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Dual Mobility Device Reduces The Risk Of Prosthetic Hip Instability For Patients With Degenerated Spine: A Case-Control Study

La dégénérescence du complexe lombo-pelvien influence le risqué de luxation de prothèse totale de hanche: étude cas-témoin

Running title: Spine Degeneration & THA Dislocation

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Ethical review committee: each author certifies that his institution has approved the reporting of these cases, that all investigations were conducted in conformity with ethical principles of research. This manuscript contains a study with human participants, which has been approved by our institutional ethics committee (CLER 2017_CLER-MTP_10-10).

Abstract

Introduction: The pelvic incidence is an anatomical and biomechanical pelvic parameter determining spine sagittal morphology and kinematics. Stiffening of the lumbo-pelvic complex, a result of degeneration, affects the functional cup positioning, putting prosthetic hip patients at risk of instability. The anti-dislocation dual mobility (DM) device may be clinically advantageous by reducing the risk of prosthetic instability for older patients with spine ageing. Our study aims to answer the following questions: 1) is there a relationship between prosthetic hip instability and the standing cup position, 2) is there a relationships between prosthetic hip instability and the pelvic incidence, 3) is there a relationships between prosthetic hip instability and the severity of the spine degeneration? 4) Is the DM cup device an effective option for reducing the risk of prosthetic instability related to spine degeneration?

Hypothesis: There is a relationship between prosthetic hip instability and the standing cup position and pelvic parameters.

Methods: Case-control study on prospectively collected data since 2009. From 1672 conventional total hip replacements (THR – 5.4% dislocation rate) and 1056 DM-THRs (1.1% dislocation rate) performed at our institute since 2009, we created three groups: 33 patients with unstable THR (group 1-case), 41 patients with stable THR (group 2- control), and 42 patients with stable DM-THR (group 3- control). The cup orientation was measured on standing pelvic radiographs and the spino-pelvic parameters were measured on standing EOS™ biplanar images or lateral full spine radiographs.

Results: By comparing patients from group 1 with those of group 2 we found they had similar cup position (57% versus 51% fitting the safe zone, $p=0.58$), higher pelvic incidence (58° versus 51° , $p=0.01$), and more severe spine degeneration (smaller anterior pelvic plane Tilt (2° versus 7° ($p=0.002$)), a larger pelvic incidence – lumbar lordosis mismatch (17° versus 8° ($p=0.005$)), and a higher proportion of spino-sacral angle $< 127^\circ$ (70% versus 43%, ($p=0.02$)). Patients from group 3 had similar cup position, pelvic incidence, and spine degeneration compared to patients from group 1.

Discussion/Conclusion: Patients with spine-hip relation type 2C/D (high pelvic incidence and severe spine degeneration) have an increased risk of instability that is partly compensated for by the use of a DM device. Preoperative screening of patients with abnormal spine-hip relation would improve THR planning and reduce the risk of prosthetic hip instability. The use of a DM device on spine-degenerated elderly patients is probably sound.

Level of evidence: III, case-control study.

Keywords: total hip replacement, instability, spine-hip relation, spine degeneration, pelvic incidence, dual mobility cup

1) Introduction

Instability of modern total hip replacement (THR) represents the first cause of early revision [1–3], but its pathophysiology is yet to be fully understood. To illustrate, several authors found that a large proportion of unstable patients had their acetabular component oriented in the radiographic zone recommended by Lewinnek [4–6], thus suggesting the static component orientation alone is of low value in predicting the risk of instability. This is probably related to the fact that the acetabular orientation is functional, with values for orientation dependent on the highly inter-individually variable lumbo-pelvic kinematics [7,8] and spine-hip relation [9,10]. Following on, the pelvic incidence (PI) is a highly inter-individually variable anatomical and biomechanical pelvic parameter which determines the spine sagittal morphology and kinematics [11]; its relationship with prosthetic hip instability remains unclear [9,12]. Spine degeneration, a frequent cause of abnormal spine-hip relations, has also been linked to the risk of prosthetic hip instability [12–14]. By tending to stiffen the spine with a pelvis that progressively becomes excessively retroverted in the standing position, the process of spine ageing results in a compensatory increased range of hip motion during daily activities of life [9,15] and a poor standing cup position [9,12,16], which both contribute to an increased risk of prosthetic hip instability.

The dual mobility (DM) cup, a recently promoted device, aims to reduce the occurrence of prosthetic hip instability. Compared to traditional cup designs, DM cups have an overall higher tolerance to articular impingement (high mobile liner-neck ratio), a higher jumping distance, and are more constrained [17,18]. Its benefit for spine-degenerated patients remains to be proven.

Our study aims to answer the following questions: 1) is there a relationships between prosthetic hip instability and the standing cup position, 2) is there a relationships between prosthetic hip instability and the pelvic incidence, 3) is there a relationships between prosthetic hip instability and the severity of the spine degeneration? 4) Is the DM cup device an effective option for reducing the risk of prosthetic instability related to spine degeneration? We hypothesized here is a relationship between prosthetic hip instability and the standing cup position and pelvic parameters

2. Methods

2.1 Patients

The study flow chart is illustrated in figure 1. We performed a retrospective case-control study on prospectively collected data since January 2009. We consulted our database in April 2017 in order to identify all patients who suffered from prosthetic instability following a primary hip replacement. Amongst the 1672 conventional THRs and 1056 DM-THRs performed during this time period, 90

(5.4%) and 12 (1.1%) dislocations were recorded, respectively. All patients had EOS™ (Biospace, Paris, France) standing imaging or lateral full spine view preoperatively; THRs were performed through a posterior approach with posterior capsule and external rotator repairs by two senior surgeons (LD, FC); a DM device was used if the patient had a recognised risk factor for instability and/or was greater than 70 years of age. Amongst the 90 unstable THRs, 66 (73%) occurred during the first year, and the dislocation was recurrent in for 62 (69%) of patients. After exclusion of patients with a well-recognized cause for instability (lumbar instrumentation, dementia, traumatic dislocation, abductor mechanism deficiency) and/or incomplete data, we were left with 32 patients who had unexplained instability (group 1 – unstable THR). Two control groups were then generated; one group of 41 patients with a stable THR (group 2) and one group of 41 patients with a stable DM-THR (group 3). Patients from groups 2 and 3 were randomly selected from the cohorts of 1582 stable THRs and 1044 stable DM-THRs, respectively. Demographic data and initial diagnosis for each group are shown in Table 1. This study has been fully approved by our local Ethics Committee: CLER 2017_CLER-MTP_10-10.

2.2 Methods

The cup position (inclination and anteversion) was measured 6 weeks postoperatively on standing pelvic radiographs using Centricity software (GE Healthcare, Ill, USA) (figures 2 and 3). The spino-pelvic parameters (lumbar lordosis (LL), spino-sacral angle (SSA), sagittal vertical axis (SVA) distance, pelvic incidence (PI), pelvic version (PV), sacral slope (SS), anterior pelvic plane tilt (APP Tilt – positive value meaning anterior tilt)) were measured on 6 months postoperative lateral standing EOS™ views as illustrated in the figure 2. The individual spine degenerative status was defined according to published data, with good recognised reliability: sagittal vertical axis distance >50 mm, spino-sacral angle <127°, Pelvic version >0.24*Pelvic incidence, and Pelvic incidence-Lumbar lordosis >15° [19–21].

2.3 Statistical analysis

Continuous variables were expressed using means and standard deviation, and were compared using Student t-test or Wilcoxon rank-sum test. Categorical variables were reported as frequencies and proportions, and were compared using Chi-square or Fisher exact tests. The level of evidence (p value) was set at <0.05. Statistical analysis was performed using SPSS for Windows version 20.0 (SPSS, Chicago, IL).

3. Results

Groups 1 and 2 had similar cup anteversion ($14^{\circ}\pm 7$ versus $13^{\circ}\pm 6$, $p=0.53$), inclination ($47^{\circ}\pm 5$ versus $49^{\circ}\pm 6$, $p=0.13$), and proportion of cup orientation within the recommended safe zone (57%

versus 51%, $p=0.58$). Cup orientations for groups 1 and 2 are shown in figure 3 and table 2.

Group 1 had a larger Pelvic incidence ($58^\circ(\pm 13)$ versus $51^\circ (\pm 11)$, $p=0.01$) and Pelvic version ($18^\circ\pm 12$ versus $13^\circ\pm 9$, $p=0.03$) compared with group 2. Pelvic parameters for groups 1 and 2 are illustrated in table 3.

Group 1 had a smaller anterior pelvic plane tilt (2° versus 7° , $p=0.002$), a larger Pelvic incidence-Lumbar lordosis mismatch (17° versus 8° , $p=0.005$), and a higher proportion of spino-sacral angle $< 127^\circ$ (70% versus 43%, $p=0.02$). Spino-pelvic parameters for groups 1 and 2 are illustrated in table 4.

Cup anteversion ($14^\circ\pm 7$ versus $13^\circ\pm 5$, $p=0.37$), cup inclination ($47^\circ\pm 5$ versus $46^\circ\pm 5$, $p=0.32$), proportion of cup orientation within the recommended safe zone (57% versus 54%, $p=0.8$), pelvic incidence ($58^\circ(\pm 13)$ versus $56^\circ (\pm 12)$, $p=0.49$), pelvic version ($18^\circ\pm 12$ versus $19^\circ\pm 9$, $p=0.95$), and all spino-pelvic parameters were similar between groups 1 and 3. Cup orientation, pelvic and spino-pelvic parameters for groups 1 and 3 are illustrated in tables 2, 3, and 4, respectively.

4. Discussion

Instability represents the first cause of early revision after primary THR. Assessing the influence of the static cup orientation and spino-pelvic parameters on the risk of instability is of importance in gaining a better understanding of the pathophysiology and thus reducing the occurrence. Our main findings are that patients with a spine-hip relation type 2C/D (high Pelvic incidence and severe spine degeneration – Bordeaux classification [9,10]) have an increased risk of instability, which the use of a DM device partially compensates for. We were unable to detect a relationship between standing cup position and risk of prosthetic instability. Our finding is in line with those from Abdel et al. [4], Esposito et al. [5], and Reina et al. [21]. This is probably because other parameters, such as other acetabular orientations (the functional, the static sitting, etc.) [13,15], combined anteversion [22], and the individual spine-hip relation (spine or hips user) [9,10], may be more relevant parameters influencing the prosthetic stability.

Similar to Delesole et al. [12], we found unstable THR patients to have a higher Pelvic incidence. This may be because the Pelvic incidence is an anatomical and biomechanical pelvic parameter which determines the sagittal spine morphology and kinematics [9], thus affecting the risk of prosthetic instability [9,12]. Therefore, the severity of the spine-hip syndrome (determining the risk of prosthetic instability) may be proportional to the value of the Pelvic incidence, as patients switch from being a constitutional “spine user” to an unhabitual new “hip user” [9,10]. To illustrate, when flexing the thighs over the trunk (sitting task), patients with normal Pelvic incidence are likely

to share this motion between their spine and their hips, defined as being a “spine user”. In cases where a stiff degenerated spine has developed, the same task for the same patient would result in a compensatory increased hip flexion (unhabitual “hip user” condition), acting around an abnormally functionally oriented acetabulum [9]. If the patient has a low Pelvic incidence, they would tend to constitutionally be a “hip user”, thus the development of spine degeneration would slightly accentuate their “hip user” condition, moving the patient not far from their constitutional state.

We found that unstable THR patients had more severe spine degeneration compared to stable THR patients. Our findings are in line with those from Delsole et al. [12], Nam et al. [13], and Fessy et al. [14]. This is probably because a degenerated spine is stiffer, with a pelvis excessively posteriorly tilted in the standing position. This is responsible for a poor standing acetabular orientation (abnormally high acetabular anteversion and inclination), potentially compromising the prosthetic stability [9,10]. The risk of prosthetic instability is further accentuated by the compensatory increased range of hip motion used for daily activities of life, which results from spine stiffening [9,15]. Figure 4 illustrates an unstable THR patient affected by severe spine degeneration. Interestingly, we found high PI and severe spine degeneration to be associated with the risk of instability; this combination defines patients with spine-hip relation type 2C/D (Bordeaux classification [9,10]).

We found that stable DM-THR patients (group 3) had similar standing cup position, pelvic incidence, and severity of spine degeneration, but were older. In addition, a sample group of patients had a 5 times lower dislocation rate (1.1% versus 5.4%) compared to unstable THR patients (group 1). This suggests the use of a DM device is probably beneficial in reducing the risk of instability related to spine degeneration. The DM device therefore confirms its status as an anti-dislocation device, which is due to its higher tolerance for articular impingement (high mobile liner-neck ratio), higher jumping distance, and higher constraint, compared to traditional cup designs [17,18]. Therefore when faced with older patients, the use of a DM device is probably a sound option to increase the THR stability and make the surgery safer.

Before interpreting our results, it is important to acknowledge some limitations in our methods. Firstly, the fact that our control groups were not paired may have generated confounding bias. However, as demographics between groups 1 and 2 were similar, and our results for questions 1, 2, and 3 (comparison groups 1 and 2) are in line with published literature, it is likely that this bias did not significantly affect the quality of our results for these questions. Similarly, the fact that patients from group 3 were older than those from groups 1 and 2, a recognised risk factor for prosthetic hip instability, cannot act as a confounding bias to explain the lower rate of instability of patients with DM-THR compared to those with conventional THR (1.1% versus 5.4%, respectively). Secondly, the 57 excluded unstable THR patients (identified cause for instability and/or incomplete

data) may have generated a selection bias, hindering the quality of all our results. However, by only selecting patients with unexplained instability, we have reduced the risk of confounding bias with regards to causes of instability, which has probably contributed to the identification of a relationship between some spino-pelvic parameters and prosthetic instability. Finally, we found similar a radiographic cup orientation between groups 1 and 2, which may be the result of a lack of statistical power. However, as we found unstable THR patients to have, while not significant, a better cup orientation than stable THR patients, it is very likely that the standing radiographic cup orientation is of poor value in predicting the risk of instability. This finding is in line with the conclusion from previously published reports [4,5].

5. Conclusion

Patients with spine-hip relation type 2C/D (high Pelvic incidence and severe spine degeneration) have an increased risk of instability that is partly compensated for by the use of a DM device. Preoperative screening of patients with abnormal spine-hip relation would improve THR planning and reduce the risk of prosthetic hip instability. The use of a DM device on spine-degenerated elderly patients is probably sound.

Conflicts of Interest: none of the authors report a conflict of interest with this study. Apart from this work, CR declares to have been consultant for Medacta. FC is an educational consultant for Zimmer GmbH during the last three years. LD received a research scholarship grant from the French Society of Orthopedic surgery (SOFCOT) in 2013, that is not related to this work.

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Authors' contribution: (1) the conception and design of the study, or acquisition of data, or analysis and interpretation of data, (2) drafting the article or revising it critically for important intellectual content, (3) final approval of the version to be submitted, (4) Statistics, (5) experimentation or surgery performance.

LD: 1 - 2 - 3 - 5

SM: 1 - 2 - 4

CM: 2 - 3

FC: 1 - 2 - 3 - 5

CR: 1 - 2 - 3

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Figures legends:

Figure 1: Study flow-chart

Figure 2: Standing EOS™ lateral view with measured spino-pelvic parameters. Pelvic Incidence (PI), Pelvic Version (PV), Sacral Slope (SS), Spino-sacral angle (SSA), Sacral Vertical Axis (SVA), Lumbar Lordosis (LL), Pelvic Tilt (PT).

Figure 3: A scatter plot showing a similar dispersion of the standing cup inclination and anteversion angles between the 33 unstable THR patients (group 1), the 41 stable THR patients (group 2), and the 41 stable DM-THR patients (group 3).

Figure 4: Standing EOS™ lateral view of a group 1 patient with significant spine degeneration with a compensated sagittal imbalance. Note the excessive pelvic retroversion (Pelvic Version (PV) = 50°, Sacral Slope (SS) = 32°), reduced standing Lumbar Lordosis (LL) (56°), Pelvic Incidence-Lumbar Lordosis mismatch (26°), and excessive anterior projection of the C7 plumb line (Sacral Vertical Axis (SVA) = 97mm) in standing position.

Table 1: Comparison of demographic data and origin of hip osteoarthritis between groups.

*: Significant difference. AVN: Avascular Necrosis of the femoral head, OA: Osteoarthritis. NA: Not

	Group 1	Group 2	Group 3	<i>p (G1 vs G2)</i>	<i>p (G1 vs G3)</i>
Age	67±11	63±8	77±7	0.10	0.01*
Female (%)	63%	53%	66%	0.38	0.78
BMI	27±6	26±3	26±6	0.64	0.37
ASA Score	2.1±0.7	1.8±0.7	2±0.5	0.07	0.56
Prosthetic head diameter	33±2.4	33±2.4	NA	0.73	NA
Non-instrumented spinal surgery	18%	7%	7%	0.15	0.15
reasons for THR					
• AVN	9%	2%	5%	0.17	0.38
• Dysplastic OA	3%	7%	2%	0.41	0.86
• traumatic OA	6%	10%	2%	0.56	0.4
• Primary OA	72%	78%	85%	0.59	0.16

Available

Table 2. Comparison of the standing cup orientation between groups.

	Group 1	Group 2	Group 3	<i>p (G1 vs G2)</i>	<i>p (G1 vs G3)</i>
Cup anteversion (°)	14±7	13±6	13±5	0.53	0.37
Cup inclination (°)	47±5	49±6	46±5	0.13	0.32
% within safe zone:					
• Cup anteversion	81%	87%	90%	0.47	0.27
• Cup inclination	75%	58%	64%	0.11	0.28
• Cup A+I	57%	51%	54%	0,58	0,8

*: Significant difference.

Table 3. Comparison of pelvic parameters between groups.

	Group 1	Group 2	Group 3	<i>p (G1 vs G2)</i>	<i>p (G1 vs G3)</i>
Pelvic Incidence	58±13	51±11	56±12	0.01*	0.49
Sacral Slope	40±8	37±8	37±7	0.29	0.2
Pelvic Version	18±12	13±9	19±9	0.03*	0.95

*: Significant difference.

Table 4. Comparison of spino-pelvic parameters between groups.

	Group 1	Group 2	Group 3	<i>p (G1 vs G2)</i>	<i>p (G1 vs G3)</i>
Anterior Pelvic Plane Tilt	2±8	7±6	3±6	0.002*	0.36
Lumbar Lordosis	41±11	43°±12	41±14	0.47	0.93
Sacral Vertical Axis (mm)	68±64	36±46	70±52	0.02*	0.87
Sacral Vertical Axis >50mm	53%	34%	59%	0.10	0.6
Sacro-spinal angle	122±11	126±12	121±10	0.16	0.61
Sacro-spinal angle < 127°	70%	43%	68%	0.02*	0.76
Pelvic Incidence- Lumbar Lordosis	17±15	8±12	15±14	0.005*	0.61
Pelvic Incidence- Lumbar Lordosis> 15°	60%	29%	55%	0.006*	0.61
Pelvic Version >0.24* Pelvic Incidence	66%	51%	78%	0.18	0.24

*: Significant difference.

1672 primary conventional THA
(database between 2009 and 2017)

1056 primary DM THA
(database between 2009 and 2017)

90 dislocations

12 dislocations

57 patients excluded

8 lumbar instrumentation
6 dementia
4 ASA 4
4 repetitive falls
8 revision surgery
8 obvious implants positioning errors
19 incomplete files

1052 stable
conventional THA

1044 stable
DM THA

Group 1:

33 patients with unexplained
conventional THA instability

Group 2:

41 patients with stable
conventional THA

Group 3:

41 patients with stable
DM THA

Spino-pelvic parameters measurements





