

CAN BE THE CEMENT AUGMENTATION AN IMPROVEMENT METHOD OF PREVENTING HIP FRACTURES IN OSTEOPOROTIC PATIENTS?

Pode ser a cimentoplastia um método aprimorado para a prevenção de fraturas do quadril em pacientes osteoporóticos?

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ABSTRACT

INTRODUCTION: The population around the world is aging. With this, there will be an increased incidence of fractures due to osteoporosis of the hip and this will be a serious global health problem. A World Health Organization (WHO) estimate suggests that the incidence of hip osteoporotic fractures worldwide will triple by 2050. **OBJECTIVE:** To present, through a literature review, the main results of the femoral reinforcement, a technique described by scientific articles, with the potential to increase the proximal femoral load for the occurrence of fractures, whether using polymethylmethacrylate (PMMA), phosphate cement calcium (CPC), elastomers and metal implants. **METHODS:** Through electronic search in databases PubMed, Latin American and Caribbean Center of Health Information Information (Bireme), Coordination for the Improvement of Higher Education Personnel (Capes), Scientific Electronic Library Online (SciELO), Google Scholar And Cochrane, using the terms *cementoplasty* and *femoroplasty*, the studies were selected according to a specific inclusion criterion, describing the main findings of the biomechanical results, type of study and material used to perform the femoral reinforcement. **RESULTS:** Of the 15 articles analyzed, 14 were experimental analyzes and one was a clinical trial, seven studies used PMMA, two used CPC, four elastomers and two metal implants, 13 of them showed favorable Newton load (N) results for the fracture hip. **CONCLUSION:** Most of the studies on femoral reinforcement is experimental, and mostly used the PMMA, presenting an increase in the load in N for fracture occurrence.

KEYWORDS: polymethyl methacrylate; hip fractures; osteoporosis; hip.

RESUMO

INTRODUÇÃO: A população em todo o mundo está envelhecendo. Com isso, haverá aumento da incidência de fraturas por osteoporose do quadril e esse será um grave problema de saúde mundial. Uma previsão da Organização Mundial de Saúde (OMS) mostra que a incidência de fraturas osteoporóticas do quadril em todo o mundo triplicará até o ano 2050. **OBJETIVO:** Apresentar por meio de revisão da literatura os principais resultados do reforço femoral, técnica descrita por artigos científicos, com potencial de incrementar a carga do fêmur proximal para a ocorrência de fraturas, seja com uso de polimetilmetacrilato (PMMA), cimento fosfato de cálcio (CPC), elastômeros ou implantes metálicos. **MÉTODOS:** Por meio de busca eletrônica nas bases de dados PubMed, Latin American and Caribbean Center of Health Science Information (Bireme), Coordination for the Improvement of Higher Education Personnel (Capes), Scientific Electronic Library Online (SciELO), Google Scholar and Cochrane, utilizando os termos *Cementoplasty* e *femoroplasty*, foram selecionados os trabalhos respeitando um critério de inclusão específico, descrevendo os principais achados dos resultados biomecânicos, o tipo de estudo e o material utilizado na realização do reforço femoral. **RESULTADOS:** Dos 15 artigos analisados, 14 são análises experimentais e um é ensaio clínico, sete estudos utilizaram PMMA, dois usaram CPC, quatro elastômeros e dois implantes metálicos, 13 deles mostram resultados favoráveis na carga em Newton (N) para a ocorrência da fratura do quadril. **CONCLUSÃO:** A maioria dos estudos sobre reforço femoral é experimental e em sua maioria utilizou o PMMA, apresentando incremento da carga em N para a ocorrência de fratura.

PALAVRAS-CHAVE: polimetil metacrilato; fraturas do quadril; osteoporose; quadril.

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Received on: 09/30/2016. Accepted on: 11/08/2016

DOI: 10.5327/Z2447-211520171600064

INTRODUCTION

Twenty-two million women and 5.5 million men in the European Union (EU) were diagnosed with osteoporosis in 2010. There were 3.5 million new fractures due to osteoporosis occurring that year, and 610,000 of them were fractures in the hip region.¹

The World Health Organization (WHO) predicts that the incidence of osteoporotic fractures of the hip will triple by 2050.^{1,2} In the population under 65 years old, the incidence of femoral neck fractures is two to four cases per 10,000 inhabitants. However, the incidence increases in the population above 70 years old, being of 28/10,000 in men and 64/10,000 in women. It is estimated that in 2050 there will occur 6.3 million fractures of the hip due to osteoporosis, a number three times greater than the current one, half of those fractures will happen only in Asia.²

This situation is very concerning, not just in the health point of view, but also economically, since the treatment of these fractures is a very expensive procedure, combining to antibiotics, analgesics and time of hospitalization, and still the mortality rates are very high. The annual cost in the United States related to the treatment of osteoporotic fractures is US\$ 20 billion, and the contribution of hip fractures in this cost is above 60%.¹⁻³

About 1.5% of all hospital beds in Europe are occupied by patients being treated for osteoporotic fractures, and the cost for treating these fractures is € 37 billion, being expected to increase 25% by 2025.¹

Mortality rate due to the fracture of the proximal femur out of osteoporosis reaches 30% in the first year after surgery. Patients with this type of fracture are at risk of up to 30% to suffer a new fracture in the contralateral hip within two years after the first fracture, and this rate may increase after five years.⁴ In cases of non-simultaneous contralateral hip fracture, the mortality rate can reach 64% in men and 58% in women.⁵

Since the hip fracture is, of all osteoporotic fractures, the one with highest morbidity and mortality and the highest cost, we need to find associations, or even new methods to prevent with more efficiency this type of fracture.^{1,3-5}

Several methods have been applied in order to reduce the risk of fracture of the proximal femoral end due to osteoporosis, such as home care, multidisciplinary treatments, and use of hip protectors, although the most frequent measure is the use of medicines.^{1,6}

Care measures for patients with osteoporosis in the EU have had very significant results, with multidisciplinary techniques that are capable of reducing about 80% occurrences of new fractures. However, when we look at the effectiveness of these interventions in preventing new fractures in the hip region, the figure is approximately 40%. This same number is found regarding the use of medicines to prevent hip fractures, besides the undesirable consequences of its use, as significant

side effects, adverse effects in long-term use, contraindications and high cost, happening in 50% of the patients.^{3,6,7}

Analogous to vertebroplasty, cement-augmentation of the proximal femur, femoroplasty, can reinforce osteoporotic bones.⁸ This procedure is still not yet very much used and stimulated by orthopedic society, but most of the studies about this method are *in vitro*, and there it has proven to reduce the risk of hip fractures, and should not be underestimated.

Cement augmentation is described in various ways, using several products, but the experimental uses of polymethylmethacrylate (PMMA) and calcium phosphate cement (CPC) have been most frequently studied.^{8,9}

In consideration to the importance of this subject, the authors present a literature review related to prevention of the fractures of the hip, presenting data in order to encourage the possibility of better results with this scientific development and ensuring this big step in the change of the evolution of fractures of the proximal femur in elderly patients.

METHODS

Femoral augmentation is a surgical procedure, minimally invasive, performed percutaneously by an incision of about 1 cm in length in the lateral region of the patient's thigh. Through this incision, a metallic guide is inserted on the lateral cortex of the femur, in direction of the femoral head, through the femoral calcar, region in which the main forces of compression of the proximal femur are concentrated. This wire, introduced with fluoroscopy assistance, serves as a guide for introduction of the other instrumentals, like drills and cannulas. After the introduction of a drill, preparing the intraosseous space to be filled by "bone substitutes", a cannula is inserted through the same incision side, following the path of metallic wire and drill, by pressurizing with a syringe the prepared space which is refilled by femoral augmentation, replacing the bone portion with compromised quality by other substances and increasing the strength of the proximal femur.

The calcium phosphate based bone cements are ceramic materials, as the PMMA are acrylic materials, both having good biocompatibility due to their chemical composition similar to the bone and bioactivity, promoting osteoconduction. With these characteristics, the use of these materials as filling or bone implants is possible. The bone cements are materials consisting of a powder and a liquid which, upon mixing, form a paste that hardens spontaneously at room or body temperature.

All published articles, between the years 2004 and 2014, that were related to the prevention of osteoporotic fractures of the hip (femoral neck and intertrochanteric region) were selected from the following databases: PubMed, Latin American and Caribbean Center of Health Science

Information (Bireme), Coordination for the Improvement of Higher Education Personnel (Capes), Scientific Electronic Library Online (SciELO), Google Scholar and Cochrane.

By using the words *cementoplasty* and *femoroplasty* in each of the databases, we selected all of the files and selected the papers according to the inclusion criteria.

To match the inclusion criteria, only the articles that reported or analyzed exclusively human bone reinforcement, without any focal pathology and whichever methodology or material that was used as augmentation, were selected.

After the selection of the articles included, we analyzed the specific data: study type, material used in the femoral reinforcement and the obtained results of the procedures.

RESULTS

The electronic database search showed 1,828 articles, but 1,813 of them were excluded of our study for not matching the inclusion criteria and the 15 remaining articles were selected for analysis (Table 1).

For the study type results, we found 14 experimental studies and only one clinical trial related to the subject in consideration.

The materials used in all experimental studies were cadaveric femurs with mineral density compatible with osteoporotic bones, and the augments were of many types: PMMA (seven studies),¹⁰⁻¹⁶ CPC (two studies),^{17,18} elastomers (four studies),¹⁹⁻²² metal implants (two studies).^{23,24} The metal implants were of two types, a titanium screw and a steel spiral shaped implant.

Two of the articles showed unsatisfactory results: it was used PMMA in both of them, the rise of temperature during the induration of the PMMA was indicated as a possibility of thermal injury to the bone tissue and possibly been the cause of the failure. Although one of these studies found an

increase of resistance to the possibility of the fracture, using a mean volume of 36 mL,¹⁵ the other one found no enhancement of mechanical strength, with a mean volume of 15 mL.¹⁶

The other papers, with favorable results, had PMMA, elastomers, CPC and metal implants as material for the femoral augmentation.

According to all the five studies using PMMA, it was proved an improvement in mechanical strength to the occurrence of the fractures. As the thought of the thermal injury occurring to the bone tissue in the indurating process, it was found that the optimization of the amount of volume of PMMA could reduce the rise of temperature and consequently shorten the possibility of a thermal lesion.¹⁷⁻²⁰ One of them even described the optimized volume, 6 mL, and the best positioning for the finite element use for the optimal mechanical result.¹⁴

The studies using elastomers showed an enhancement of the bone strength against the fracture occurrence. When it occurred, it happened with a minor deviation and no temperature rise was detected, avoiding consequent tissue damage.²²⁻²⁴ The use of silicone showed equivalent result to the CPC group, with minimal deviation after fracture, preserving the “Caput-Collum-Diaphysis” angle.²⁵ In case of fracture occurrence, difficulties weren't found for elastomer removal neither treatment of the fracture with local osteosynthesis.

Using the CPC, brought a lower temperature rise in both studies, as they exposed as results the increase of mechanical resistance and a reduced possibility of thermal injury to the bone tissue.^{21,23}

Both of the metal implants studies showed favorable results,^{26,27} even though one of them was a clinical trial with short term follow up and with a small number of patients included, lowering its evidence value, putting in doubt its favorable result.²⁸

Table 1 Apresentação do tipo de estudo, método de avaliação da densidade mineral óssea (DMO), material utilizado no reforço femoral e principais achados dos estudos analisados.

Study	Study type	Evaluation method DMO	Material used	Outcomes
Heini et al., ¹⁵ 2004	Exp	DXA-scan	PMMA	Volumes of 28-41 mL of cement (mean, 36 mL). The increase of surface temperature at the femoral neck ranged from 18.4° to 29.8°C. For the single limb stance configurations, the peak fracture load was increased by 21%, and for the simulated fall on the hip by 82%. The corresponding values for energy absorption were +48%; and +188% respectively.
Beckmann et al., ¹⁷ 2011	Exp	DXA-scan	PMMA	The energy applied until fracture could be significantly increased by two of the four methods by 160 and 164%, respectively. The peak load to failure was significantly increased by three of the methods by 23, 35 and 12%, respectively.

Continue...

Table 1 Continuation.

Study	Study type	Evaluation method DMO	Material used	Outcomes
Fliri et al., ¹⁸ 2013	Exp	QCT	PMMA	Augmented samples absorbed 124% more energy until fracture compared to their controls. No significant differences were found between the two groups for fracture load, yield load and stiffness.
Sutter et al., ¹⁶ 2010	Exp	DXA-scan	PMMA	It was found that femoroplasty with 15 mL of cement did not significantly increase stiffness, yield energy, yield load, ultimate load, or ultimate energy relative to paired controls.
Sutter et al., ²⁰ 2010	Exp	DXA-scan	PMMA	Femoroplasty significantly increased yield load (22.0%), ultimate load (37.3%), yield energy (79.6%), and ultimate energy (154%) relative to matched controls, but did not significantly change stiffness (-10.9%).
Basafa et al., ⁹ 2015	Exp	DXA-scan	PMMA	An average of 9.5 (+/-1.7) mL of cement was injected in the augmented set. Augmentation significantly increased the yield load by 33%, maximum load by 30%, yield energy by 118%, and maximum energy by 94% relative to the non-augmented controls.
Basafa et al., ¹⁹ 2015	Exp	DXA-scan	PMMA	Simulations showed that the yield load can be significantly increased by more than 30%, using only 9 mL of bone cement.
Strauss et al., ²¹ 2007	Exp	DXA-scan	CPC	Calcium phosphate cement augmentation of the lag screw defect significantly increased the mean femoral neck failure strength compared to specimens in which the defect was left untreated.
Beckmann et al., ²² 2007	Exp	DXA-scan	CPC	Cement could be injected easily, with a moderate temperature rise. A positive correlation between BMD and fracture load and a significant increase in fracture load (+43%) of the augmented femora compared to their native controls, as well as a significant increase in energy-to-failure (+187%) was found. Osteosynthesis was possible in cement-augmented.
Van et al., ²⁹ 2009	Exp	DXA-scan	Elastomer	Fracture loads were approximately 10% lower in the treated group (P = 0.304). Forces needed to dislocate the proximal femur fractures did not significantly differ in both groups nor did the fracture type and AO-classification. All treated femurs showed complete reposition according to Caput-Collum-Diaphysis angle after dislocation <i>versus</i> only two of the controls (P < 0.001).
Van et al., ³⁰ 2011	Exp	DXA-scan	Elastomer	There was no significant difference in fracture load between controls and treated femora for group A and group B. In group A the mean displacement was 35° for the control femora and 3° in the treated femora. In group B the mean displacement was 38° for the controls and 8° for the treated femora.
Van et al., ²⁵ 2012	Exp.	DXA-scan	Elastomer	The mean failure load was 2,709 N. The number of completed cycles until failure was 60. The mean translation during maximum loading was 5.25 mm. At 1,500 N the extension was 3.16 mm.
Schaasberg et al., ²⁶ 2014	Exp	DXA-scan	Elastomer	The mean time to perform osteosynthesis was 20 (6) minutes in the control-group and 19 (5) minutes in the elastomer femoroplasty-group. During osteosynthesis of the fractured hip in the elastomer femoroplasty-group, no difficulties including the need for additional instruments to remove elastomer from the proximal femur were recorded. Postoperative energy-to-failure load was similar in the control-group and the elastomer femoroplasty-group.
Springorum et al., ²⁷ 2014	Exp	QCT	Steel spiral	The peak load to failure was significantly higher in the steel spiral group and in the cemented group compared with the intra individual controls. The peak load to failure showed a median of 3,167 N in the spiral group and 2,485 N in the spiral control group. The peak load to failure in the cemented group was 3,698 N compared with 2,763 N in the cement control group.
Giannini et al., ²⁸ 2011	Clinic trial	DXA scan	Titanium tubular screw with a coated hydroxyapatite thread	In the prospective randomized clinical with 67 patients, 34 in the control group and 33 in the reinforcement group (screw), after 16 months follow-up, No contralateral FNF* occurred in either group. Twelve patients reported one or more falls and in four cases a new non-femoral fragility fracture occurred: two in group A (one wrist and one vertebral) and two in group B (two vertebral fractures).

Exp: experimental; DXA-scan: dual energy X-ray absorptiometry; QCT: quantitative computed tomography; PMMA: polymethylmethacrylate; CPC: calcium phosphate cement; FNF: femoral neck fracture; BMD: bone mineral density; AO: Arbeitsgemeinschaft für Osteosynthesefragen.

DISCUSSION

Bone reinforcement for the hip is already present in literature descriptions for preventing fractures in focal neoplasia,^{29,30} however its use in order to prevent osteoporotic fractures require clinical trials with good levels of evidence in order to validate its results, because, even with statistically validated proves of improvement in mechanical strength, most of the published articles are experimental studies.

The analysis of studies using PMMA for femoral reinforcement showed the necessity of an increased peak load to the occurrence of a fracture in values up to 33%, using augmentation volumes ranged from 6 to 40 mL. The authors using a lower volume of PMMA intended to decrease the thermal lesion, but, in those cases, they determined an optimization of the augmentation location in the proximal femur. As negative possible outcomes, most of them described the possibility of thermal injury, a more difficult surgery for treatment in case of fracture occurrence and a chance of happening different patterns, more complex or unusual, of fracture due to the local density change.¹⁵⁻²⁰

The results of studies using the CPC showed an increase in the peak loading to fracture occurrence in values ranging from 21 to 43%, but the augmentation volumes used of such substance weren't described, but observing the radiography images of their articles we noted that the one with best results showed a complete filling of the proximal femur, a questionable fact for its application *in vivo*. There was no significant rise of temperature during polymerization of this product, as it was not observed description of optimization

in their positioning. It was not found a rise in difficulty for the treatment with osteosynthesis material in cases of fracture occurrence.^{21,22}

The studies using elastomers described the need of cavity expanders for its intraosseous introduction, and there was no description of the volume used. However, observing the radiographs shown in the articles, there was a tendency to fill the entire proximal femur. There is also no description of temperature rise, since there was no polymerization in this process. The results showed no improvement of peak loading levels, although there was only minimized deviation of the fracture, comparing to the control group.²³⁻²⁶

The presentation of these results is very important to expose the need of information to develop future clinical trials, so that these results can be validated in experimental analysis.

CONCLUSION

The use of femoral reinforcement to prevent osteoporotic fractures has literary description, in most cases, exposed as experimental studies. They show a mechanical improvement of the bone for the occurrence of fractures, and this fact makes possible, and necessary, the realization of studies with better levels of evidence.

By the analysis of the most recent and subject related publications, the femoral augmentation is a successful method of preventing hip fractures in osteoporotic patients, and can be considered as a future improvement of this type of fracture prevention.

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