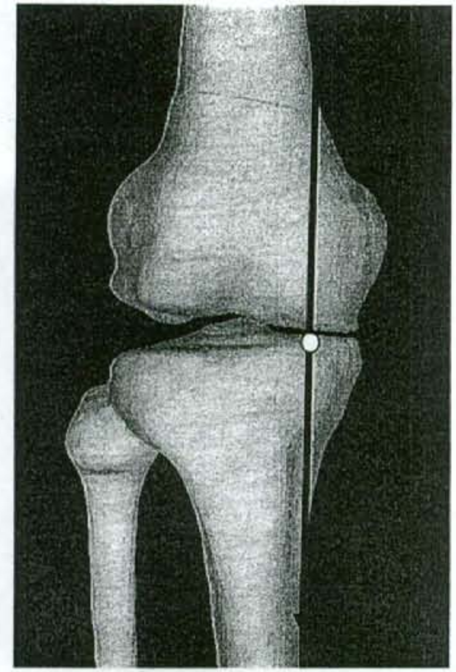
Information

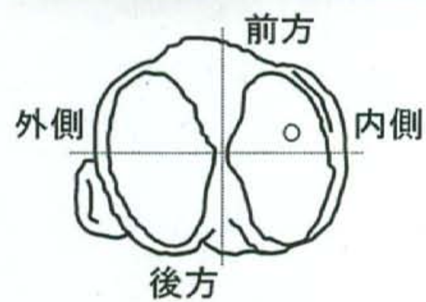
患者情報　下肢アライメント | 設置位置 | ガイド | 座標情

算出対象：3次元モデル

大腿骨弯曲度		4.03 %
大腿骨前弯度		3.89 %
大腿骨外弯度		1.22 %
大腿骨最大弯曲位置		47.90 %
大腿骨前捻角		47.73 度
大腿骨頚体角		115.87 度
大腿骨顆部後方接線角	内旋	1.01 度
脛骨弯曲度		1.97 %
脛骨前弯度		1.93 %
脛骨外弯度		0.38 %
脛骨最大弯曲位置		46.80 %
脛骨捻れ角	外捻	1.02 度
脛骨後方傾斜角(内側)	後傾	11.47 度
脛骨後方傾斜角(外側)	後傾	3.14 度
脛骨顆部後方接線角	内旋	1.72 度
脛骨遠位関節面傾斜	外反	5.25 度
大腿脛骨角(FTA)		186.55 度
膝関節伸展角	屈曲	10.20 度
下肢荷重線通過点(内外)	内側	75.44 %
下肢荷重線通過点(前後)	後方	17.58 %
膝関節回旋角	外旋	19.17 度
関節裂隙角	内反	4.92 度
関節裂隙		2.34 mm
大腿脛骨後方接線角	内旋	0.65 度
腓骨後方回旋度	後方	41.55 度
腓骨中央後方回旋度	後方	31.02 度
腓骨回旋角	前方	25.04 度
関節面高さ		320.12 mm
関節面高さ(術後)		**********
関節面高さ変化		**********

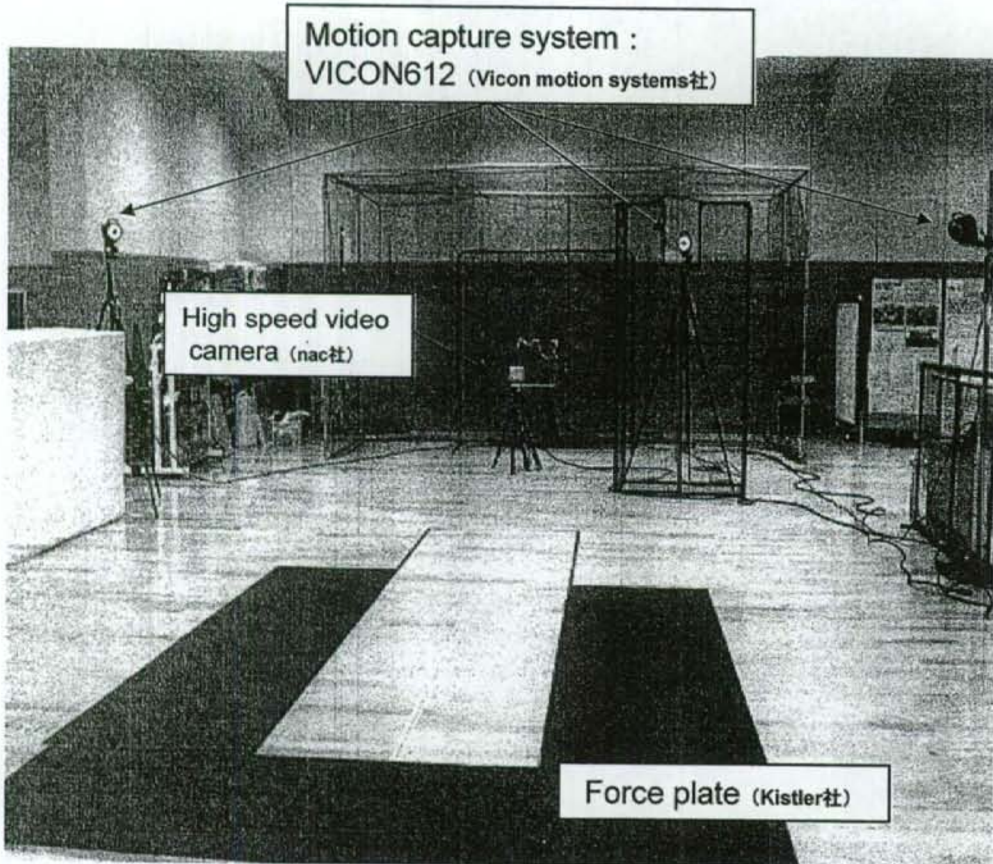
静的アライメントの
パラメター表示

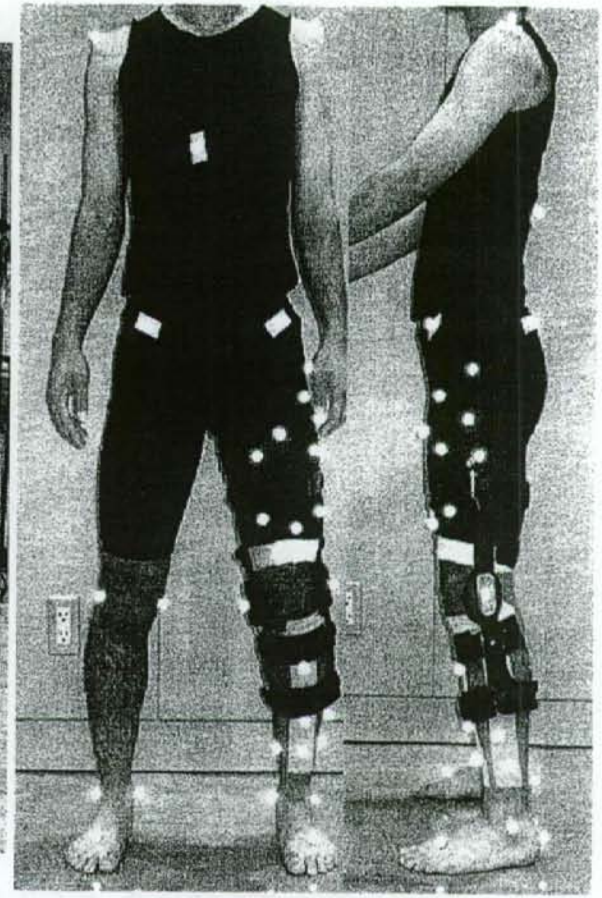




3次元下肢荷重線の
膝関節通過位置

3次元歩行解析システム(VICON)



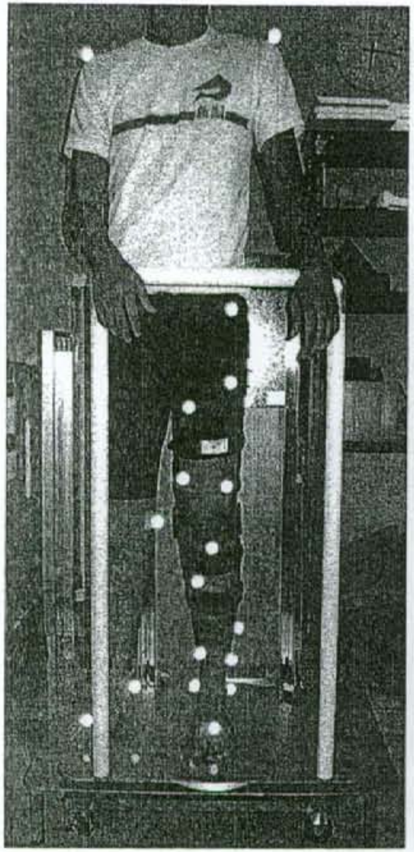


サンプリング周期：120[Hz]
測定空間：
3.5×2.5×2.5[m³]

1mm径鋼球入反射マーカ
大腿部：12点、下腿部：8点

測定方法

～３次元下肢アライメント評価システム～

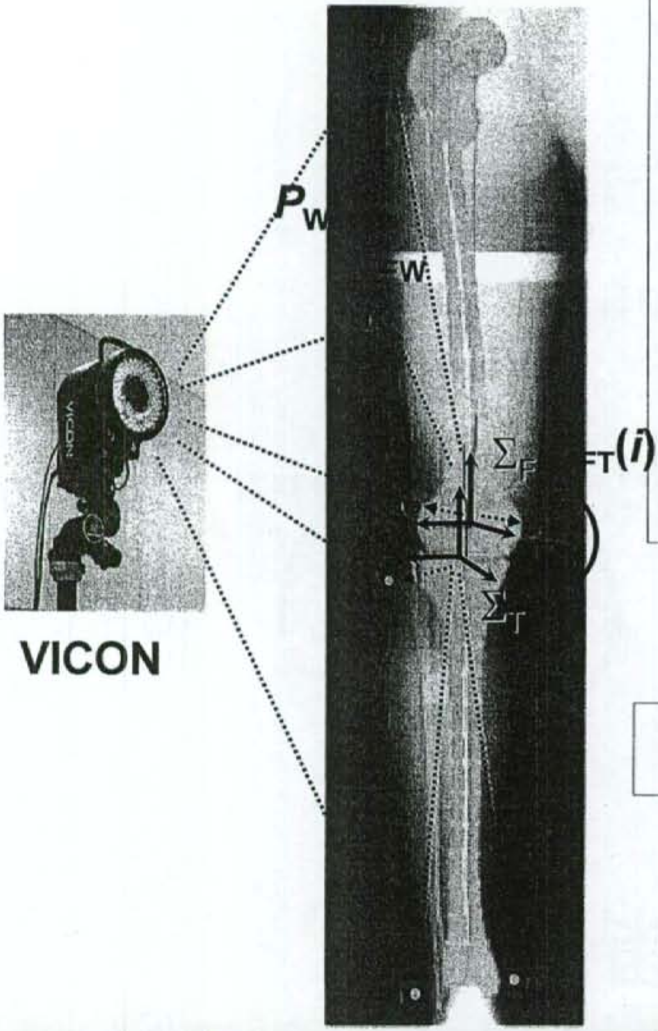


KneeCAS（㈱LEXI）

0-60度の２方向Ｘ線撮影
→３次元再構成により
大腿骨座標系 Σ_F
脛骨座標系 Σ_T
を決定。

他に
骨頭などの特徴点位置
前捻角、頚体角
弯曲度 Bowing
捻れ角 Torsion
FTA
屈曲角
などを評価。

大腿脛骨間の6自由度運動推定



1．骨座標系(Σ_F, Σ_T)と反射マーカ群との位置関係T_{FW}, T_{TW}を伸展位X線像上で算出。

2．位置関係T_{FW}, T_{TW}

＋

運動中の反射マーカの位置データ$P_W(i)$

＝

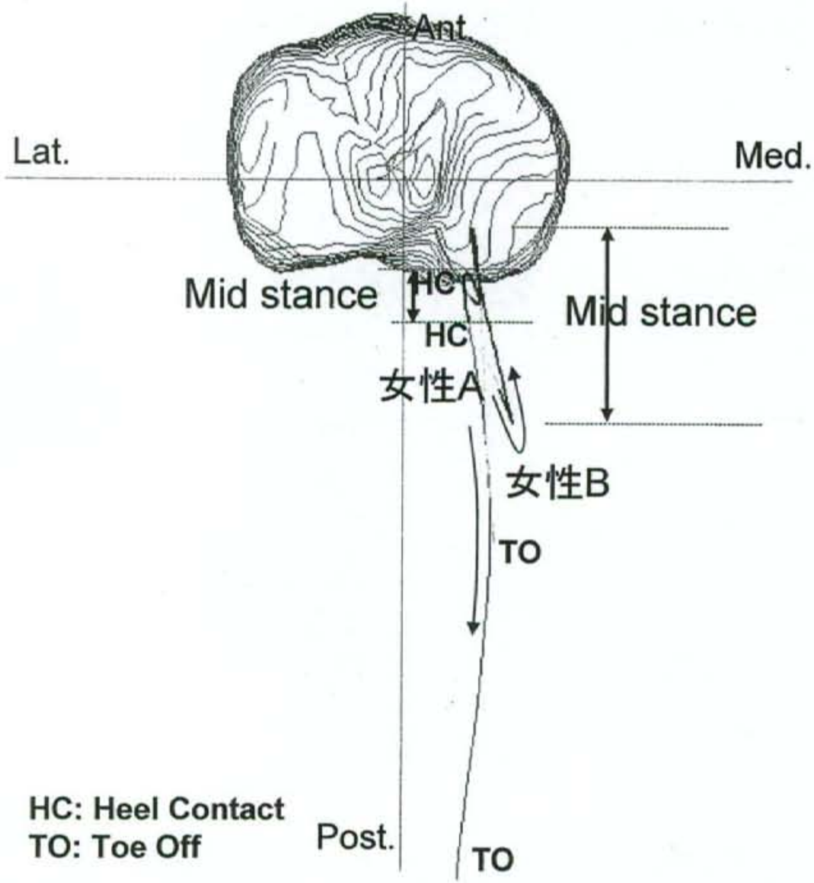
大腿骨に対する脛骨の相対運動$T_{FT}(i)$

⇩

運動の評価基準が常に対象の骨座標系

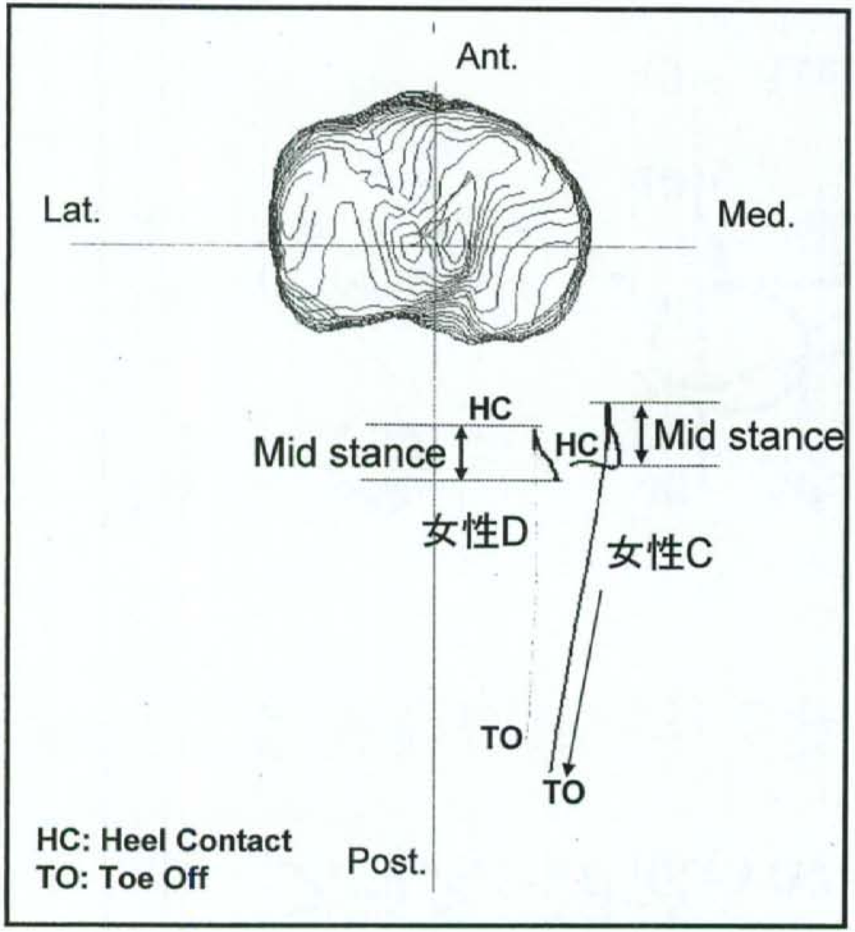
測定精度：膝屈曲30度
脛骨　：並進2.4mm, 回転0.8度
大腿骨：並進5.8mm, 回転2.5度

結果(正常例)



Ant.
Lat.
Med.
Mid stance
HC
HC
Mid stance
女性A
女性B
TO
TO
Post.
HC: Heel Contact
TO: Toe Off

結果（膝OA例）


Ant.
Lat.
Med.
HC
Mid stance
HC
Mid stance
女性D
女性C
TO
TO
HC: Heel Contact
TO: Toe Off
Post.