1	Evaluation of the magnitude of hip joint deformation in subjects with avascular necrosis
2	of the hip joint during walking with and without Scottish Rite Orthosis
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26 Abstract:

27 The femoral head in subjects with leg calve perthes disease (LCPD) is generally considerably 28 deformed. It is debatable whether this deformation is due to an increase in applied loads, a 29 decrease in bone mineral density or a change in containment of articular surfaces. The aim of 30 this study was to determine the influence of these factors on deformation of the femoral head. 31 Two subjects with LCPD participated in this study. Subject motion and the forces applied on 32 the affected leg were recorded using a motion analysis system (*QualsisTM*) and a Kistler force plate. OpenSim software was used to determine joint contact force of the hip joint whilst 33 34 walking with and without a Scottish rite orthosis. 3D Models of hip joints of both subjects 35 were produced by *Mimics software*. The deformation of femoral bone was determined by 36 Abaqus.

Mean values of the force applied on the leg increased while walking with the orthosis. There was no difference between bone mineral density (BMD) of the femoral bone of normal and LCPD sides (p-value>0.05) and no difference between hip joint contact force of normal and LCPD sides. Hip joint containment appeared to decrease follow the use of the orthosis.

It can be concluded that the deformation of femoral head in LCPD may not be due to change in BMD or applied load. Although the Scottish rite orthosis is used mostly to increase hip joint containment, it appears to reduce hip joint contact area. It is recommended that a similar study is conducted using a higher number of subjects.

45 Key words: LCPD, orthosis, Scottish rite, walking, joint contact force, hip joint deformation

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51 Introduction

In Leg Calve Perthes Disease (LCPD) the blood supply of femoral head is disconnected and the femoral head temporarily dies (1). The incidence of this disease varies from a country to country from 0.45 to 10.5 per 100000 and occurs mostly in children between 5 and 12 years (1-4). Although it is claimed that genetic or deprivation factors influence the incidence of this disease, its etiology is likely to be multifactorial and is not clear (1).

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A variety of different approaches to treatment have been used for LCPD, including surgery, the use of orthoses, observation and physical therapy (5-12). The main reason for treatment is to reduce deformation of the femoral bone (7) which may increase the incidence of hip joint degeneration and pain in adolescence (13, 14).

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Treatment approaches used to decrease femoral head deformation are based on reducing the applied load on the femoral head and increasing hip joint containment (5, 7, 10, 15, 16). Containment of the femoral head within acetabulum is achieved by putting the hip joint in a few degrees of abduction and internal rotation until the femoral epiphysis is well inside Perkins line (5, 12, 17).

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Offloading of the hip joint has being conducted using assistive devices such as the
Birmingham splint, Snider sling, or Ischial weight bearing orthoses (10, 11, 15, 16).

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The main LCPD treatment aims are to contain and prevent further deformity of the femoral head; relieve painful symptoms and restore hip joint range of motion (7). Results of various research studies demonstrate no difference between the outputs of treatment based on surgery, orthoses, physical therapy or observational treatment. This means current treatment
pathways have not demonstrated success in relation to treatment aims (7).

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It remains unclear exactly why the femoral bone is deformed in this disease. The deformation
of the femoral bone is currently presumed to be as a result of increase in the applied loads,
decrease in bone density or a decrease in femoral head containment within acetabular cavity
(7).

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Results of previous studies have demonstrated no significant difference between forces applied between normal and LCPD legs (18, 19). Moments applied on the hip joint in the LCPD side may actually be less than that of normal side (20). It was concluded that these subjects altered their walking pattern to decrease the hip joint moment and hence load on hip joint (21, 22). Although previous studies have examined hip joint load of LCPD subjects, all are based on inverse dynamics and kinematics (18,19, 22). To the best of our knowledge, no study on hip joint contact forces has previously been described in this group of subjects.

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Bone mineral density (BMD) is another important parameter which is mostly dependent on applied femoral load. Baily et al. demonstrated that BMD of femoral head in LCPD side was less than that of sound side, which may be due to decrease in loads applied. It was demonstrated that the maximum difference of density related to the femoral neck region (20). Based on these findings it may be fair to conclude that a decrease in BMD may be related to a reduction in applied load, which should return to expected values if the subjects walked normally.

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99 Although the theory of femoral head containment within the acetabulum was described more 100 than 50 years ago, there are no studies which evaluate the effects of this hip joint position on 101 increase of the contact area of the hip joint (7).

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There are no studies which evaluate hip joint contact forces in LCPD. The effect of hip joint containment on the acetabular contact area in these subjects remains undecided; there is little information on the effect of containment on the stress and final deformation of the femoral bone. Therefore, the aim of this study was to examine the effect of orthotic management on the resulting stress which develops in the hip joint and to determine the effects of alignment change in relation to this stress.

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110 Methods

Two seven year old boys with symptoms of avascular necrosis of the hip joint participated in this study, Table 1. Both had involvement of hip joint on the right side. The severity of LCPD was determined based on the latest X-ray of the patients (Mose et al)(23). Ethical approval was obtained from Isfahan University of Medical Sciences, Ethical Committee , a consent form was signed by the parents of each participant before date collection.

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Both subjects were asked to walk with and without Scottish rite orthosis. This is a welldeveloped orthosis for the subjects with LCPD and holds the hip joint in some degree of abduction and medial rotation to increase hip joint containment. The Scottish rite orthosis is one of the most popular used orthoses for the subjects with LCPD and was originally developed at Scotish rite hospital for crippled children in Atlanta in 1971. This orthoses consists of three main parts, including plastic thigh cuffs, a pelvic band and a single axis hip hinge. The main reason to use this orthoses is to put the hip joint in an abducted and internally rotated posture. (18, 24). It should be emphasised that the orthosis was built
specifically for each subject and the subjects used their orthosis for at least 6 months before
participated in this study. The following parameters were evaluated in this study:
Spatiotemporal gait parameters during walking with and without orthosis, forces applied on
the leg, kinematic of the lower limb joints and pelvic, hip joint moments, joint contact forces
of the hip joints, the containment of the hip joint in various aligned positions, and the stress
and strain of hip joint in walking with and without orthosis.

131 **Procedure**:

132 Kinetic and kinematic analysis: A motion analysis system consisted of seven high speed 133 camera (Qualysis motion analysis system) and Kistler force plates were used to collect the 134 kinetic and kinematic parameters. 22 markers were attached on the right and left anterior and 135 posterior superior iliac spines, right and left greater trochanters, right and left medial and lateral sides of knee joint, right and left medial and lateral malleolus, first and fifth metatarsal 136 137 heads, right and left heels and right and left acromioclavicular joints. Additionally, four 138 markers clusters were attached on the lateral side of thighs and shanks in both right and left 139 sides. The subjects were asked to walk at a comfortable self-selected speed with and without 140 the orthosis. Tests were repeated to collect five successful trials.

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Force plate data and cameras were collected with frequency of 120 Hz. Data was filtered with
Butterworth low pass filter with cut off frequency of 10 Hz. Markers were labeled in *QualysisTM Tract Manager Software* and were exported as 3-D files. Files were opened with *MokkaTM software* to produce *trc* files to be analyzed with *OpenSIMTM* software. *OpenSIMTM*software is open source software developed by Stanford University, USA. It can be used to
analysis kinetic, kinematic, muscles forces, muscles length and joint contact forces. Figure 1

shows the procedure used to determine joint contact forces of the hip joint by use of *OpenSIMTM* software (25).

The scaling was done with high accuracy as was recommended by *OpenSIMTM* developer (25), the RMS of error was less than 2mm for whole model. Moreover, the RMS of model error was evaluated in inverse kinematic frame by frame. (Based on the reports produced by the software automatically the RMS of error was less than 2cm.)

Producing 3-D files of hip joint: 3-D modeling of the hip joint with specific material assignment was done by use of *MimicsTM* and *AbaqusTM* software, based on CT scan slices of the patient's hip joint. Hip joint files were opened in *MimicsTM* software to produce a 3-D mask and different segments (femoral and pelvic) modeled individually. Resulting segments were exported to *AbaqusTM* software to change the format of the mesh from 'tri' to 'tet'. INP files were then imported to *MimicsTM* to assign the material.

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161 The software defines a number of sampling points within each element and interpolates the

162 gray level relating to their coordinate from the original CT. Gray level is proportional to

163 apparent bone density. Young Modules (E) was automatically calculated by mimics software

164 based on equation developed by Schileo et al. and Morgan et al. (26, 27) :

165 E=6850ρ^{1.49}

166 In which, E was Young Modules of elasticity and ρ was appearance bone density.

Hip joint alignment changes (femoral head and pelvic components) were simulated using *MimicsTM* software. The femoral bone was placed in abduction, external rotation, and internal rotation with respect to the acetabulum (pelvic). The influence of changes in alignment of hip joint on joint containment was determined based on the number of nodes of femoral head which were covered by acetabulum of hip bone. Resulting femoral head stress developed in various positions and deformation was determined based on the forces obtained from *OpenSIMTM* software. It was done by help of Abaqus software. Due to lack of information
regarding stress analysis of femoral bone in children the analysis was done based on elastioplastic approach in *AbaqusTM* software.

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Mean values of the kinematic, kinetic parameters and joint contact forces were determined in walking with and without orthosis conditions. At least 10 successful trials for each subject was collected under each condition. Statistical analysis was conductedseparately for each subject, based on conditions (walking with and without orthosis). The difference between the mean values of the gait parameters was evaluated by use of two sample tests.

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183 **Results**

184 The mean values of the gait parameters of both subjects while walking with orthosis and

185 without orthosis are shown in Table 2. As can be seen from this table, walking speed and

stride length decreased especially while walking with orthosis (P-value of difference < 0.05

187 for subject 1).

Hip and pelvic kinematics were also evaluated in this study, Table 3. Although the range of 188 189 flexion and extension motions of hip joint did not decrease significantly in subject 1, they did 190 so in subject 2 following the use of orthosis $(29.75\pm3.14 \text{ without orthosis vs. } 9.6\pm1.52 \text{ when}$ 191 walking with an orthosis). In contrast, the hip joint range of motion in frontal plane decreased 192 significantly in both subjects (P-value < 0.05). The pelvic range of motion in the frontal plane 193 increased notably in both of participants (Table 3). Although the peaks of the ground reaction 194 force components applied on the leg increased while walking with orthosis, the difference 195 was only significant for mediolateral force (P-value = 0.04 and 0.01 for the first and second,

subjects, respectively), Table 4. Most of the peaks of hip joint moments increased
significantly during walking with the orthosis in both subjects (p-value<0.05), Table 5.

199 The hip joint contact force of both subjects while walking with and without orthosis are 200 shown in Table 6. Vertical component peaks of hip joint contact force were 13.74 ± 6.13 and 6.27 ± 2.53 N/BW in subject 1 in walking without and with the orthosis, respectively. In 201 202 contrast, it was 9.96 ± 3.54 and 12.8 ± 2.1 N/BW, in subject 2 for walking without and with 203 orthosis. Although the mean values of anteroposterior component of hip joint contact force 204 increased in both subjects, the difference was not significant (p-value > 0.05). The hip joint 205 contact force of the sound side was also evaluated in this study. As can be seen from Table 7, 206 there was no difference between hip joint contact force between involved and healthy sides 207 (p-value>0.05).

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209 Mean values of femoral bone density and femoral bone Young Modules of elasticity of the 210 involved side were $805129.9 \pm 467632.5 \text{ g/m}^3$ and $4770396420 \pm 2770722483$ Pascal for 211 subject 1 and 900077.3 \pm 564158 g/m³ and 4648782493 \pm 2642671981 Pascal for subject 2, 212 respectively. There was no difference between density and Young modulus of elasticity 213 between involved and sound sides, Table 8. The results of joint containment in various 214 alignment of hip joint are shown in Table 9. As can be seen from this table, the maximum 215 contact area of hip joint was in neutral position in both subjects. However, the minimum 216 number of nodes was in abduction and internal rotation in subject 1 and abduction in subject 217 2.

Femoral bone deformation and stress magnitude in the femur, (based on the elastic approach), are shown in figure 2. As can be seen from this figure, the stress developed was more than the stress which can feasibly be tolerated by the bone. Therefore, all analysis was conducted based on an elasto-plastic approach. The results of deformation of femoral bone in various
aligned positions are shown in Table 10. The average deformation of femoral bone was 2.318
mm and 1.964 mm in subject 1 while walking with and without orthosis. Although in subject
1 using the orthosis reduced the deformation of the femoral head, in subject 2 the deformation
of the bone in walking with orthosis was more than that without orthosis. Regarding the
effects of alignment on femoral head deformation, the deformation in abduction and neutral
position was less than that in other conditions.

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Discussion:

230 Although the etiology of LCPD was described over 100 years ago, there is still a lack of 231 consensus on which treatment approach should be used to decrease the deformities associated 232 with this disease. Although various treatment approaches have being used to decrease the deformation of femoral head and decrease the incidence of hip joint degenerative change, 233 234 most of them are not successful (7). One of the broadly used methods to reach to this goal is 235 the use of an orthosis. Therefore, the aim of this study was to determine the effect of the use 236 of an orthosis to decrease the load applied on hip joint and hence the deformation of femoral head. Additionally, the study aimed to evaluate the influence of femoral alignment change on 237 238 containment and stress developed in the hip joint.

Femoral bone deformation in this disease may be due to three main reasons which include: Increase in loads applied on the hip joint, change in containment of articular surfaces and decrease in bone mineral density. As can be seen from the results of this study presented in Table 7, there was no difference between joint contact forces of LCPD affected and healthy sides. It may therefore be concluded that femoral bone deformation is not related to an alteration in hip joint load. No other previous studies have been identified to examine the joint contact force in subjects with LCPD. 246 The results of BMD of both subjects demonstrated no difference between BMD and Young modulus of elasticity of LCPD and sound sides. Table 8. Results of this part of this research 247 248 did not support the finding of Bailey et al (20). Some parameters such as the time between 249 start of disease and follow up may be the reason for the difference. It should be noted that the 250 BMD in the current research was measured based on Shailey et al approach, which was conducted using *MimicsTM* software (26). The BMD of different parts of femur (up to 5cm 251 252 below the greater trochanter) were evaluated in this study. Although there was no difference 253 between the mean values of BMD of femur, the BMD of specific parts may be decreased due 254 to this disease. Overall, no significant difference was detected between the BMD of LCPD 255 and sound sides.

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Results demonstrate that femoral head deformation in LCPD is not due to a change in BMD or applied load. The remaining reason discussed may be due to a change in hip joint containment. The difference between hip joint containment between LCPD and normal subjects was not evaluated in this study. Therefore, it is recommended that this parameter should be considered in the future.

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263 However, subjects with LCPD are recommended to use Scottish rite orthosis to increase joint containment and to reduce applied loads. The results of this research also highlighted that 264 265 although the walking speed and stride length decreased significantly while walking with 266 orthosis, Table 2, the moments applied on hip joints and some components of ground reaction force increased significantly, Tables 4 and 5. This is the same as the results of the study done 267 by Karimi et al (18). However the results of joint contact force demonstrated that although 268 269 the mediolateral component of hip joint contact force increased in both subjects following the 270 use of the orthosis, the mean value of vertical components increased in subject 2 (it decreased in subject 1), Table 6. Results of this study therefore do not support the use of orthosis toreduce hip joint contact force.

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274 The results of stress analysis demonstrated that stress developed in the femoral bone based on 275 elastic approach exceeded the stress which may feasibly be tolerated by the femur. Therefore, 276 it was decided that the stress analysis of the bone be conducted using an elasto-plastic 277 approach. The results of stress analysis demonstrated that the deformation of femoral head 278 decreased in walking with orthosis condition (in neutral condition) in subject 1, compared to 279 an increase in subject 2. As this part of analysis was done in neutral condition the difference 280 in deformation of femoral bone may be due to change in hip joint contact force. As can be 281 seen from Table 6, the vertical component of joint contact force decreased and increased 282 slightly in subjects 1 and 2, respectively.

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The effect of hip joint alignment change was also evaluated in this study. Results indicate that positioning of the hip joint articular surfaces in a neutral position may provide maximum contact area, Table 9. Although abduction and internal rotation increased the contact area of the hip joint surface in subject 2, it deceased the contact surface in subject 1. It may therefore be concluded that the position achieved by use of the orthosis may be not optimal in promoting maximum joint containment.

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The results of stress-strain analysis demonstrated that use of orthosis may decrease the deformation of femoral head in subject 1 but increased it in subject 2. As this part of comparison was done in neutral position it can be concluded that it may be due to a change in applied loads on hip joint. As can be seen from Table 7, the vertical component of hip joint contact force in subject 1 in walking with orthosis was less than that of normal walking, however, this increased in subject 2. Alignment of the hip joint in the aforementioned positions by use of orthosis seems to increase the deformation of femoral head, due to decrease in joint containment.

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The main limitation of this study was the number of participants. It is recommended that future studies should be conducted using a larger sample size. Moreover, it is recommended that bone mineral density of different parts of bone be evaluated in an increased number of subjects with LCPD.

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305 Conclusion

306 Whilst considering the limited number of participants in this study, it may be concluded that

307 the deformation of femoral bone is neither due to a change in hip joint load or a change in

308 bone mineral density. Additionally, results indicate that the containment of the hip joint in the

309 positions aligned by use of the Scottish rite orthosis does not increase the contact area of hip

310 joint in all subjects. It is recommended that further studies be conducted using a larger sample

311 size.

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313 314	Journal: MEDICAL ENGINEERING & PHYSICS	Title of Paper : Evaluation the magnitude of hip joint deformation in subjects with Avascular Necrosis of Hip joint		
315		during walking with and without Scottish Rite Orthosis		
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321 322	declare in any of these categories then this sho	ould be stated.		
323	Conflict of interest			
324		sonal relationships with other people or organisations		
325	, j	work. Examples of potential conflicts of interest include		
326	employment, consultancies, stock ownership, honoraria, paid expert testimony, patent			
327	applications/registrations, and grants or other f	funding.		
328 329	Ethical Approval			
329	Ethical Approval			

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research involving human subjects. Adopted by the 18th World Medical Assembly, Helsinki, Finland,

333 334 335 336 337 338	June 1964, amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975, the 35th World Medical Assembly, Venice, Italy, October 1983, and the 41st World Medical Assembly, Hong Kong, September 1989. You should include information as to whether the work has been approved by the appropriate ethical committees related to the institution(s) in which it was performed and that subjects gave informed consent to the work.
339	Competing Interests
	No competing interests
340 341	Please state any sources of funding for your research
571	No source of funding
342	
343	DOES YOUR STUDY INVOLVE HUMAN SUBJECTS? Please cross out whichever is not
344	applicable.
345	✓ Yes
346	No
347 348 349 350	If your study involves human subjects you MUST have obtained ethical approval. Please state whether Ethical Approval was given, by whom and the relevant Judgement's reference number The authors state that an ethical approval was obtained from Isfahan University of Medical Sciences, Ethical Committee. Moreover, a consent form was signed by the parents of each participant before date collection.
351 352 353 354 355	This information must also be inserted into your manuscript under the acknowledgements section prior to the References.
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