









RADIOGRAPHIC EVALUATION OF OSSEOINTEGRATION OF UNCEMENTED TARGOS® STEMS. A 5-YEAR FOLLOW-UP

AVALIAÇÃO RADIOGRÁFICA DA OSSEOINTEGRAÇÃO DE HASTES NÃO CIMENTADAS TARGOS®. UM SEGUIMENTO DE 5 ANOS

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ABSTRACT

Introduction: Total hip arthroplasty is a widespread treatment and is considered the gold standard in cases of hip osteoarthritis, with high rates of success in improving pain and function when well performed. After five years of follow-up, this study evaluates the osseointegration of uncemented Targos® collared stems in arthroplasties. **Methods:** Observational study of 182 total hip arthroplasties performed in 2014 with Targos® cementless collared femoral stems (Lepine). Bone quality was assessed according to the Dorr scale and osseointegration according to the Engh score. **Results:** The overall mean age was 56.5 years, consisting of 104 men (57.1%) and 103 women (56.6%). The osseointegration rate of the stems (total Engh>0) was 100%. There was no statistical difference between groups concerning age ($p=0.262$), gender ($p=0.463$), primary diagnosis ($p=0.585$), affected side ($p=0.459$), and degree of Dorr ($p=0.857$). **Conclusion:** Targos® cementless collared femoral stems showed excellent osseointegration in all patients evaluated, regardless of age, gender, and preoperative bone quality. Moreover, spot welds observed on preoperative radiographs have the best association with implant osseointegration. **Level of evidence IV, case series.**

Keywords: Hip Arthroplasty. Osseointegration. Femur. Osteoarthritis, Hip.

RESUMO

Introdução: A artroplastia total do quadril é um tratamento amplamente difundido, sendo considerado padrão ouro nos casos de osteoartrose do quadril, com altos índices de sucesso na melhora da dor e função, quando bem realizada. Este estudo avalia a presença de osseointegração de hastes com colar não cimentadas Targos® em artroplastias após cinco anos de seguimento. **Métodos:** Estudo observacional com 182 artroplastias totais de quadril realizadas em 2014 com hastes femorais com colar não cimentadas Targos® (Lepine). A qualidade óssea foi avaliada de acordo com a escala de Dorr e a osseointegração de acordo com o escore de Engh. **Resultados:** A média geral de idade foi de 56,5 anos, sendo 104 homens (57,1%) e 103 mulheres (56,6%). A taxa de osseointegração das hastes (Engh total>0) foi de 100%. Não houve diferença estatística nos grupos quanto à idade ($p=0,262$), sexo ($p=0,463$), diagnóstico primário ($p=0,585$), lado acometido ($p=0,459$) e grau de Dorr ($p=0,857$). **Conclusão:** As hastes femorais com colar não cimentadas Targos® apresentaram excelente osseointegração em todos os pacientes avaliados, independentemente da idade, sexo e qualidade óssea pré-operatória. Além disso, a presença de "spot welds" observados nas radiografias pré-operatórias tem a melhor associação com a osseointegração do implante. **Nível de evidência IV, case series.**

Descritores: Artroplastia de Quadril. Osseointegração. Fêmur. Osteoartrite do Quadril.

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INTRODUCTION

The total hip arthroplasty is a widely widespread treatment, being considered gold standard in cases of hip osteoarthrosis, with high levels of success in pain and function improvement. With the ageing of the population, associated to the global obesity epidemic, degenerative diseases has become increasingly prevalent.¹ In advanced cases, the hip osteoarthrosis can be manifested

with important pain and function limitation, impacting the individual quality of life. Furthermore, the loss years of work and the resources employed to treat this condition result in high costs to the national health system.²

In last years, both surgical technique and implants have evolved, bring less morbidity and a better functional outcome. After increasing number of procedures and improving in cement implantation

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process, with development of centralizers and distal restrictors, several studies with excellent cemented implants survival have been published.^{3,4} At the same time, bone cement implantation syndrome (BCIS) cases has been notified. This syndrome involves several cardiovascular alterations that might occurs during cement introduction in bone medullar canal, ranging from hypotension to acute cardiac insufficiency.⁵ As an alternative to the cemented stems and a way to avoid the BCIS, the cementless femoral stems was developed, based on fixation by osseointegration, obtained through microporosities in the implant and the guarantee of immediate stability ("press fit").⁶

Classically, the cemented stems was indicated for patients with worse bone quality (Dorr C), since the initial implant stability can be deficient in this cases, predisposing the micromovement of the stem and consequent loosening of the femoral implant. However, there are studies that emphasize the presence of osseointegration in cementless femoral stems used in patients with worse bone quality after several years of follow-up (Dorr C).⁷

OBJECTIVES

The primary objective of this study is evaluate the presence of cementless femoral with collar stems osseointegration (Targos®, Groupe Lépine, Genay) in patients submitted to total hip arthroplasty in 2014 by the hip surgery team from an orthopedic hospital. The secondary objective is correlate the individual bone quality, age, gender, and preoperative diagnosis with possible complications related to that implant.

METHODS

This is a transversal observational study with 182 patients submitted to total hip arthroplasty using a cementless femoral with collar steam (Targos® - Lepine) performed in the year of 2014 by the hip surgery team from an orthopedic hospital.

All patients submitted to total hip arthroplasty in the year of 2014 who used the cementless femoral with collar steam (Targos®) collar and were in good clinical condition at the time of the evaluation (walking without support and without limitation for usual activities) were included. The patients with a preoperative complication that difficult the "press fit" evaluation or these that fail to perform the rehab protocol was excluded. These that refuse to sign the participation term also has been excluded. The epidemiologic evaluation has been done by medical records analysis with data on age, gender, follow up period, operated side and initial diagnosis being recorded.

The bone quality evaluation was done by the classic Dorr scale, that considers the bone quality through evaluation of anteroposterior and lateral radiographs of the femur, ranging between a good bone quality (Dorr A), which the patient presents thick cortices in both incidences, intermediate bone quality (Dorr B), which is possible to observe thinning of the posterior cortex and, finally, worse bone quality (Dorr C), which the cortex present thinning, both in anteroposterior and lateral radiographs.

The evaluation of osseointegration was done based on the scale proposed by Engh (Table 1)⁸ which radiographic signs are evaluated in anteroposterior images of the hip, predicting the degree of osteointegration of the porous femoral stems. These signs are: the presence of radiolucency in the porous area, the presence of "spot welds", the presence of radiolucency in the smooth area, the presence of pedestal, the calcar modelling, the stem migration and the particle shedding. Each of these aspects receives a specific value and the final score can vary from -28.5 to +24.5. (Table 1)

The stratification of patients in the original article is done in four groups, in which values bigger than +10, indicate the presence of osseointegration. Values between 0 and +10 suggest osseointegration and

Table 1. Engh's score.

Variables	Category	Score
	Presence >50%	-5
Presence of radiolucency in the porous area (ENGH 1)	Absence	5
	Presence <50%	0
Presence of "spot welds" (ENGH 2)	Presence	5
	Absence	-2,5
	Presence	0
Presence of radiolucency in the smooth area (ENGH 3)	Presence >50%	-3,5
	Absence	5
	Presence <50%	0
Presence of pedestal (ENGH 4)	Unstable	-3,5
	Absence	2
	Stable	0
Calcar modelling (ENGH 5)	Hypertrophic	-4
	Atrophic	3
Stem migration (ENGH 6)	Presence	-5
	Absence	3
	Indefinite	0
Particle shedding (ENGH 7)	Presence	-5
	Absence	1

indicate stable implant. Values between - 10 and 0 indicate failure of osseointegration, however with stem fibrous stabilization, and values less than -10, indicate unstable stem. (Table 1) The patients have been separated in two groups accords to the value obtained by Engh's score, which are: Integration (Engh >10), Suspected Osseointegration (0<Engh≤10) and Non-integration (Engh<0).

All patients were submitted to the same institutional protocol of physical therapy analgesia: orthostasis and gait training with partial load protected by a walker, since the first day of post-op, maintaining progressive partial load until the sixth week of post-op and full load after this time. Activities without jumps or running were aloud from the third week of post-op, according to the patients tolerance. The ways of surgical access were the Hardinge's side way and Moore's posterior way.

The assumptions of normal data distribution and homogeneity of variances were checked for continual variables by Kolmogorov-Smirnov test and Levene test. The comparison between the groups that presented *Integration* (Score ENGH >10), *Suspected Integration* (Score ENGH ≤ 10) and *Non-integration* (Engh<0), were done by T Test of Student or U Test of Mann Whitney, for continual variables and Chi-square test, for categorical variables. The significant differences related to the comparisons between proportions were identified on contingency charts through the analysis of standardized residuals (under -2 or more than 2).⁹

The variables that presented significant differences between *Integration* and *Suspected Integration* groups were analyzed by models of Binary Logistic Regression to test the influence of the patients characterization parameters and ENGH's score subitems, about bone integration. Categorical variable with more than two levels of comparison, were treated as dummy variable in these models. The effect of each variable for the prediction of bone integration were presented through the odds ratios (OR) and breaks with 95% of trust (IC 95%). All the analyses were conducted in the PASW software statistics 18.0 (SPSS Inc., Chicago, USA), adopting significance level of 5% (p< 0.05).

This study was approved by the hospital ethics committee.

RESULTS

Two hundred total hip arthroplasties which used cementless femoral with collar stem (Targos® - Lepine) were initially selected. Among the 200 selected cases, 18 patients were excluded because a perioperative complication that could difficult the implant “press fit” evaluation or the accomplishment of the rehab protocol (15 intraoperative femur fractures, 2 nerve injuries, 1 perioperative dislocation). A total of 182 patients were considered for analysis. The mean age found was 56.5 years, with a male majority (57.1%). The primary osteoarthritis was the most prevalent diagnosis in the sample (56.6%), followed by secondary causes of osteoarthritis. None of the cases have negative value in Engh’s score. There was no statistical difference between bone *Integration* and *Suspected Integration* groups about age, gender, diagnosis, affected member and Door’s rating ($p > 0.05$). (Table 2) The integration index of the implants was 100% (Engh total > 0).

When we considered each criteria of the Engh score (Table 3), we could observe that *Integration* group presented bigger proportion of patients with absence of radiolucency in stem porous area (ENGH 1) in comparison to bone *Suspected Integration* group (52.6% vs. 25.5% - $p = 0.001$). About the “spot welds” (ENGH 2), *Integration* group presented less proportion of patients with absence of this signal in comparison to *Suspected Integration* group (3.0% vs. 40.4%, standard waste = 5.4 - $p < 0.001$).

The ENGH 3 criteria (radiolucency in stem flat area) was adapted to our stem model, once that the Targos® stem doesn’t present flat area. Therefore, we evaluated radiolucency in its diaphyseal area. It has been observed bigger absence of radiolucency in *Integration* group (39.3% vs. 10.6% - $p < 0.001$, standard waste = -2.6).

No statistical difference between bone *Integration* and *Suspected Integration* groups about radiographic finding of pedestal (ENGH 4) and the presence of metallic particles (ENGH 7) was observed. Finally, the *Integration* group presented a lower calcar hypertrophy proportion (ENGH 5) and stem migration (ENGH 6) in comparison to *Suspected Integration* group (1.5% vs. 14.9%, $p = 0.001$, standard waste = 3.1 and 0.7% vs. 10.6%, $p = 0.003$, standard waste = 2.8).

The binary logistic regression model 1 was capable to predict correctly *Integration* or *Suspected Integration* in 87.2% and 89.1% of the patients, from the presence of “spot welds” (ENGH 2). Patients that obtained maximum score in this criteria, presented 55.9 times more chances of bone integration in comparison to

patients that recorded the lower score. From the obtained record by ENGH 2, it was possible to explain 59.2% (r^2 -Nagelkerke), from the variance related to the patients rating in *Integration* or *Suspected Integration* groups. (Table 4)

DISCUSSION

Comparing our studies with the studies found in literature, the average age, more prevalent gender and initial diagnosis, most of studies show male prevalence, with average age around 60 years old, having primary osteoarthritis as main diagnosis.¹⁰⁻¹⁴ However, it is also possible to observe studies with female prevalence with initial diagnosis of dysplasia and lower average age (50 years old).¹⁵⁻¹⁷ Among the evaluated groups, there was no statistical difference of femoral stem osseointegration about the age ($p = 0.262$), gender ($p = 0.463$), initial diagnosis ($p = 0.585$) and Dorr’s rating ($p = 0.857$). All the analyzed patients obtained > 0 score in Engh’s rating, which can be interpreted as absence of osseointegration radiologic failure

Table 3. Partial and total score ENGH.

Items	Integration (n = 182)		Suspected Integration (n = 18)		P-value
	No.	(%)	No.	(%)	
ENGH 1 [No. (%)]					
-5	0	(0)	0	(0)	0.001
0	64	(47.4)	35	(74.5)	
5	71	(52.6)	12	(25.5)	
ENGH 2 [No. (%)]					
-2,5	4	(3.0)	19	(40.4)	< 0.001
0	14	(10.4)	23	(48.9)	
5	117	(86.7)	5	(10.6)	
ENGH 3 [No. (%)]					
-3,5	14	(10.4)	0	(0)	< 0.001
0	68	(50.4)	42	(89.4)	
5	53	(39.3)	5	(10.6)	
ENGH 4 [No. (%)]					
-3,5	1	(0.7)	3	(6.4)	0.069
0	65	(48.1)	23	(48.9)	
2,5	69	(51.1)	21	(44.7)	
ENGH 5 [No. (%)]					
-4	2	(1.5)	7	(14.9)	0.001
3	133	(98.5)	40	(85.1)	
ENGH 6 [No. (%)]					
-5	1	(0.7)	1	(2.1)	0.003
0	1	(0.7)	5	(10.6)	
5	133	(98.5)	41	(87.2)	
ENGH 7 [No. (%)]					
1	135	(100)	47	(100)	-----
5	0	(0)	0	(0)	
ENGH Total [average (interquartile range)] (score)	15	(12 a 22)	9	(7 a 10)	< 0.001

Table 2. Patients characteristics.

Variables	Integration (n = 135)		Suspected Integration (n = 47)		p-value
	No.	(%)	No.	(%)	
Age [average (standard deviation)] (years)	55		58		0.262
Gender					
Woman	60	(44.4)	18	(38.3)	0.463
Man	75	(55.6)	29	(61.7)	
Diagnosis [No. (%)]					
Primary osteoarthritis	78	(57.8)	25	(53.2)	0.585
Other	57	(42.2)	22	(46.8)	
Affected member [No. (%)]					
Right	72	(53.3)	28	(59.6)	0.459
Left	63	(46.7)	19	(40.4)	
DORR's rating [No. (%)]					
A	95	(70.4)	33	(70.2)	0.857
B	34	(25.2)	11	(23.4)	
C	6	(4.4)	3	(6.4)	

Table 4. Model of logistic regression for prediction of bone integration.

Variables	B	P-Value	OR	IC 95% (OR)	r ²
Model 1					
ENGH 2 (score 5) ^a	4.0	< 0.001	56.0	19.4 a 161.3	0.592
Constant	-3.1	< 0.001		-----	

^a Reference to obtaining a score 5 in ENGH 2. B = angular coefficient. OR = Odds ratio that indicates the likelihood of bone Integration from the occurrence of the reference predictor. IC 95% = range with 95% of trust. r² = Variance explained according to Nagelkerke.

of the implants. It is important to notice, that there was no statistical difference between groups about the individual's previous bone quality, evaluated by Dorr's scale. Therefore, the individual's previous bone quality did not interfere in a statistically significant way with the osteointegration of cementless femoral stems with Targos® collar, considering that, in this study, the failure tax of the implants osseointegration was 0%. This conclusion is in agreement with a large part of the literature, which confirms that most of the cementless femoral implants, integrate with the bone and that the individual's previous bone quality doesn't have a direct relationship with the failure in this process, although some studies have been done in specific populations, such as individuals with dysplasia sequelae or with rheumatoid arthritis, or differentiated implants.¹⁸⁻²² Other authors have investigated the capacity of osseointegration of cementless femoral stems and obtained similar outcome. Casper et al.²³ observed that review tax of Accolade® type femoral component, conical and with total proximal porosity, in an average follow-up of 7.6 years, it was only 0.6%, considering aseptic loosening. Froimson et al.²⁴ reported that all the 96 arthroplasties done with Corail® type stem, conical and with metaphyseal micro porosity, presented radiographic signs of osseointegration after follow-up of 10 years. Finally, McLaughlin and Lee²⁵ reported that after an average follow-up of 20 years, 99% of 65 arthroplasties done with Taperloc® type femoral component, conical and with proximal porosity, presented osseointegration. It was possible to observe that the presence of radiolucency in the stem porous and diaphyseal areas and the presence of "spot welds" were the most important relate to the score of Integration and Suspected Integration group, what we understand as the most

important criteria to be observed in radiographs. In a similar way, as expected, it was observed that the Integration group obtained a lower proportion of individuals with negative score in ENGH 5 and ENGH 6 rating, which means that the integrated stems don't present bone foot remodeling and had no subsidence.

Those outcomes confirm the applicability of Engh's score to predict the presence of radiological osseointegration of cementless femoral implants. The isolated evaluation of "spot welds" presence, allow us to infer that this criterion, when present, it the most reliable to evaluate an appropriate osseointegration, among the other Engh's criteria. For the detachment of metallic particles, both groups present all patients with maximum positive score. This finding can be explained by the stem type used in this study, that has a peculiar porous structure, with extremely small porosities and all over the surface, preventing particles loosening.

It must be pointed that the patients don't present any difference about Integration and Suspected Integration subgroups, since patients were selected without complaints of pain in the lame femoral joint and who don't have functional limitations for their daily activities.

CONCLUSION

Our study allows to conclude that the non-cemented femoral stems with Targos® have a excellent outcome in a follow-up of 5 years, regardless of age, gender, initial diagnosis and bone quality, with 100% survival rate. It is also possible to affirm that the presence of "spot welds" in a postoperative control radiography suggests osseointegration in more than 85% of the cases. Long term studies are needed to confirm this implant survival.

AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to the development of the manuscript. HSM and JGLC were the main contributors in writing the manuscript. LE, BAR and HMCG performed the surgery, followed the patients and gathered clinical data. JHN evaluated the data from the statistical analysis. ATC performed the bibliographic research, revised the manuscript and contributed to the intellectual concept of the study.

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