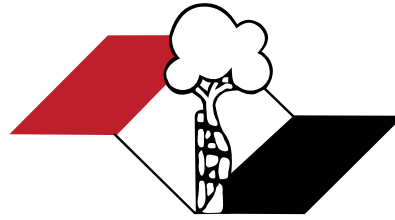


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(Reviewed January 2016)

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Type of Article	Abstract	Number of words	References	Figures	Tables	Maximum number of authors allowed
Original	Structured, up to 200 words	2,500 Excluding abstract, references, tables and figures	20	10	6	6
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Editorial*	No abstract	500	0	0	0	1

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The generic names should be used for all drugs. The drugs can be referred to by their trade name, however, the manufacturer's name, city and country or electronic address should be stated in brackets in the Materials and Methods section.

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Link the conclusions with the goals of the study, but avoid statements and conclusions that are not supported by the data, in particular the distinction between clinical and statistical relevance. Avoid making statements on economic benefits and costs, unless the manuscript includes data and appropriate economic analysis. Avoid priority claim ("this is the first study of ...") or refer to work that has not yet been completed.

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Levels of Evidence for Primary Research Question^a

(This chart was adapted from material published by the Centre for Evidence-Based Medicine, Oxford, UK.
For more information, please visit www.cebm.net.)

Types of study				
Level	Therapeutic Studies Investigating the Results of Treatment	Prognostic Studies – Investigating the Effect of a Patient Characteristic on the Outcome of Disease	Diagnostic Studies – Investigating a Diagnostic Test	Economic and Decision Analyses – Developing an Economic or Decision Model
I	High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals	High quality prospective study ^d (all patients were enrolled at the same point in their disease with ≥80% of enrolled patients)	Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard)	Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses
	Systematic review ^b of Level RCTs (and study results were homogenous ^c)	Systematic review ^b of Level I studies	Systematic review ^b of Level I studies	Systematic review ^b of Level I studies
II	Lesser quality RCT (eg, < 80% followup, no blinding, or improper randomization)	Retrospective ^f study	Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard)	Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses
	Prospective ^d comparative study ^e	Untreated controls from an RCT	Systematic review ^b of Level II studies	Systematic review ^b of Level II studies
	Systematic review ^b of Level II studies or Level I studies with inconsistent results	Lesser quality prospective study (eg, patients enrolled at different points in their disease or <80% followup)		
		Systematic review ^b of Level II studies		
III	Case control study ^g	Case control study ^g	Study of non consecutive patients; without consistently applied reference "gold" standard	Analyses based on limited alternatives and costs; and poor estimates
	Retrospective ^f comparative study ^e		Systematic review ^b of Level III studies	Systematic review ^b of Level III studies
	Systematic review ^b of Level III studies		Case-control study	
			Poor reference standard	
IV	Case series ^h	Case series		Analyses with no sensitivity analyses
V	Expert opinion	Expert opinion	Expert opinion	Expert opinion

^a A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.

^b A combination of results from two or more prior studies.

^c Studies provided consistent results.

^d Study was started before the first patient enrolled.

^e Patients treated one way (eg, cemented hip arthroplasty) compared with a group of patients treated in another way (eg, uncemented hip arthroplasty) at the same institution.

^f The study was started after the first patient enrolled.

^g Patients identified for the study based on their outcome, called "cases" eg, failed total arthroplasty, are compared with patients who did not have outcome, called "controls" eg, successful total hip arthroplasty.

^h Patients treated one way with no comparison group of patients treated in another way.

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PONSETI METHOD IN BRAZIL: FIRST TEN YEARS OF A CLUBFOOT WEBSITE – USERS PROFILE

MÉTODO PONSETI NO BRASIL: 10 ANOS DE UM SITE SOBRE PÉ TORTO – PERFIL DE USUÁRIOS

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ABSTRACT

Objective: To analyze the profiles of the individuals who access the website regarding congenital clubfoot (CC) information and the first ten years of Ponseti method implementation in Brazil. **Methods:** This is a retrospective documentary study, with quantitative database analysis, from 2002 to 2012. Parents or caregivers completed a semi-structured questionnaire regarding the main difficulties encountered, the search for different professionals in the area, and what were the main questions the reader might have when searching on a technical website. **Results:** In total, 94% of participants had a family member or acquaintance with CC, most participants were women (74%), higher education level (40%), married (75%), income above one minimum wage (80%), working in administrative positions (21%), and living in the urban area (99%). Of the participants, 44% sought three or more physicians at the beginning of treatment, and an average of 77% of the participants used health insurance or a private physician. **Conclusion:** The participants' profile regarding CC is composed of women, married, living in urban areas, predominantly from Southeastern Brazil, higher education level, with income above 1.5 minimum wages, and who were treating their children with a private physician. **Level of Evidence II, Retrospective study.**

Keywords: Clubfoot. Internet. Family. Information.

RESUMO

Objetivo: Analisar o perfil de indivíduos que acessam o site de informações sobre o pé torto congênito (PTC) e o tratamento do Método Ponseti nos primeiros dez anos da implantação do método no Brasil. **Métodos:** Trata-se de um estudo retrospectivo com análise de bases de dados, de caráter quantitativo, de 2002 a 2012. Aplicou-se um questionário semiestruturado que abordou as dificuldades encontradas, busca por diferentes profissionais e quais eram as principais dúvidas. **Resultados:** dos respondentes, 94% tinham algum familiar com PTC, os respondentes foram 74% do sexo feminino, 40% com ensino superior, 75% casados(as), 80% com renda acima de um salário mínimo, 21% de cargos administrativos e 99% residentes em área urbana. Dos respondentes, 44% procuraram três ou mais médicos no início do tratamento, e, em média, 77% fizeram o tratamento usando convênio médico ou usando médico particular. **Conclusão:** O perfil de indivíduos que acessam o site de informações sobre PTC e o tratamento do Método Ponseti é composto de respondentes do sexo feminino, casadas, residentes em área urbana, predominantemente do sudeste do Brasil, com ensino superior, com renda acima de 1,5 salários mínimos, e que estavam tratando seus filhos pela rede de saúde particular. **Nível de Evidência II, Estudo retrospectivo.**

Descritores: Pé Torto Equinovaro. Internet. Família. Informação.

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INTRODUCTION

Internet has evolved exponentially. Just over ten years ago, a computer and telephone network was required to access the internet. Today, you can access it using a phone, tablet, computers, or notebooks. Internet has reached an incredible potential. Through digital technologies, it is possible to know about everything, from everywhere, at any time of day or night.¹ According to Pandey et al.,² the internet has been incorporated in recent years into the millions of lives worldwide, and the individuals can use it to obtain information about health conditions and participate in the disease processes.

In cases of congenital diseases such as clubfoot, the search for information begins soon after the diagnosis. This condition can be identified in the intrauterine period, from the first trimester of pregnancy by ultrasound. It is an orthopedic deformity that involves specialized treatment and affects one in 1,000 live births.³ CC treatment underwent significant changes in the early 2000s. The clubfoot treatment has gone from a long time of serial casts and extensive surgery to a few weeks of casts, minor outpatient surgery, and use of night cast. This new, more efficient, and effective method was proposed by Ponseti.⁴ Twenty years ago, the technique described by Kite⁵ in 1939 was based on serial cast changes, from 6 months to a year,

All authors declare no potential conflict of interest related to this article.

The study was conducted at Instituto de Assistência Médica ao Servidor Público Estadual.

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correcting the adduction first, the varus, and then the equinus. However, most feet could not be corrected after this period, thus requiring extensive surgery, releasing all capsules and medial ligaments of the foot, with fixation in the plantigrade position. Long-term results were still not very satisfactory when considering foot function, showing limited movement, lack of strength, and early arthrosis.³

In the 1940s, the Spanish physician Ignacio Ponseti, from the University of Iowa, developed a treatment based on the functioning of the foot joints and their movements. The method consisted of specific foot manipulation with weekly serial casts (from five to seven), followed by the complete section of the Achilles tendon under local anesthesia. Continuous use of an abduction brace for three months and after this period only at night until the age of four aims to prevent recurrences.⁶

Our study seeks to understand the profile of the families that search for information on CC, in the first ten years of this transition phase of the clubfoot treatment method, with the beginning of the diffusion of the Ponseti Method in Brazil.

MATERIALS AND METHODS

This study was approved by the Institutional Review Board and registered on the Plataforma Brazil database under Ethics Evaluation Submission Certificate (CAAE) number: 49627115.8.00005463. All patients have signed an informed consent form.

This is a retrospective documentary study, with quantitative database analysis, from 2002 to 2012.

One hundred twenty-six participants who access the website during the first ten years of Ponseti method implementation in Brazil filled in a questionnaire.

The inclusion criteria were information related to the profile of patients with CC. Incomplete questionnaires were excluded.

Data collection procedure and instrument

The survey was conducted with the participants who access www.petorto.com.br website and filled in a 38-question semi-structured form.

The questionnaire consisted of socioeconomic information and specific pathology aspects, access to the internet, understanding the level of the information provided in the website, main difficulties encountered, and the main questions the user might have had when browsing a technical website.

The research complied with International Ethical Standards for human research.

RESULTS

Socioeconomic characterization

Epidemiological data such as gender, education, marital status, state, city, country, family income, and occupation were evaluated. Most participants were women (74%), compared to men (26%). Regarding the educational level, data show that 28% (35 individuals) were postgraduate, and 40% (51 individuals) attended an undergraduate course – either concluded or not (Figures 1, 2, 3 and 4).

Data on marital status show that 75% were married, and 15% were single. Family income shows that 29% had an income above 13 minimum wages or more and 14% had up to 13 minimum wages, 25% (Figures 1, 2, 3 and 4 and Table 1).

Regarding participants' profession, 21% were from the administrative area, 20% from public area, 20% worked in the health field, 18% in education, and 8% were self-employed (Figures 1, 2, 3 and 4).

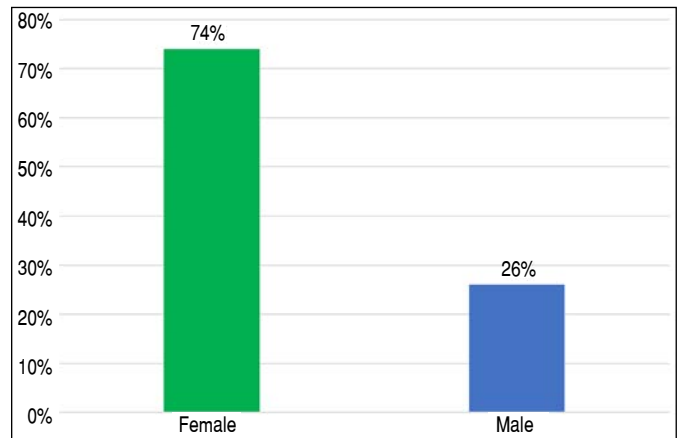


Figure 1. Participants' gender.

Source: Pé Torto.⁷

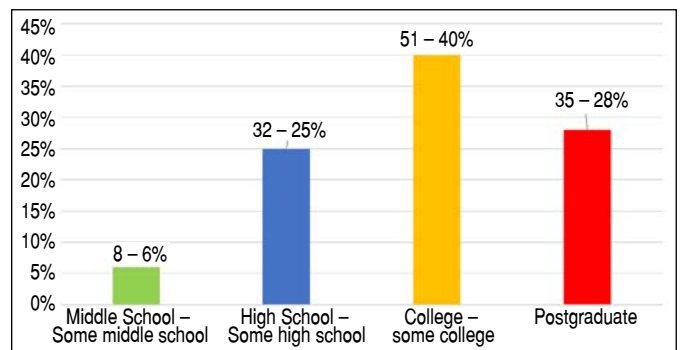


Figure 2. Participants' educational level.

Source: Pé Torto.⁷

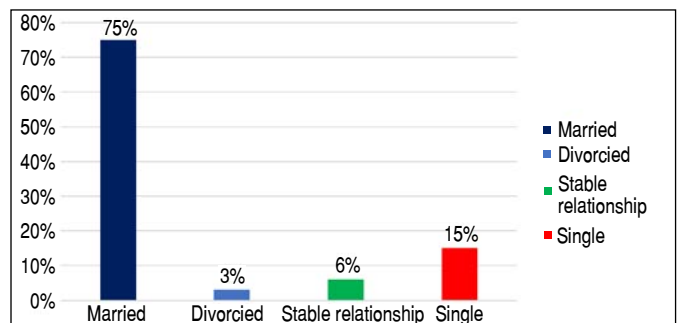


Figure 3. Participants' marital status.

Source: Pé Torto.⁷

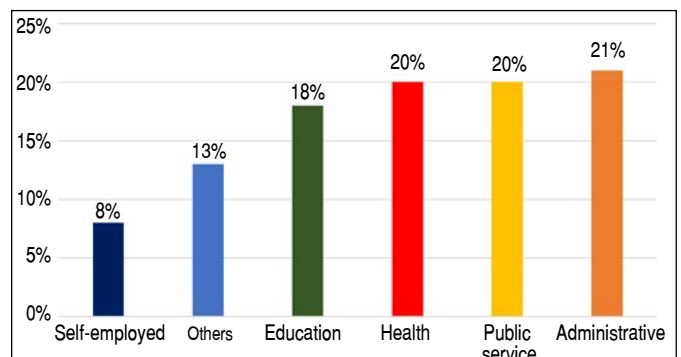


Figure 4. Participants' occupation.

Source: Pé Torto.⁷

Table 1. Participants' family income.

Monthly income	(n = 99) –%
Up to 3 minimum wage	4 – 4%
Up to 4 minimum wage	13 – 13%
Up to 5 minimum wage	14 – 14%
Up to 8 minimum wage	25 – 25%
Up to 13 minimum wage	14 – 14%
Over 13 minimum wage	29 – 29%

Source: Pé Torto.⁷

Figure 5 shows the division by state, São Paulo (49 records), Minas Gerais (11 records), Bahia (9 records), Espírito Santo (9 records), Rio de Janeiro (9 records) and Paraná (8 records). The states of Roraima, Pará, Rondônia, Tocantins, Piauí, Rio Grande do Norte and Sergipe had no records on the website.

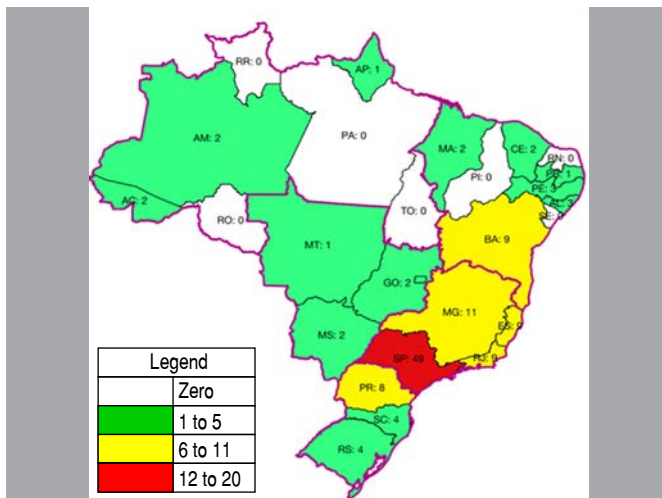


Figure 5. The number of participants who accessed and registered on Pé Torto website, by states and regions of Brazil.

Source: Pé Torto.⁷

The website registration frequency by region was: Southeast 61.90% (n = 78); Northeast 15.87% (n = 20); South 12.70% (n = 16); Midwest 5.56% (n = 7) and North 3.97% (n = 5).

Data show that 52% of professionals were informative and provided information in a humanized manner (Figure 6).

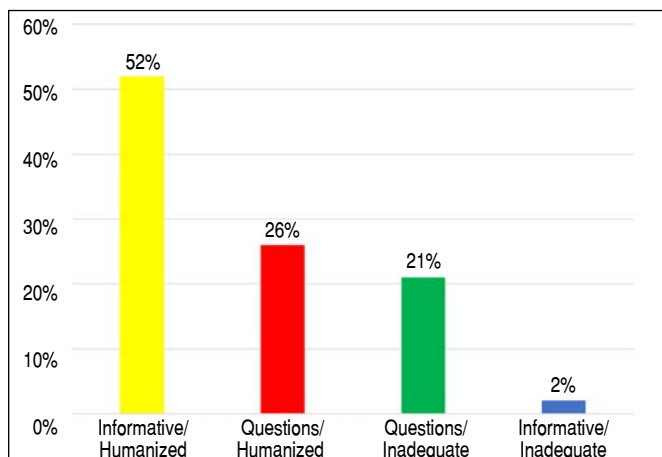


Figure 6. Communication between professionals and participants.

Source: Pé Torto.⁷

For the clubfoot treatment, an average of 35% of individuals consulted two physicians; 44% sought more than three professionals (Figure 7).

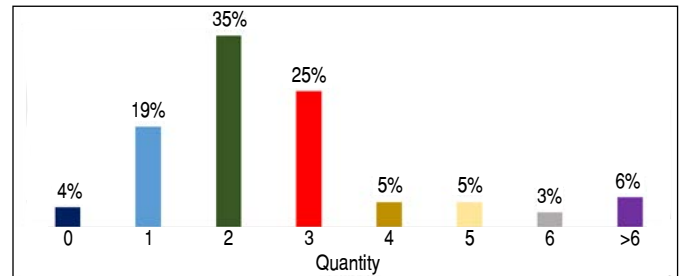


Figure 7. Numbers of consulted physicians regarding congenital clubfoot treatment.

Source: Pé Torto.⁷

Regarding the health system, 83% of individuals were in private care and 23% were in public care (Figure 8).

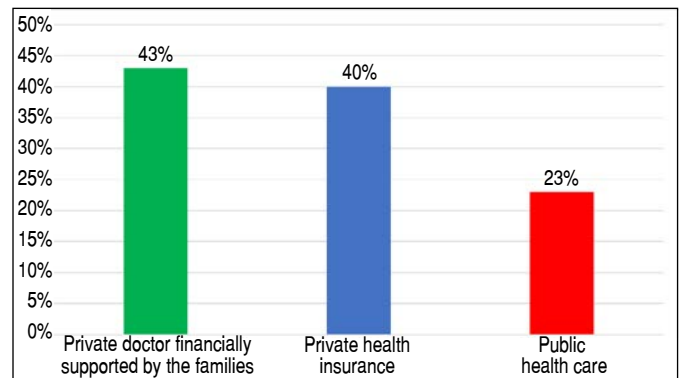


Figure 8. Health system regarding congenital clubfoot treatment.

Source: Pé Torto.⁷

Most participants reported undergoing percutaneous Achilles tendon tenotomy treatment (73%), more than half under general anesthesia (Figure 9).

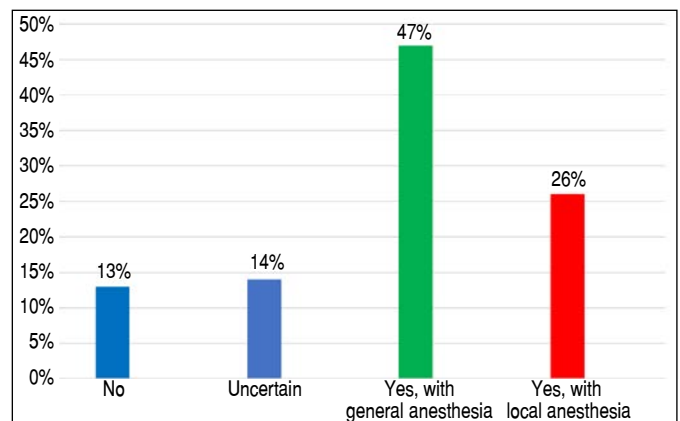


Figure 9. Data on the congenital clubfoot tenotomy procedure.

Source: Pé Torto.⁷

Regarding abduction braces during CC treatment, 68% of the participants reported its use and 20% declared non-use. Participants reported difficulties in obtaining or acquiring the abduction braces 16%, and 62% had no difficulty in obtaining it (Figures 10 and 11).

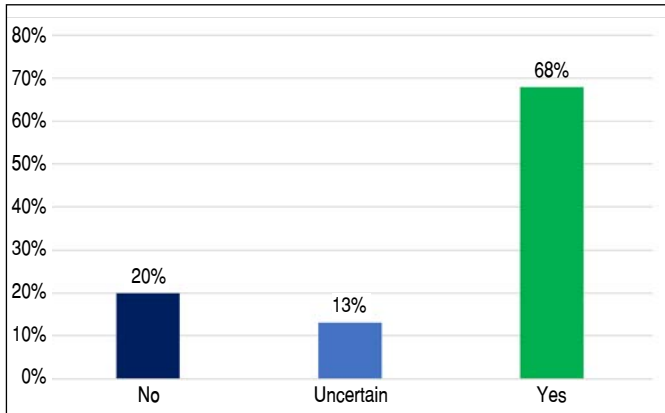


Figure 10. Congenital clubfoot treatment.

Source: Pé Torto.⁷

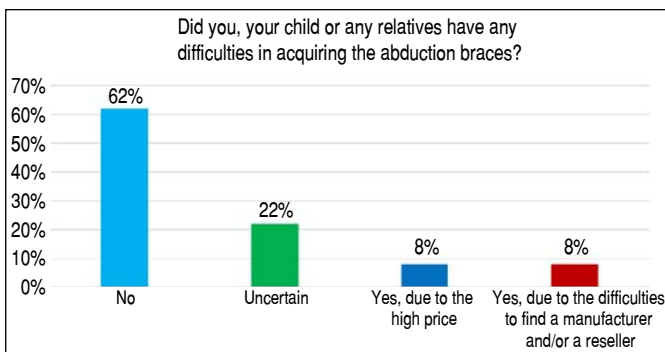


Figure 11. Relationship between the use of braces and difficulties of acquiring it.

Source: Pé Torto.⁷

Regarding the destination of abduction braces after the treatment conclusion, 31% donated to the physician, 12% to other patients with CC, 5% donated to institutions, 12% discarded them, and 40% were uncertain (Figure 12). Regarding the amount paid for the first abduction braces, there was a wide variation (Figure 13). Figures 14 and 15 show the continuous use of abduction braces (23 hours a day), 29% were uncertain, 27% used during 03 months, 17% between 04 and 06 months, 12% between 07 and 12 months, 9% over 12 months, and 6% less than 03 months. More than half of the participants (58%) reported that physicians considered the acquired abduction braces adequate.

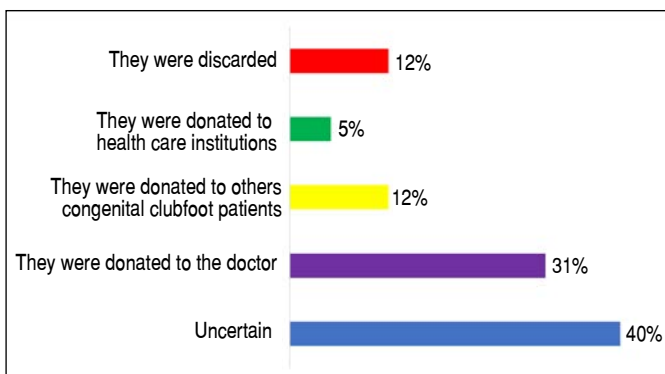


Figure 12. Destination of abduction braces used in the treatment.

Source: Pé Torto.⁷

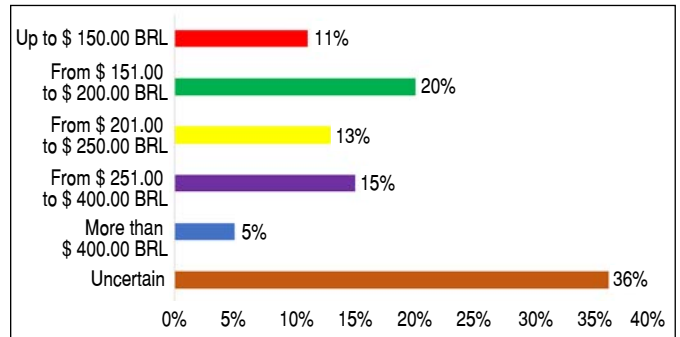


Figure 13. Abduction brace prices in Brazilian currency.

Source: Pé Torto.⁷

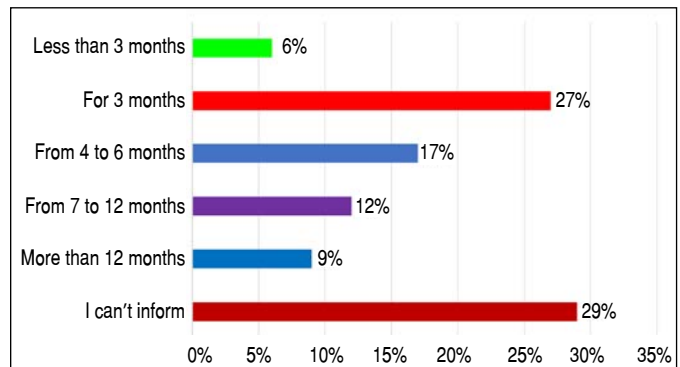


Figure 14. Time of continuous use of foot abduction brace.

Source: Pé Torto.⁷

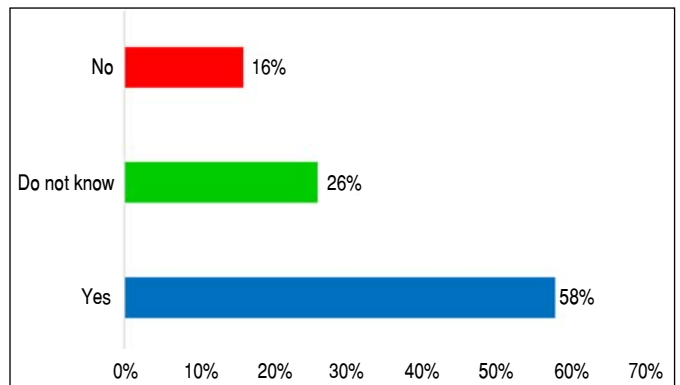


Figure 15. Abduction brace time of use considered adequate by the physician.

Source: Pé Torto.⁷

Figure 16 shows that 29% used 16 or more casts, 29% used between 6 and 10, 19% between 1 and 5, and 13% could not inform. About 70% of CC patients used more than six casts; 68% used abduction braces during treatment, 62% had no difficulty obtaining/acquiring it, 41% donated to the doctor that assisted the patient, 27% used the braces for 3 months and 58% considered the first acquired braces adequate. Ninety-two percent rated the clubfoot website as above 4 on a Likert scale ranging from 1 to 5. Among the website users, 63% asked for a professional's help via the "CONTACT US" link. Of these, 67% had their questions answered, and 75% considered that they had received adequate and sufficient information about all stages of CC treatment.

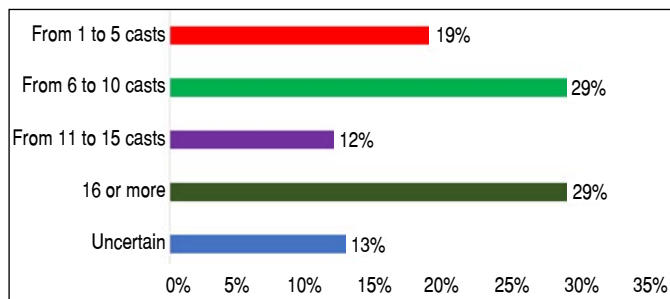


Figure 16. Quantity of casts used during congenital clubfoot treatment. Source: Pé Torto.⁷

DISCUSSION

From 2002 to 2012, the participants belonged to higher income and educated families, 83% had the treatment financially supported by the private health system, were mostly from urban areas, with a good socioeconomic level, which justifies the high use of internet to search for more information on CC. Low-income families are not represented in our study, possibly unaware of treatment breakthroughs due to less accessibility to internet.

According to Nogueira,⁸ the families (77%) search on the internet for more information, since the condition mostly affects one family member, being new in the family nucleus, thus requiring a better understanding. Pregnancy is a period when women are more emotional, fragile, with more free time, and they use this period together with their families to search for information on the internet. Orthopedic consultations for clubfoot treatment (49.7%) before or after birth by physicians experienced in the Ponseti Method were referenced via the internet.⁹

Brazilian data are comparable to US statistics presented at the Ponseti International Association Meeting, November 2009, Washington – DC. In this study, 74% of US parents and 51% parents of other nationalities sought the University of Iowa for treating their child using the Ponseti Method after internet searches.¹⁰

Increased availability of information on professionals and their academic backgrounds is also an essential source of information for patients. The dissemination of knowledge and communication by electronic means still influence clinical practice. Regarding CC treatment, the contribution was vital to the diffusion of the Ponseti Method.¹¹ Internet is a fast, convenient, and anonymous source, with abundant information. Due to the continuous advances in technology and increasing accessibility, searching online has become more attractive. Moreover, internet allows access to specific populations, being a useful tool for scientific research groups.

According to Morcuende et al.,¹¹ 160 websites provided information on clubfoot and received approximately 30,000 messages (average 1,000 messages/month) posted on the user support area. After visiting internet support groups, 125 parents either changed the treatment to or started treatment for their children with a physician that adopted the Ponseti method.

Skinner et al.¹² affirm that some issues may affect the quality of access to clubfoot treatment, namely punctuality, literacy, privacy, relevance, and internet access such as by broadband. The authors state that these barriers can hinder the access to health benefits by populations in need.

The survey showed that 91% of parents interviewed relied on the website to find relevant data, and most adults believe the information found on these websites is reliable, which correlates with the data of our study, validating its reliability.¹³

Patients use health care information to investigate treatment options, to ask new questions, to get a second opinion, which may influence their decision to visit a physician.¹⁴

Patients consult their physician as a primary source of information. However, internet is increasing as a secondary source, and fewer patients rely on friends, family, journals, radio, or television.¹⁵ The search for information was positively correlated to social support. One possible explanation is that, when parents search for information about their children's health condition, they are more likely to come across and join an online support community.¹⁰

Online support communities are an essential source of information for parents. More than 60% of participants visit an online support community on a regular basis, even daily.¹⁶

Online communities can be an active channel for parents to seek and provide the information needed to manage clubfoot uncertainties. To improve communication with parents, health institutions should invest in additional resources, e.g. online interactions with caregivers of children with uncommon diseases, such as clubfoot.

Searching and providing information in online communities can provide valuable data for research and interdisciplinary health practice.¹⁷ Internet offers a means for parents to obtain specific information about diseases in a timely manner.¹⁸

Percutaneous Achilles tenotomy is part of CC treatment by the Ponseti Method, performed in 90 to 95% of cases. In the participants of our study, tenotomy was completed in only 73% of patients. Likewise, abduction braces are also part of the method, and only 68% of participants confirmed its recommendation/use. In almost half of the cases, participants also reported treatments with more than ten casts. Thus, this information reflects that the Ponseti method has not yet been well established, and its prescription by physicians varied widely.¹⁹

More than 22 thousand families in Brazil join social networks related to CC treatment by the Ponseti Method, and there is much more consensus regarding the use of braces, the number of casts, and more training of orthopedic surgeons. Several factors contributed to this change, including two major medical training programs organized by the orthopedists' group Ponseti Brazil, part of Ponseti International, for the dissemination and correct use of the Ponseti Method (Nogueira et al.⁹ – Ponseti Brazil Program – 2007 and 2008).⁹ One took place in 2007 and 2008, including 556 Brazilian orthopedic surgeons from 21 Brazilian cities in different states that underwent training in a 2-day seminar. A new medical training program, "Eradicating Clubfoot in Brazil" in 2016-2018, a new partnership of the Ponseti Brazil Doctors Group with Rotary, supported by the Association of Parents of Clubfoot, with the training of 50 orthopedists who were already working at the Brazilian Unified Health System (SUS) through the educational model of mentoring.²⁰ The treatment of clubfoot by Ponseti Method has become better known, and social networks support this data.²¹

During treatment, parents consulted more than one specialist for a second opinion, and they reported feeling insecure if their medical opinion were clear or objective.

This may reflect the insecurity regarding the change of treatment, of which physicians were still not in consensus on what treatment to adopt. Despite the socioeconomic level, which does not reflect the totality of the parents of clubfoot children in Brazil, participants' families raise doubts, anxieties, and concerns arising from a paradigm shift in the treatment.

CONCLUSION

The profile of the participants that access the website regarding CC and Ponseti Method is composed of women, married, living in urban areas, predominantly from Southeastern Brazil, having graduated level, with income above 1.5 minimum wages, and that treat their children with a private physician. The gathered information represents the decade (2002-2012) of the change in clubfoot treatment, from cast changes for a long time followed by extensive surgical release to the Ponseti method.











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IMPACT OF DIABETIC NEUROPATHY ON QUALITY OF LIFE AND POSTURAL BALANCE IN BRAZILIAN OLDER ADULTS

O IMPACTO DA NEUROPATIA DIABÉTICA NA QUALIDADE DE VIDA E EQUILÍBRIO POSTURAL EM IDOSOS BRASILEIROS

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ABSTRACT

Objective: To analyze the impact of the Peripheral Diabetic Neuropathy (PDN) on the postural and functional balance and quality of life of Brazilian older adults. **Methods:** A cross-sectional study. Sixty older men and women (60-79 years) were divided into three groups: control, DM without and with PDN. The following parameters were evaluated: anthropometry; quality of life; postural balance (BESTest); functional balance in force plate (NeuroCom Balance). **Results:** PDN group presented significant differences compared with the other groups, with the worst performance in quality of life than DM2 without PDN in: sensory functioning ($p = 0.030$); past and future ($p = 0.036$); death and dying ($p = 0.035$). Postural balance deficit in the total score ($p = 0.025$) and biomedical constraints section ($p = 0.043$) of the BESTest, compared with DM2 without PDN ($p = 0.007$). In the functional balance (Neurocom), PDN group presented a worse performance in the time spent on the left side ($p = 0.030$) than the control group. During step up over test, the control group performed the task faster than the group with PDN ($p = 0.004$). **Conclusion:** This study showed that neuropaths presented worse physical performance and postural balance deficits, sensorial limitations, affecting the daily tasks and, as a consequence, decreasing the quality of life in Brazilian older adults. **Level of Evidence II, Cross-sectional observational study.**

Keywords: Diabetes Mellitus. Neuropathy. Postural Balance. Quality of life.

RESUMO

Objetivo: Analisar a influência da neuropatia diabética periférica (NDP) no equilíbrio postural, atividades funcionais e na qualidade de vida em idosos. **Métodos:** Estudo transversal. Avaliamos 60 homens e mulheres idosos (60-79 anos) divididos em três grupos: controle, DM sem e com NDP. Foram avaliados: antropometria; qualidade de vida; equilíbrio postural (BESTest); atividades funcionais pelo equilíbrio funcional na placa de força (NeuroCom Balance). **Resultados:** Grupo NDP apresentou diferenças comparado a outros grupos, pior desempenho na qualidade de vida que o DM2 sem NDP em: funcionamento sensorial ($p = 0,030$); passado e futuro ($p = 0,036$); morte e morrer ($p = 0,035$). Déficit de equilíbrio postural no escore total ($p = 0,025$) e seção de restrições biomédicas ($p = 0,043$) do BESTest comparado ao DM2 sem NDP ($p = 0,007$). No equilíbrio funcional (Neurocom), o grupo NDP apresentou pior desempenho no tempo gasto no lado esquerdo ($p = 0,030$) comparado ao grupo controle. Durante a etapa de teste, o grupo controle executou a tarefa mais rapidamente que o grupo NDP ($p = 0,004$). **Conclusão:** Neuropatas apresentaram pior desempenho físico e déficits no equilíbrio postural, limitações sensoriais, afetando as tarefas diárias da doença e, conseqüentemente, diminuição da qualidade de vida em idosos brasileiros. **Nível de Evidência II, Estudo observacional transversal.**

Palavras-chave: Diabetes Mellitus. Neuropatia. Equilíbrio Postural. Qualidade de vida.

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INTRODUCTION

It is estimated that 425 million people have Diabetes Mellitus (DM) in the world, and by 2045, there will be about 629 million people. Today, 98 million older adults (65-79 years) are susceptible to the disease, and by 2045, there could be 191 million.¹

Peripheral Diabetic Neuropathy (PDN) is one of the most frequent complications of DM,² which is progressive and irreversible. This complication is related to the reduction in sensory and motor peripheral pathways, possibly due to abnormal neuromuscular response to postural disorders. Thus, it leads to an inability to detect temperature,

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The study was conducted at Universidade São Judas Tadeu and developed in partnership with the Kinesiology Laboratory of the Institute of Orthopedics and Traumatology at the Clinic Hospital of the Medical School, Universidade de São Paulo (HCFMUSP) and Universidade Anhembi Morumbi.

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vibration, pressure and proprioception changes, modifying thus the static and dynamic postural balance.²⁻⁴

In addition, complications related to DM can reduce autonomy, individual and social well-being, thus reducing patients' quality of life (QoL).^{5,6}

However, it is necessary to understand and verify if the loss of postural balance gets worse with patients with PDN, consequently worsening the quality of life. Additionally, the loss of postural balance can increase the risk of fall and worsen the quality of life. This way, specific interventions could be adapted to reduce falls and physical incapacities in older adults with DM2.

The aim of the study was to analyze the influence of PDN on the postural and functional balance and quality of life of Brazilian older adults.

MATERIALS AND METHODS

Study location and ethical issues

This study was developed at the Motion Study Laboratory of the Institute of Orthopedics and Traumatology, at the Falls Prevention Program in the Department of Geriatrics, Hospital das Clínicas (HC), Medical School, Universidade de São Paulo (FMUSP) with the approved granted by Ethical Committee (registration number: 60952116.4.0000.0089) and developed in partnership with the Universidade Anhembi Morumbi. All participants provided written informed consent.

Type of study and subjects

This was a cross-sectional study that used as convenience sampling the older adults of a community. Sixty older adults both female and male between 60 and 79 years old were divided into three groups: 1) Control; 2) DM2 without PDN and 3) DM2 with PDN.

The subjects were recruited from the Integrated Health Center (CIS), endocrinology department of the Universidade Anhembi Morumbi. The inclusion criteria for both groups were: absence of foot ulcers and/or partial and total lower limb amputations, disease or functional impairment of any system: auditory, vestibular, proprioceptive, neurological, musculoskeletal; no use medications that could affect the postural balance; irregular activity according to the IPAQ questionnaire; and presence of normative parameters in the cognitive test (MoCA).

For DM2 groups, the disease should have been present for more than three years, subdivided into two groups: without PDN, with tactile sensitivity and preserved blood pressure; and with PDN with loss of tactile and sensitivity pressure. As exclusion criteria: if for any reason, subjects could not perform any of the proposed tests.

Measurements

The same researcher performed all evaluations.

PDN measurements and subjective questionnaires

Personal data, such as medical history, number of falls (Participants were questioned about a fall event, "Have you fallen?", considering fall an unintentional event that changed individuals' body position to a lower level, when compared with their initial position, whether having associated consequences or not); body mass and height were initially collected.

For confirmation of PDN the criteria used were the American Diabetes Association (ADA) criteria based on insensitivity to 10-g Semmes-Weinstein monofilament, for testing the thermal stimuli, two tubes were used, one preheated and one pre-cooled. The vibration perception threshold (VPT) scores were recorded to quantify the level of neuropathy with a cut off of 25 mV as an indicator of neuropathy at recommended plantar foot sites (assessed at the great toe, fifth metatarsal, and heel of both feet using VPT Meter).

Older adults should have plantar insensitivity in four of the ten points analyzed or not distinguish temperature or vibration (decreased), to be considered PDN.⁷

Quality of life evaluation

All the older adults answered the World Health Organization Quality of Life Instrument-Older Adults Module (WHOQOL-OLD) questionnaire, in the Portuguese version. WHOQOL-OLD comprises 24 items divided into six domains: sensory abilities, autonomy, past-present-future activities, social participation, death and dying, and intimacy.⁸

Balance Evaluation Systems Test (BESTest)

Balance Evaluation Systems Test (BESTest) was used to evaluate postural balance. Containing 27 items, with a total of 36 tasks organized in six sections (biomechanical constraints, stability limits, postural responses, anticipatory postural adjustments, sensory orientation, and dynamic balance during gait, and cognitive). All domains followed the protocol established by the translation and adaptation to the Portuguese language.⁹

Functional balance evaluation

The postural balance assessment (posturography) was performed on the NeuroCom Balance Master® force platform system (NeuroCom International, Inc., Clackamas, OR, USA). The system uses a fixed 18 in. Å~ 60 in. dual force plate to measure the vertical forces exerted by the patient's feet ND.¹⁰ The following tests were performed:

Sit-to-stand: the sit-to-stand transfer test was done on the platform, with the individual initially sitting on a bench (height of 30 cm) without a backrest, with the knees flexed at 90° and the feet separated by 10 cm in relation to the heels. The arms were kept at the side of the body throughout the test. The subjects were instructed to stand up safely and quickly. Three repetitions of the movement were made at intervals of 30 sec between each attempt. The parameters measured were the mean weight transfer and center of gravity (COG) sway velocity while rising. The weight transfer was the time in seconds required to voluntarily shift the COG forward, beginning in the seated position and ending with full weight-bearing on the feet. The COG sway velocity documented the degree of control over the COG above the support base during the rising phase and for 5 sec thereafter. Sway was expressed in degrees per second.¹¹

Step/Quick Turn: the older adult was advised to walk on the platform, rotate 180 degrees, and return to the starting place. The test started first to the left side and then to the right side, repeating each side three times in a 30-second interval. The measured parameters were the time required in seconds of the rotation on both sides; speed of travel in seconds in both directions.¹²

Step up-and-over: for this test, the subjects were instructed to step up on a 20-cm high step, putting only one foot on the step. The other foot was expected to go directly over the step and down off the platform without contacting the step. When both feet reached the platform, after going up the step, the subjects were instructed to remain as stationary as possible. Three attempts were made for each leg, starting with the left leg. The variables evaluated in this protocol were the mean weight transfer index, mean movement time, and mean impact index. In all of the balance tests performed in this study, the subjects could only make three attempts to perform each movement in each test. If they were unable to successfully perform the test after three incomplete attempts, the test was excluded.^{10,12}

Statistical Analysis

Data were stored in the IBM SPSS Statistics 24 program and presented by means and standard deviation. The Shapiro Wilk test was performed to verify if the variables adjusted to normality and to use the relevant comparative tests. The Chi-square test was used to compare categorical variables (gender and falls). The ANOVA test

was used to compare the three groups with Bonferroni post hoc. The Student's t-test was used for the period of the disease in the DM2 groups, with and without NDP. The 5% level of significance was adopted throughout the analysis.

RESULTS

The gender distribution in relation to the groups was: control, 8 (40%) women and 12 (60%) men; in the group without PDN, 7 (35%) women and 13 (65%) men; PDN group, 11 (55%) women and 9 (45%) men [χ^2 (p) = 1.765 (0.41)]. Falls were more frequent in PDN groups, but with significant difference [χ^2 (p) = 1,304 (0.52)]; in the group distribution: 5 (25%) of the control group, 3 (15%) in the group without PDN and 6 (30%) in the PDN group.

Age, a period of the disease, body mass, height, body mass index (BMI) classification, years of schooling and cognition (MoCA) did not present significant differences between the groups. Regarding the period of disease (DM2), there was a significant difference between the groups with DM2, since subjects of the group with PDN presented higher duration of disease (Table 1).

Table 1. Anthropometric characteristics; age; time disease, years of school and cognition (Moca).

	Control	DM2 Without PDN	DM2 With PDN
	Mean (SD) n = 20	Mean (SD) n = 20	Mean (SD) n = 20
Age (years)	70.50 (6.20)	69.55 (5.87)	72.9 (3.90)
Duration of disease (years)	-	10.35 (6.22)	13.30 (11.30)*
Body mass (Kg)	70.50 (13.70)	71.55 (12.62)	75.0 (13.7)
Height (m)	1.62 (0.08)	1.58 (0.09)	1.64 (0.09)
BMI (kg/m ²)	26.54 (4.17)	28.18 (2.87)	28.26 (4.10)
Years of Schooling	12.20 (3.45)	11.45 (5.88)	10.85 (4.60)
Cognition (MoCA)	23.55 (3.63)	23.95 (2.92)	22.55 (2.89)

ANOVA – Post Hoc Bonferroni test; § Student's t-test. * $p \leq 0.05$
SD: standard deviation; BMI: body mass index; MoCA: Montreal Cognitive Assessment.

Quality of life, assessed with the WHOQOL-OLD test, in three groups (control, diabetics without and with PDN) in the total score had a QoL classified as regular (3 to 3.9), according to the classification suggested by Fleck et al.^{13,14} and Power et al.¹⁵ Among the DM2 groups, subjects without PDN were better in the following domains: sensory abilities ($p = 0.030$), past-present-future activities ($p = 0.036$), and death and dying ($p = 0.035$). They were also better in past-present-future activities ($p = 0.036$) than the control group. There were no significant differences in relation to the other domains (autonomy, social participation, and intimacy) in the three groups (Table 2).

Table 2. Comparison of Quality of Life in groups DM2 with and without PDN and control.

	Control	DM2 Without PDN	DM2 With PDN
	Mean (SD) n = 20	Mean (SD) n = 20	Mean (SD) n = 20
Intimacy	3.5 (0.8)	4.0 (0.7)	3.6 (0.7)
Sensory abilities	3.7 (0.5)	4.1 (0.5) ^a	3.5 (0.9) ^a
Autonomy	3.8 (0.6)	3.5 (0.9)	3.7 (0.6)
PPF Activities	3.5 (0.4) ^b	4.1 (0.7) ^{a,b}	3.6 (0.4) ^a
Social Participation	3.6 (0.6)	4.0 (0.6)	3.6 (0.6)
Death and Dying	3.5 (0.7)	3.9 (0.7) ^a	3.2 (1.0) ^a
QoL (total)	3.6 (0.6)	3.9 (0.4)	3.5 (0.4)

ANOVA – Post hoc Bonferroni test. * $p \leq 0.05$.
QoL: Quality of Life; PPF: past-present-future.
a: difference between DM2 without PDN group versus DM2 with PDN group; b: difference between DM2 without PDN group versus control.

Regarding the postural balance (BESTest), the total score of the DM2 group with PDN presented worse performance and balance deficits ($p = 0.025$) when compared with subjects in the control group. In detailed domain analysis, on the biomechanical constraints section, the control group presented significantly better performance among the DM2 group without PDN ($p = 0.007$) and with NPD ($p = 0.043$); no significant differences were found between the other domains (Table 3).

Table 3. Comparison of Balance Evaluation Systems in DM2 groups with and without PDN and control.

	Control	Without PDN	With PDN
	Mean (SD) n = 20	Mean (SD) n = 20	Mean (SD) n = 20
BESTest total	89.4 (5.1) ^b	83.75 (8.2)	81.75 (11.8) ^b
Biomechanical Constraints	11.70 (2.4) ^{b,c}	9.10 (2.3) ^c	9.65 (2.9) ^b
Stability Limits	17.2 (2.7)	15.9 (2.5)	15.5 (2.6)
Anticipatory Postural Adjustments	15.20 (1.5)	14.70 (2.0)	14.00 (2.5)
Reactive	14.05 (1.7)	13.05 (3.1)	12.70 (2.7)
Sensory Orientation	14.15 (.9)	14.00 (1.5)	13.60 (2.4)
Gait stability	17.00 (1.5)	17.10 (1.9)	16.30 (3.1)

ANOVA – Post hoc Bonferroni test. * $p \leq 0.05$.
b: difference between control group versus DM2 with PDN; c: difference between control group versus DM2 without PDN.

Functional balance of the older adults was evaluated using the Neurocom Balance equipment; no significant difference was found between the groups in the sit-to-stand test. In the Step/Quick Turn, the older adults with DM2 and NPD had worse performance in the time spent on the left side ($p = 0.030$) compared with the control group, and in the Step up Over test, the control group performed the task faster than the DM2 group with PDN ($p = 0.004$) (Table 4).

Table 4. Comparison of Functional Balance Evaluation (posturography) in groups DM2 with and without PDN and control.

	Control	Without PDN	With PDN
	Mean (SD) n = 20	Mean (SD) n = 20	Mean (SD) n = 20
Sit to Stand			
Transfer time (sec)	0.51 (0.6)	0.4 (0.2)	0.5 (.03)
Weight transfer (%)	19.5 (8.9)	17.0 (5.1)	20.1 (10.1)
Balance velocity (°/sec)	9.4 (15.5)	4.15 (1.1)	4.15 (1.0)
Step/Quick Turn			
Time spent in the task LS (sec)	2.2 (0.7) ^a	2.3 (0.7)	3.1 (1.5) ^a
Time spent in the task RS (sec)	2.3 (0.7)	2.41 (0.7)	2.91 (1.3)
Balance velocity – LS (°/s)	47.9 (11.6)	49.7 (14.8)	55.6 (15.7)
Balance velocity – RS (°/s)	50.7 (15.8)	49.8 (12.5)	54.0 (15.7)
Step up and Over			
Step up the step LS (%)	39.2 (9.4)	33.7 (8.8)	32.4 (10.8)
Step up the step RS (%)	39.7 (8.5)	37.7 (9.0)	33.1 (12.1)
Time spent in the task LS (sec)	1.5 (0.3) ^a	1.8 (0.5)	1.9 (0.5) ^a
Time spent in the task RS (sec)	1.5 (0.3)	1.7 (.4)	2.0 (1.0)
Impact to step down LS (%)	52.0 (13.3)	42.8 (11.8)	46.2 (12.2)
Impact to step down RS (%)	57.6 (16.7)	56.9 (19.1)	46.3 (11.1)

ANOVA – Post hoc Bonferroni test. * $p \leq 0.05$.
SD: standard deviation; sec: seconds; LS: left side; RS: right side; a: difference between control group versus DM2 with NPD; b: difference between DM2 without NPD group versus DM2 with NPD.

DISCUSSION

The main findings of this study were that PDN interfered negatively in QoL (sensory functioning domains, past, future and present

activities; and death and dying), postural balance (total score and biomechanical constraints domain), functional balance (Step/Quick turn and Step up Over).

QoL in older adults was evaluated by the WHOQOL-OLD, which showed that the PDN compromised the sensorial abilities affecting daily life, thereby compromising their availability in participating in activities and interacting (sensory functioning domain). These findings corroborate that DM2 complications worsen the quality of health.¹⁶ In the domain of present, past and future activities, we have noticed that with time, DM2 and its complications, such as PDN, can cause dissatisfaction with life and culminate in anxieties about continuing to achieve or receive merit of life itself. Lee et al.¹⁷ associate several chronic diseases, especially DM2, with the worsening of QoL in this domain.

Our findings also confirmed that PDN interfered when older adults were analyzed in the death and dying domain. Neuropathy showed greater concern and fear of being unable to control death. Previous studies have shown that health status and chronic diseases such as DM2 can lead to greater vulnerability and dependence in old age, contributing to the reduction of well-being and QoL in older adults.^{2,18} When the groups were submitted to the BESTest for postural balance analysis, in general, and in detailed dimension, we observed that the DM2 without and with PDN have losses in the body control in relation to the base of support. The disease can also be an aggravator of such clinical manifestations. Petrofsky et al.¹⁹ observed that when they analyzed a group of older adults with DM2 and a control group, under full and low lighting conditions using computerized posturography, such group presented gait disturbances and higher risks of falls, previously to the sensory losses that could decrease the adaptation mechanism (lack of sensory feedback), because the altered balance leads to the redistribution of the feet pressure.¹⁹ With sensory losses in the feet, neuropathy tends not to complete the function of body balance in response to the disturbance, unable to achieve stability for a given task due to the deficiencies.²⁰ The progressive nature of neuropathy can lead to loss of protective sensation in the feet, making them vulnerable to lesions and ulcerations.¹

In detailed analysis (BESTest), in the biomechanical restrictions section, older adults of DM2 with and without PDN presented a destabilization regarding postural control, and this could start from the base of support, body alignment, amplitude and strength of the ankle-foot and hip, leading to postural imbalance. Stability limits affect movement selection and deficits in postural control and functional strength associated with PDN, interfere negatively in these parameters.^{21,22} As plantar innervation decreases, muscle wastage is observed. Over time, these imbalances lead to flexibility deformities that become progressively more rigid.^{1,23} Studies on

different conditions (firm surface, foam surface, open and closed eyes in full, low and dark light, and in gait conditions) that prioritized the sensorial systems (visual and motor), show worse performance in patients with DM2, and the peripheral information caused by the disease, affect the postural balance and leave this population more susceptible to falls.^{19,24} Changes in the biomechanical properties can also be considered, since the calcaneus tendon is more rigid in these individuals, causing difficulties in maintaining the balance.²⁵ In contrast, Fulk et al.²⁶ concluded that despite changes detected, PDN may not be the only cause of impaired balance in people with the disease.

Neuropathy also showed impaired performance in functional balance tests. In the Quick walk and turn test, we observed that the PDN influenced the performance and execution of this task, evidencing the delay in the time spent to turn on the left side. The reaction time and walking speed of older adults with DM2 is slower and emphasize that changes in body positions may be useful in identifying a strategy for older adults with impaired balance.²⁷

The time (seconds) to do the task Step up and Over involves: reaction time, motor activity and postural balance; PDN group needed more time to do this task, which may be related to decreased sensory inputs, an important source of information for the central nervous system (CNS) to perform and control the movement. There is a consensus among some authors^{7,25,26} that DM2, as well as PDN, leads to motor control disorders.

This study contributes to DM2 regarding functionality, showing possible guidelines of how to conduct an exercise program that can improve the physical abilities of these older adults, as well as prevent the risk of falls. Including a routine with postural balance and exercise will bring not only physical benefits to the older adults but will make their life safer (less risk of falls) and make them more confident and prepared to act more consciously and assertively. The limitations of this study are related to the multifactorial characteristics of both disease and motor control. As the focus of the research was motor control and quality of life, other aspects such as glycemic control and vision, which are also affected by DM2, were not analyzed.

CONCLUSION

This study showed that neuropaths presented worse physical performance and postural balance deficits, sensorial limitations, affecting daily tasks and, as a consequence, decreasing quality of life in Brazilian older adults.

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IMPROVEMENTS IN HIP OSTEOARTHRITIS WITH LAVAGE, TRIAMCINOLONE AND HILAN G-F20

MELHORA NA OSTEOARTRITE DE QUADRIL POR LAVAGEM, TRIANCINOLONA E HILANO

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ABSTRACT

Objective: To verify whether the use of Hylan G-F20 improves saline lavage and triamcinolone injection results in the treatment of hip osteoarthritis (HOA). **Methods:** 82 patients with HOA categorized as grades II and III severity, according to Kellgren and Lawrence criteria, were randomized into the groups: lavage and triamcinolone (G0); lavage, triamcinolone, and 2 mL of hylan G-F20 (G1); lavage, triamcinolone, and 4 mL of hylan G-F20 (G2); lavage, triamcinolone, and 6 mL of hylan G-F20 (G3). The VAS, range of motion (ROM), WOMAC, and Lequesne questionnaires were administered at baseline, one, three, six, and twelve months post-injection. **Results:** All groups showed clinically relevant improvements (> 20%) between baseline and first month post-injection, maintaining subjective results throughout the study period ($p < 0.001$). We found no differences between groups in any subjective evaluations ($p > 0.05$, for all). G2 and G3 obtained improved flexion results up to a year ($p = 0.028$). Hylan groups presented an improved external rotation since the first postoperative month and maintained the results up to a year (G1, $p = 0.041$; G2, $p = 0.007$), whereas G0 showed no improvement ($p = 0.336$). **Conclusion:** Hip lavage and triamcinolone injection, with or without the use of hylan, improves pain, function, and quality of life up to a year in HOA. Hylan may improve ROM up to one year. **Level of Evidence IB, Randomized clinical trial.**

Keywords: Hyaluronic Acid. Viscosupplementation. Triamcinolone. Osteoarthritis, Hip. Randomized Controlled Trial. Minimal Clinically Important Difference.

RESUMO

Objetivo: Verificar se o Hylan G-F20 melhora os resultados da lavagem e injeção de triancinolona na osteoartrite do quadril (OAQ). **Métodos:** 82 pacientes com HOA Kellgren e Lawrence graus II e III foram randomizados: lavagem e triancinolona (G0); lavagem, triancinolona e 2 mL de Hylan G-F20 (G1); lavagem, triancinolona e 4 mL de Hylan G-F20 (G2); lavagem, triancinolona e 6 mL de Hylan G-F20 (G3). A escala visual analógica (EVA), amplitude de movimento (ADM), questionários Womac e Lequesne foram obtidos no início, um, três, seis e doze meses após a injeção. **Resultados:** Todos os grupos apresentaram melhora clinicamente relevante (> 20%) entre o início e o primeiro mês, mantendo resultados subjetivos durante o estudo ($p < 0,001$). Não foram encontradas diferenças entre os grupos nas avaliações subjetivas ($p > 0,05$). A flexão aumentou no G2 e G3 até um ano ($p = 0,028$). A rotação externa melhorou nos grupos Hylan no primeiro mês, mantendo os resultados até um ano (G1, $p = 0,041$; G2, $p = 0,007$), enquanto G0 nunca melhorou ($p = 0,336$). **Conclusão:** Lavagem do quadril e injeção de triancinolona, com ou sem Hylan, melhoram a dor, função e qualidade de vida até um ano na OAQ. Hylan pode melhorar a ADM até um ano. **Nível de evidência IB, Ensaio clínico randomizado.**

Descritores: Ácido Hialurônico. Viscosuplementação. Triancinolona. Osteoartrite do Quadril. Ensaio Clínico Controlado Aleatório. Diferença Mínima Clinicamente Importante.

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INTRODUCTION

Osteoarthritis (OA) is the leading cause of musculoskeletal disability worldwide¹ and hip osteoarthritis (HOA) has one of the highest disease burdens.² Risk factors interaction (joint- and patient-level) determine

whether HOA will eventually manifest as a clinical disease. The synovial membrane participates actively in HOA progression.³ Joint lavage and capsular distension followed either by weekly hylan G-F 20 or corticosteroids (CS) improve pain and function in HOA patients.^{4,5}

All authors declare no potential conflict of interest related to this article.

The study was conducted at Universidade de São Paulo, Hospital das Clínicas, Medical School, Osteometabolic Diseases Group of the Institute of Orthopedics and Traumatology. Correspondence: Márcia Uchôa de Rezende. Rua Dr. Ovídio Pires de Campos, 333, São Paulo, SP, Brazil, 05403010. marcia.uchoa@hc.fm.usp.br

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Intra-articular CS injections improve HOA symptoms in the short-⁶ and mid-term.⁷ The efficacy of hip viscosupplementation depends on the accuracy and number of intra-articular injection, proper patient selection, and product characteristics. Intra-articular injection of hyaluronic acid (HA) is analgesic⁸ and anti-inflammatory⁹ and promotes a better distribution of forces to reduce pressure and restore synovial fluid viscoelastic properties.¹⁰ Its prolonged effect is explained by the interaction with membrane receptors CD44 that reduce the expression level of cytokines, prostaglandin E2 (PGE2), metalloproteinases, and activated T cell.

This study aimed to verify whether different Hylan G-F 20 doses could optimize hip joint lavage and hydraulic distention results in moderate HOA.

MATERIALS AND METHODS

Trial design and setting

This is a double-blind, prospective, randomized clinical trial. The protocol was approved by the Ethics Committee for the Analysis of Research Projects under the number 0255/10 and registered in clinicaltrials.gov under the number NCT 01810809. Participants were randomized into four groups (G0, G1, G2, and G3). G0 patients underwent hip lavage and received an injection of 1 mL (20 mg) triamcinolone hexacetonide and 2 mL lidocaine 2% at the affected joints. G1, G2, and G3 patients underwent the same procedure added to the injection of one (2 mL), two (4 mL), or three (6 mL) hylan G-F 20 ampoules (Synvisc®; Genzyme Biosurgery, New Jersey, USA; hylan G-F 20). Each participant reported pain intensity by the visual analogue scale (VAS) and completed the Western Ontario and McMaster Universities (WOMAC) and Lequesne questionnaires. The affected hips range of motion (ROM -flexion, extension, abduction, adduction, internal, and external rotations) was measured with a goniometer. Evaluations were repeated one, three, six, and twelve months after the procedure.

Participants

Men and women with painful HOA without joint space obliteration participated in the study. At inclusion, all patients used analgesics (paracetamol and codeine) and diacerhein, except those with contraindications. Patients did not use non-steroidal anti-inflammatory drugs (NSAIDs) routinely and were asked not to use them during study period, including seven days before the evaluation and procedure. Inclusion criteria were: patients had to meet the American College of Rheumatology diagnostic criteria for HOA; present no previous fracture or surgery on the target hip; have had no intra-articular injection on the target hip during the six months preceding the study; reach grades II and III at the Kellgren & Lawrance (K&L) criteria; understand and accept the informed consent form; present no inflammatory, auto-immune, and septic diseases; be in clinical treatment for HOA taking oral diacerhein (or another disease-modifying OA drug) over three months, without symptoms resolution; and have not used NSAIDs for over a week. Exclusion criteria were: pregnancy; allergy to hylan G-F 20; systemic CS or NSAIDs use during the study; absence in more than two evaluations.

Procedure description

All procedures were performed in an operating room. The patient was positioned supine on a radiolucent table and underwent general anesthesia. A 14- or 16- gauge needle was introduced under fluoroscopy, according to the described technique,¹¹ and iodinated contrast (Ultravist®; iopromide 300; Bayer Pharma AG, Berlin, Germany 300 mg iodine/mL) was injected (Figure 1A) to confirm intra-articular position. Then, a physiological saline injection was performed until hip capsule was distended (Figure 1B) and contrast

was withdrawn (250 to 500 mL of saline). After syringe withdrawal, contrast and saline were expelled from the catheter. Once joint was emptied (Figure 1C), medications were injected (Figure 1D) as above described and the hip was manipulated in flexion, flexion-external rotation and flexion-internal rotation, and flexion and abduction.

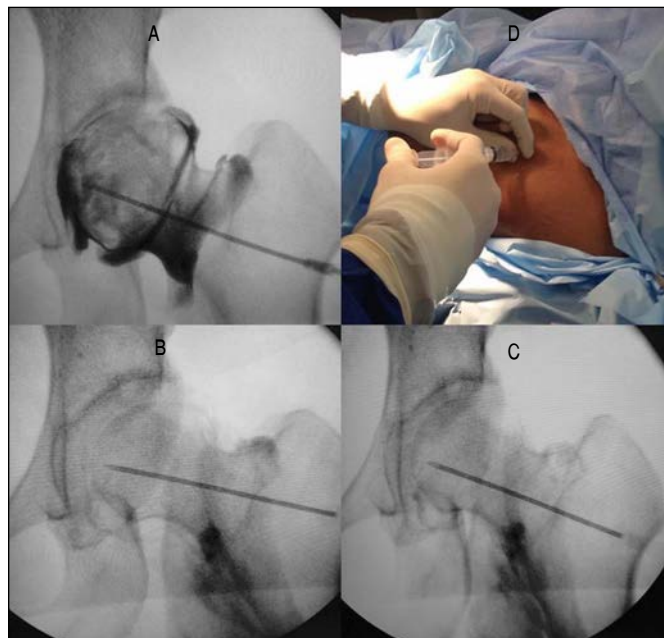


Figure 1. Procedure.

A: fluoroscopic image of the hip showing needle positioning and contrast injection that skirted femoral neck and head; B: contrast removal by saline lavage. The fluoroscopic image shows hydraulic distention by distancing the femoral head from the acetabulum; C: fluoroscopic image after emptying, in preparation for D: drug injection.

Aftercare

All patients were discharged with a naproxen 500 mg twice daily prescription, for three to five days, for pain control. Patients were also instructed to seek medical staff in case of pain, heat, redness, fever, or functional worsening at any time during the study period.

Sample Size

Sample size was calculated at the website www.lee.dante.br, applying the standard deviation found in a previous study for a one-point difference in WOMAC stiffness, enabling an 80% statistical power and a 5% significance level. We found the result of sixteen patients per group, which was increased by 20% due to possible dropouts and exclusions, resulting in twenty patients per group.

Statistical analysis

For descriptive data analysis, categorical data were described by their absolute value and respective proportion among groups, continuous data by average/median, and standard deviation and confidence interval/percentile was established at 25-75. Outcome data were continuous and underwent Kolmogorov-Smirnov normality test to verify distribution. The parametric one-way ANOVA with repeated measures was employed to test pain analysis (VAS and WOMAC pain) and functional outcomes (WOMAC stiffness, WOMAC function, WOMAC total, and Lequesne). The Kruskal-Wallis' and Friedman's nonparametric tests were used to compare groups and time for ROM measures. Subsequently, the Mann-Whitney's test was used for post-hoc pairwise comparisons with Bonferroni correction. Type I error less than or equal to 5% was accepted as statistically significant difference. The Last Observation Carried Forward (LOCF) method was used to impute missing temporal

follow-up data. The analysis was performed using the SPSS 23 software for Mac and tabulated in Excel® spreadsheet.

RESULTS

Groups were homogeneous for all data at baseline ($p > 0.05$) (Tables 1, 2, and 3). Figure 2 shows patients' flow during the study. Table 2 shows the results obtained by VAS, WOMAC, and Lequesne. All results indicate a pattern: a great improvement from baseline to one-month evaluation followed by a decline, but still maintaining clinically important improvements (more than 12%)¹² up to a year (last evaluation), showing that all groups improved over time ($p < 0.001$) for all pain and function questionnaires.

We found no differences among groups in any subjective evaluation and time (VAS, $p = 0.733$; WOMAC pain, $p = 0.986$; WOMAC stiffness, WOMAC function, WOMAC total, and Lequesne, $p = 0.274$). Each injected hip was considered one case when evaluating ROM, and at the end of the study we had 28 hips in G0, 31 in G1, 36 in G2, and 37 in G3. Extension, abduction, and internal rotation results showed no significant differences over time between groups (all $p > 0.05$). After the procedure, external rotation improved in viscosupplemented groups (G0 median results progressively worsened but not significantly, $p = 0.336$). External rotation remained improved in hyalan-injected groups throughout the study, and was not significant only in G3 (G1, $p = 0.041$, G2, $p = 0.007$ and G3, $p = 0.058$, Table 3).

Table 1. Baseline data for age, body mass index, gender, laterality, number of affected joints, and pain severity according to Kellgren & Lawrance grade by group.

	Group			
	G0 n = 19	G1 n = 19	G2 n = 22	G3 n = 22
Age	<i>Mean (SD)</i>			
	60.1 (12.8)	62.2 (13.8)	61.5 (11.6)	64.1 (11.7)
BMI	<i>Mean (SD)</i>			
	29.6 (4.6)	28.5 (4.6)	28.7 (7.2)	28.4 (5.4)
Female Gender	<i>Mean (SD)</i>			
	16 (84.2%)	18 (94.7%)	16 (72.7%)	16 (72.7%)
Laterality	<i>Mean (SD)</i>			
Right	5 (26.3%)	2 (10.5%)	5 (22.7%)	3 (13.6%)
Left	3 (15.8%)	4 (21.1%)	3 (13.6%)	4 (18.2%)
Bilateral	11 (57.9%)	13 (68.4%)	14 (63.6%)	15 (68.2%)
Affected joints	<i>Mean (SD)</i>			
Unilateral	4 (21.1%)	4 (21.1%)	5 (22.7%)	6 (27.3%)
Bilateral	5 (26.3%)	8 (42.1%)	8 (36.4%)	5 (22.7%)
Multiple arthritis	10 (52.6%)	7 (36.8%)	9 (40.9%)	11 (50.0%)
K&L	<i>Mean (SD)</i>			
2	18 (60.0%)	16 (50.0%)	24 (70.6%)	25 (67.6%)
3	12 (40.0%)	16 (50.0%)	10 (29.4%)	12 (32.4%)

BMI: body mass index; K&L: Kellgren & Lawrance; SD: standard deviation.

Table 2. Results (mean and standard deviation) for VAS, WOMAC pain, WOMAC stiffness, WOMAC function, WOMAC total, and Lequesne according to group and assessment.

	Group			
	G0 n = 19	G1 n = 19	G2 n = 22	G3 n = 22
VAS	<i>Mean (SD)</i>			
Baseline	63.8 (21.5)	68.2 (21.8)	55.8 (31.4)	69.2 (20.9)
One Month	35.5 (33.4)	31.9 (22.0)	28.4 (27.2)	44.0 (34.3)
Three Months	44.3 (31.7)	43.3 (21.9)	40.1 (29.3)	43.0 (29.7)
Six Months	46.2 (28.0)	49.9 (30.0)	37.6 (28.9)	43.0 (31.4)
Twelve Months	40.3 (34.4)	48.4 (27.0)	40.8 (27.8)	46.6 (27.7)
WOMAC Pain	<i>Mean (SD)</i>			
Baseline	11.1 (3.3)	10.4 (3.3)	10.5 (4.9)	10.5 (4.4)
One Month	6.6 (5.4)	6.0 (3.9)	6.9 (5.2)	6.8 (4.4)
Three Months	7.1 (4.2)	7.9 (3.3)	7.4 (4.4)	7.0 (5.0)
Six Months	6.9 (4.6)	8.0 (4.7)	6.4 (4.9)	7.9 (4.7)
Twelve Months	6.4 (4.1)	7.7 (4.8)	8.0 (5.2)	7.6 (4.7)
WOMAC Stiffness	<i>Mean (SD)</i>			
Baseline	4.4 (1.8)	4.1 (1.8)	4.0 (2.3)	4.9 (2.0)
One Month	2.7 (2.2)	2.4 (1.9)	2.8 (2.3)	3.2 (2.4)
Three Months	3.0 (2.1)	2.7 (1.4)	2.5 (2.2)	3.4 (2.4)
Six Months	2.8 (2.2)	3.2 (2.2)	2.1 (2.2)	3.6 (2.3)
Twelve Months	3.4 (2.0)	2.8 (2.1)	2.8 (2.0)	3.6 (2.3)

Table 2. Results (mean and standard deviation) for VAS, WOMAC pain, WOMAC stiffness, WOMAC function, WOMAC total, and Lequesne according to group and assessment.

	Group			
	G0 n = 19	G1 n = 19	G2 n = 22	G3 n = 22
WOMAC Function	<i>Mean (SD)</i>			
Baseline	42.1 (8.5)	36.2 (2.7)	35.2 (13.6)	40.6 (9.8)
One Month	22.6 (17.9)	24.7 (14.3)	24.5 (14.8)	27.6 (15.4)
Three Months	24.6 (12.7)	25.7 (13.9)	26.9 (13.9)	27.6 (16.5)
Six Months	28.4 (13.2)	29.4 (16.0)	24.9 (17.7)	29.6 (13.9)
Twelve Months	26.6 (13.2)	28.2 (15.7)	27.4 (16.7)	31.3 (16.3)
WOMAC Total	<i>Mean (SD)</i>			
Baseline	56.8 (12.2)	50.3 (16.2)	49.0 (19.5)	56.2 (16.6)
One Month	31.8 (24.9)	33.1 (19.1)	33.0 (22.7)	37.6 (21.1)
Three Months	34.6 (17.4)	36.3 (17.5)	36.8 (19.7)	38.4 (23.2)
Six Months	38.1 (18.6)	40.6 (22.3)	33.3 (24.2)	41.0 (19.7)
Twelve Months	36.4 (18.0)	38.7 (21.5)	38.3 (23.1)	42.5 (22.5)
Lequesne	<i>Mean (SD)</i>			
Baseline	13.4 (3.6)	12.3 (4.1)	11.5 (3.3)	12.9 (3.2)
One Month	8.5 (4.8)	7.9 (4.2)	8.8 (4.9)	10.5 (4.6)
Three Months	9.4 (4.5)	10.2 (4.2)	9.0 (3.9)	10.2 (4.9)
Six Months	10.6 (5.1)	10.5 (4.1)	8.5 (4.8)	11.3 (4.6)
Twelve Months	9.4 (4.6)	11.2 (4.7)	9.6 (5.5)	11.0 (5.3)

VAS: Visual Analog Scale; SD: Standard Deviation; WOMAC: Western Ontario and McMaster Universities questionnaire.

Table 3. Results (median and percentile 25-75) for range of motion according to group and evaluation.

	Group			
	G0 n = 28	G1 n = 31	G2 n = 36	G3 n = 37
Flexion	<i>Median (Percentile 25-75)</i>			
Baseline	105.0 (95.0 ; 115.0)	105.0 (95.0 ; 113.0)	109.0 (100.0 ; 115.2)	110.0 (93.0 ; 114.0)
One Month	110.0 (100.0 ; 115.0)	106.0 (94.0 ; 110.0)	113.0 (110.0 ; 120.0)	112.0 (105.0 ; 120.0)
Three Months	100.0 (95.0 ; 110.0)	104.0 (100.0 ; 110.0)	110.0 (100.0 ; 121.0)	107.0 (100.0 ; 111.0)
Six Months	106.0 (100.0 ; 120.0)	100.0 (96.0 ; 112.0)	110.0 (100.0 ; 120.0)	108.0 (100.0 ; 110.0)
Twelve Months	100.0 (90.0 ; 115.0)	100.0 (90.0 ; 110.0)	112.0 (101.5 ; 118.2)	110.0 (100.0 ; 117.0)
Extension	<i>Median (Percentile 25-75)</i>			
Baseline	15.0 (10.0 ; 18.0)	14.0 (8.0 ; 16.0)	12.5 (10.0 ; 20.0)	15.0 (10.0 ; 20.0)
One Month	15.0 (10.0 ; 20.0)	15.0 (10.0 ; 20.0)	15.0 (10.0 ; 20.0)	15.0 (10.0 ; 18.5)
Three Months	14.0 (10.0 ; 20.0)	15.0 (10.0 ; 20.0)	15.0 (12.0 ; 20.0)	14.0 (10.0 ; 18.0)
Six Months	14.0 (11.0 ; 20.0)	12.0 (10.0 ; 20.0)	15.0 (10.0 ; 20.0)	15.0 (10.0 ; 19.0)
Twelve Months	14.0 (10.0 ; 15.0)	10.0 (9.0 ; 15.0)	14.0 (10.0 ; 15.2)	12.0 (10.0 ; 15.5)
External Rotation	<i>Median (Percentile 25-75)</i>			
Baseline	40.0 (30.0 ; 45.0)	28.0 (21.0 ; 38.0)	32.0 (30.0 ; 45.0)	30.0 (21.0 ; 44.5)
One Month	38.5 (30.0 ; 45.7)	35.0 (30.0 ; 44.5)	39.0 (31.5 ; 46.2)	40.0 (15.0 ; 40.0)
Three Months	38.0 (23.5 ; 44.0)	34.0 (30.0 ; 42.0)	40.0 (32.2 ; 46.2)	40.0 (30.0 ; 45.0)
Six Months	34.5 (26.5 ; 43.7)	38.0 (31.0 ; 45.0)	35.5 (30.0 ; 44.2)	40.0 (31.0 ; 45.0)
Twelve Months	34.0 (26.5 ; 42.7)	32.0 (30.0 ; 40.0)	37.0 (30.0 ; 42.2)	36.0 (30.0 ; 44.0)
Internal Rotation	<i>Median (Percentile 25-75)</i>			
Baseline	25.5 (20.0 ; 30.7)	25.0 (15.0 ; 35.0)	23.5 (20.0 ; 30.0)	25.0 (15.0 ; 35.0)
One Month	20.0 (15.0 ; 29.0)	22.0 (10.0 ; 30.0)	26.0 (19.0 ; 34.5)	26.0 (20.0 ; 33.0)
Three Months	28.0 (11.7 ; 31.5)	29.0 (20.0 ; 34.0)	25.5 (20.0 ; 34.2)	30.0 (21.0 ; 30.0)
Six Months	26.0 (18.5 ; 30.0)	22.0 (15.0 ; 30.0)	27.0 (20.0 ; 31.0)	30.0 (21.0 ; 34.0)
Twelve Months	22.0 (20.0 ; 28.7)	26.0 (15.0 ; 33.0)	27.0 (22.7 ; 32.5)	25.0 (17.5 ; 32.0)
Adduction	<i>Median (Percentile 25-75)</i>			
Baseline	28.0 (21.0 ; 30.0)	27.0 (20.0 ; 30.0)	25.0 (20.0 ; 30.0)	28.0 (20.0 ; 30.0)
One Month	30.0 (25.0 ; 30.0)	30.0 (20.0 ; 30.0)	30.0 (25.7 ; 30.0)	29.0 (20.0 ; 30.0)
Three Months	30.0 (24.2 ; 30.0)	30.0 (25.0 ; 30.0)	30.0 (27.5 ; 30.0)	30.0 (20.0 ; 30.0)
Six Months	30.0 (28.5 ; 30.0)	30.0 (25.0 ; 30.0)	30.0 (25.0 ; 30.0)	30.0 (20.0 ; 30.0)
Twelve Months	30.0 (22.2 ; 30.0)	30.0 (25.0 ; 30.0)	30.0 (25.0 ; 30.0)	28.0 (24.0 ; 30.0)

Table 3. Results (median and percentile 25-75) for range of motion according to group and evaluation.

	Group			
	G0 n = 28	G1 n = 31	G2 n = 36	G3 n = 37
Abduction	<i>Median (Percentile 25-75)</i>			
Baseline	30.5 (26.5 ; 45.0)	30.0 (23.0 ; 40.0)	31.0 (25.7 ; 38.5)	30.0 (26.0 ; 40.0)
One Month	31.5 (30.0 ; 40.0)	34.0 (29.0 ; 40.0)	32.0 (30.0 ; 38.5)	33.0 (30.0 ; 40.0)
Three Months	32.5 (26.5 ; 40.0)	32.0 (28.0 ; 45.0)	32.5 (30.0 ; 40.0)	30.0 (29.0 ; 36.0)
Six Months	32.0 (28.5 ; 39.5)	31.0 (27.0 ; 40.0)	31.0 (28.0 ; 42.2)	32.0 (30.0 ; 36.5)
Twelve Months	35.0 (25.0 ; 41.5)	30.0 (28.0 ; 40.0)	33.5 (29.5 ; 39.2)	35.0 (30.0 ; 40.0)

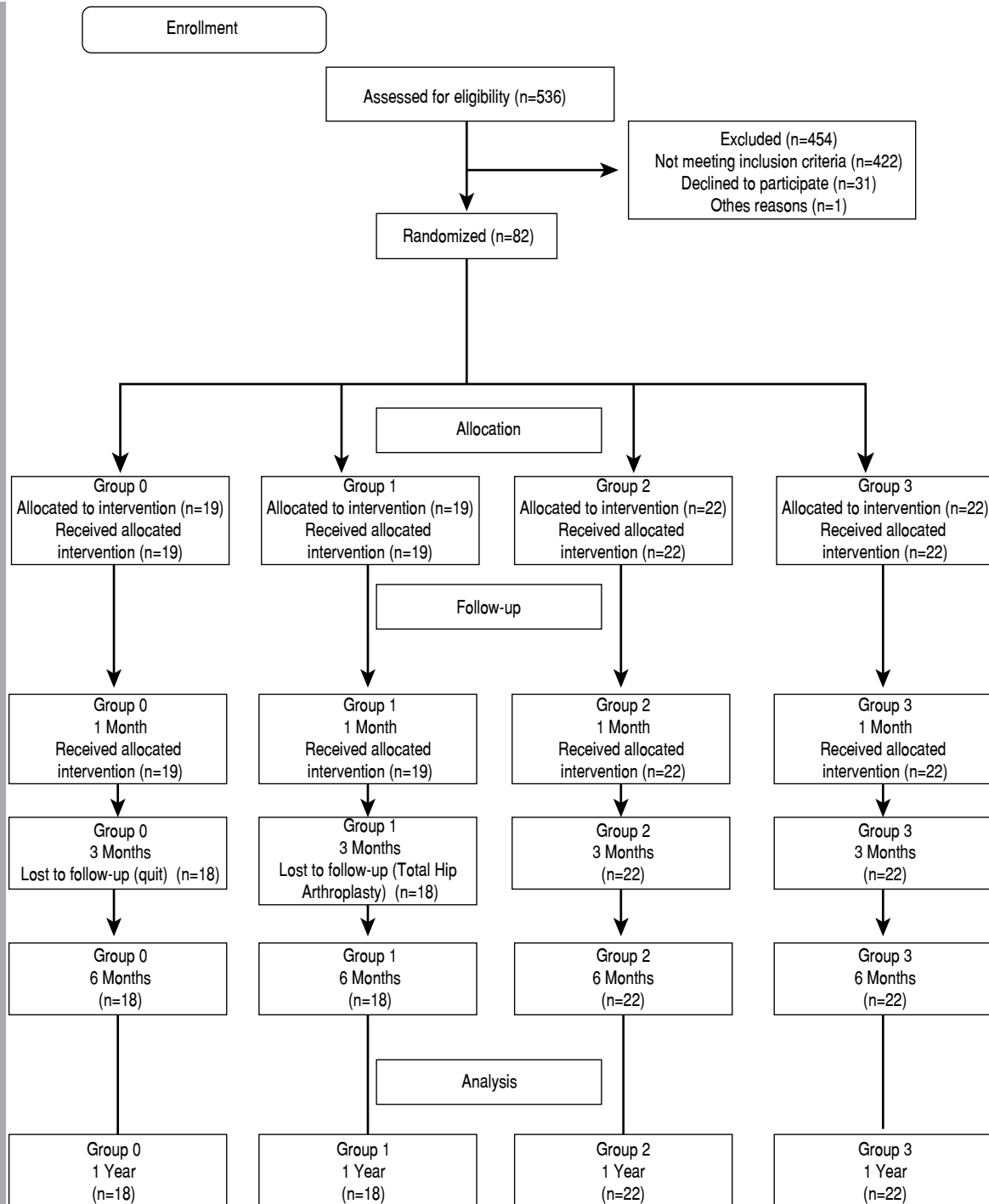


Figure 2. Patients flow in the study.

Flexion improved in all groups at the first month post-procedure evaluation, but was more significant in G2 and G3 than in G1 ($p = 0.002$ and $p = 0.006$, respectively). One year after the procedure, G2 maintained an improved ROM compared with G0 and G1 ($p = 0.048$ and $p = 0.011$, respectively), and G3 maintained improved flexion compared with G1, but not G0 ($p = 0.038$ and $p = 0.112$, respectively), (Table 3). All groups showed an improved adduction immediately after the procedure, which remained after one year and were significant for G0 ($p = 0.035$), G2 ($p < 0.001$) and G3 ($p = 0.031$, Table 3).

All patients left the hospital without pain and reported no infection, fever, or synovitis. During the study, five patients (one in G0, three in G1, and one in G3) rapidly progressed to OA grade IV and were considered complications of the procedure. In one of the patients, we observed these worsening results after six-weeks, in another after three months, and in the remaining at the sixth month of evaluation.

DISCUSSION

Our study pose some limitations: first, it does not have a control group (sham injection or lavage alone), hindering our ability to reach meaningful conclusions regarding different groups. Secondly, we observed differences in certain planes of motion, considerably small, and with questionable clinical significance. These differences may result from measurement error, indicating the need for further studies to use Cybex in the evaluation of muscle power and range of motion. Third, although statistically insignificant, G2 and G3 have a higher proportion of grade II K&L when compared with other groups, which could affect long lasting results.

Does lavage associated with triamcinolone injection improve pain and function in moderate hip osteoarthritis at one, three, six, or twelve months?

According to our results, yes. Studies have reported short-⁶ and mid-term pain improvement for intra-articular corticosteroids (CS) hip injection,⁷ but not for twelve months.¹³ Another study compared tidal lavage to CS injection in knee osteoarthritis (KOA) and found improved short and mid-term results.¹⁴ As for hip osteoarthritis (HOA), saline solution injection had no effect in improving patients' pain or function, whereas CS improved both.¹³ Sterile water (6 mL) and CS injection has shown to improve pain, stiffness, and function in HOA patients, compared with isolated CS injection, up to three months.⁵ However, in our study, pain, function, stiffness, and quality of life showed clinically important improvements (more than 12%¹² for all variables, in all evaluations, and in all groups) for up to a year, with the best results at the one month reassessment ($p < 0.001$).

Does Hylan G-F20 addition improves lavage and triamcinolone?

Considering previous experiences with triamcinolone addition to hylan G-F 20 in KOA,¹⁵ as well as the synergism of hip and knee lavage and hylan G-F 20,^{16,17} we expected a significant difference between G0 and hylan-injected groups. All groups presented clinically important improvements¹² in pain (VAS and WOMAC pain), stiffness (WOMAC stiffness), and function (WOMAC function, WOMAC total, and Lequesne) ($p < 0.001$ for all over time), and we found no differences among groups in any re-evaluation during the study period (all $p > 0.05$). However, hylan-injected groups

showed better range of motion (ROM) results. For ROM analysis, each hip was considered one case and the ROM obtained at each evaluation was compared to baseline results; we found a tendency to lose ROM among patients injected with CS alone. Flexion amplitudes improved in the first month, but then decreased below baseline angles ($p = 0.017$).

Is there a best hylan G-F20 dosage?

This study provides no support to answer this question. Although all hylan-injected groups presented an improvement in external rotation, it was only significant in G1 and G2 ($p = 0.041$, $p = 0.007$, respectively). In the last evaluation, groups showed no difference in internal rotation over time ($p > 0.05$, for all). Adduction also improved within all groups, perhaps with a more clinical relevance in G2 (five-degree increase, $p < 0.001$, Table 3) – the group with a higher percentage of grade II K&L participants. A study found that K&L grade III patients responded more to hylan than to CS, without a difference in K&L grade II.¹⁸ Our results could not endorse this finding because the groups showed no difference for this variable at any time of the study ($p > 0.05$).

Does this procedure entail any complication?

By the end of each procedure, we administered an intra-articular lidocaine (20 mg/mL) injection while retrieving the needle from the skin. Intra-articular injection of anesthetics and corticosteroids are chondrotoxic.¹⁹ Lidocaine is more chondrotoxic than bupivacaine and ropivacaine.²⁰ The co-injection of hyaluronic acid (HA) suppresses chondrocytes apoptosis caused by local anesthetics.²¹ However, we had five cases of rapidly progressive HOA, which we attributed to chondrolysis by lidocaine or/and by triamcinolone. We used 20 mg triamcinolone in each hip – half the dose described by Young et al.,⁵ who reported no adverse effects at three months. Most complications in our study were confirmed at the one-year re-evaluation. Interestingly, the group with more cases of rapid progression was not G0 but rather G1. HA protective effect depends on administered dose for both anesthetics and HA.²¹ Yet, group 3, which had the highest hylan dose, also had one case of rapid progression.

CONCLUSION

Hip lavage followed by triamcinolone injection improves short and long-term pain and function in patients with moderate HOA. ROM may be improved for a longer time period (one year) by adding hylan G-F20. Triamcinolone and local anesthetics dosage should be reduced to avoid adverse effects, and the ideal hylan G-F20 single-dose seems to be higher than 2mL.

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DOUBLE FEMORAL OSTEOTOMY FOR THE TREATMENT OF SEVERE SEQUELAE OF THE IMMATURE HIP

DUPLA OSTEOTOMIA DO FÊMUR PARA O TRATAMENTO DE GRAVES SEQUELAS NO QUADRIL IMATURO

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ABSTRACT

Objective: To evaluate the results of double femoral osteotomy for the treatment of severe sequelae of the hip. **Methods:** Immature patients with anatomical loss of the hip were treated with pelvic support osteotomy in the distal femur to correct lower limb shortening, they were evaluated clinically and radiographically. **Results:** Eleven cases (eleven hips) were assessed with average follow-up of three years. The mean age of the patients was 14.7 years. Seven patients had sequela of infectious arthritis; three had sequela of developmental dysplasia of the hip and one patient had a sequela of slipped capital femoral epiphysis. Preoperatively, the gluteus medius was insufficient in all patients, and it became negative in ten of them. The average of lower limb shortening was 5 cm (2.5 to 7 cm) and reduced shortening was 1.9 cm (0 to 4 cm). According to Paley Classification, 72.7% of complications were considered problems, 90.9% were considered obstacles and 27.2% complications, among which the limitation of the knee flexion was the most frequent. **Conclusion:** The technique yielded good results, considering the severity of the sequela and the absence of a better therapeutic option. No important sequela was associated with the treatment. **Level of Evidence IV, Case series.**

Keywords: Hip Joint. Hip Dislocation. Osteotomy. Arthritis, Infectious.

RESUMO

Objetivo: Avaliar os resultados do tratamento de graves sequelas do quadril pela dupla osteotomia do fêmur. **Métodos:** Pacientes imaturos, com perda da articulação do quadril, foram tratados com osteotomia de apoio pélvico associada à osteotomia na região distal do fêmur para correção do eixo do membro inferior e do encurtamento, foram avaliados clínica e radiograficamente. **Resultados:** Onze casos (onze quadris) foram avaliados, com seguimento médio de três anos. A média de idade no tratamento foi de 14,7 anos. Sete indivíduos tinham sequela de artrite séptica, três de displasia do desenvolvimento do quadril e um de escorregamento epifisário proximal do fêmur. Pré-operatoriamente, a marcha por insuficiência do glúteo médio esteve presente em todos os sujeitos e se tornou negativa em dez deles. O encurtamento médio inicial do membro afetado foi de 5 cm (2,5 a 7 cm) e o reduzido teve média de 1,9 cm (0 a 4 cm). Segundo classificação de Paley, 72,7% apresentaram intercorrências consideradas problemas, 90,9% obstáculos e 27,2% complicações, entre as quais a limitação da amplitude de movimento do joelho foi a mais frequente. **Conclusão:** A técnica produziu bons resultados em face da gravidade da sequela e da falta de outra opção terapêutica melhor. Não houve sequela importante associada ao tratamento. **Nível de Evidência IV, Série de casos.**

Descritores: Articulação do Quadril. Luxação do Quadril. Osteotomia. Artrite Infeciosa.

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INTRODUCTION

Hip function is very compromised by severe situations such as joint dislocations, or major joint destruction, as occurs in long-dated sequelae of infectious arthritis. There is no adequate treatment for these conditions, especially in young people, in whom the possibility of a total hip arthroplasty is discarded. The same occurs for arthrodesis since this is a radical procedure that causes great limitations and is currently little practiced.¹

Individuals with these sequelae present severe abductor insufficiency, severe shortening and vicious position of the lower limb. The outcome of this combination is a serious alteration in posture, Trendelenburg gait—due to insufficiency of the gluteus medius—, movement restriction, claudication and difficult-to-treat pain. In 1919, the first attempt to alleviate this condition occurred when Lorenz described a pelvic support osteotomy,² which was performed in the femur and caused a large valgus-related angle whose vertex

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The study was conducted at Universidade de São Paulo, Hospital das Clínicas, Ribeirão Preto Medical School, Pediatric Orthopedics Sector. Correspondence: José Batista Volpon. Rua São José, 655, Ribeirão Preto, SP, Brazil, 14010160. hc.ortopedia@gmail.com

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was introduced into the acetabulum, thus creating a support to the pelvis and reducing the insufficiency of the gluteus medius. This technique received several variations, but Schanz contributed the most, by standardizing the level of osteotomy, transferring the support from within the acetabulum to the pelvis.² Although the Trendelenburg gait—due to abductor insufficiency—was improved, a great limitation persisted because of the shortening and positioning in limb abduction caused by surgery, which created other limitations, even in the opposite knee. This scenario changed in 1980, when Ilizarov added to the original technique a distal osteotomy in the femur to realign the lower limb and lengthen it at the same time.^{3,4} Currently, this technique is the most appropriate for treating loss of hip function in young people.⁵ Nevertheless, because it is a complex technique, performed in specialized centers and requires familiarity with the external fixation apparatus, there are few international reports about it and, as far as we know, none from Brazil. This report aims to evaluate our results with the technique of double femoral osteotomy by the Ilizarov's technique to treat the sequelae of destroyed hip in young patients.

MATERIALS AND METHODS

This study is an individualized, observational and descriptive series of cases carried out in a tertiary university hospital of the SUS network, approved by the Research Ethics Committee of the Institution (No. 913, 2018) and registered in Plataforma Brasil (No. 2,501,360), according to the 1995 Declaration of Helsinki. All study participants signed an informed consent form.

The sample was composed of individuals of both genders, older than 11 years at the time of treatment, with severe sequelae in one hip, who were submitted to Schanz's pelvic support osteotomy associated with distal osteotomy of the femur, to align the lower limb and correct the shortening (Ilizarov technique). The stabilization of the two osteotomies was carried out with the Ilizarov external apparatus. Cases treated from 2007 to 2017 were included. Individuals diagnosed with cerebral palsy or other neuromuscular conditions, or with impairment of both hips were excluded.

Data collection was performed in a single phase by reviewing medical records, with the following study variables: gender, age, basic etiological diagnosis, type of hip destruction, test to detect weakness in the hip abductor (Trendelenburg), difference in length of the lower limbs on panoramic radiography, difficulties found during treatment and gait clinical characteristics.

The events that occurred in the different stages of treatment were classified, according to Paley⁶ as problems, obstacles, and complications. Problems are the difficulties that do not require surgical intervention to be solved. Obstacles are difficulties solved with new surgical interventions. Complications are defined as injuries during surgery, or difficulties during lengthening that have not been solved and compromise the result.

Surgical technique

For planning the osteotomies, an anteroposterior radiograph of the basin, in supine position, and maximum hip adduction was taken (Figure 1A). In this radiograph, a line tangent to the sciatic ischial tuberosity was drawn until crossing the affected femur, highlighting the site for the surgery (Figure 1B). A second frontal radiograph of the basin was taken with the individual standing and supported only by the affected limb. Based on the horizontal line of the pelvis, tangent to the iliac crests, a perpendicular line was drawn towards the femur. Then the angle formed between this line and the longitudinal axis of the femur was measured and 15° were added for hypercorrection (Figure 1C). This is the valgus-related angle for the proper pelvic support. In the frontal plane, if a flexural contracture occurs, it should be corrected, increasing 5°.⁷ Also, if a rotational misalignment occurs, it should be corrected at this time. The second osteotomy is carried out distally in the femur for limb lengthening and frontal axis correction and, before the

surgical procedure, it should be simulated with cut-out on tracing paper. The osteotomy level is located at the intersection site of the proximal mechanical axis (perpendicular to the horizontal line of the pelvis, passing through the apex of the proximal osteotomy) and crossing the longitudinal axis of the femur (Figure 1D). The final mechanical axis, after angular corrections, must be perpendicular to the horizontal line of the pelvis (Figure 1E).⁷

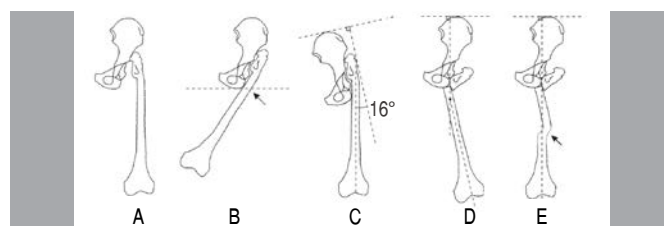


Figure 1. Surgical planning of the technical procedure.

A: example of destruction of the left femoral head, with limb shortening and pelvic-femoral instability; B: a line tangent to sciatic tuberosities is drawn on the radiograph with maximum hip adduction. This will be the valgus-related angle for the pelvic support; D: then a simulation of the proximal osteotomy is carried out, with cut-outs on tracing paper. The second osteotomy is performed distally, and it determines the positioning of the external fixation apparatus hinge that is determined by the intersection of the proximal and distal axes of the limb; E: distal osteotomy is distally located to the axis of the fixation apparatus (arrow). The final mechanical axis after lengthening and sweeping for axis correction must be perpendicular to the horizontal line of the pelvis.

In the surgery, the angulation of the proximal osteotomy was sharply carried out, according to the planned angle. Distal percutaneous osteotomy was carried out at the site previously estimated after the external fixation apparatus was installed. In this osteotomy, both angulation and lengthening were performed progressively, according to the Ilizarov technique.

RESULTS

Out of the eleven subjects studied, six (54.6%) were male, aged between 11 and 20 years old at the time of surgery, 14.7 years as means age and a median of 15 years. Seven patients presented sequelae of septic arthritis of the hip, three presented sequelae of developmental dysplasia of the hip, and one had sequelae of slipped capital femoral epiphysis. Furthermore, 10 (90.9%) patients presented a dislocated hip before the surgery and, in nine of them (81.8%) the femoral head disappeared on the radiograph. In two cases (18.2%) the head of the femur had been surgically resected. The mean follow-up time was three years.

Figure 2 shows a case, with radiographs before, during and at the end of the treatment.

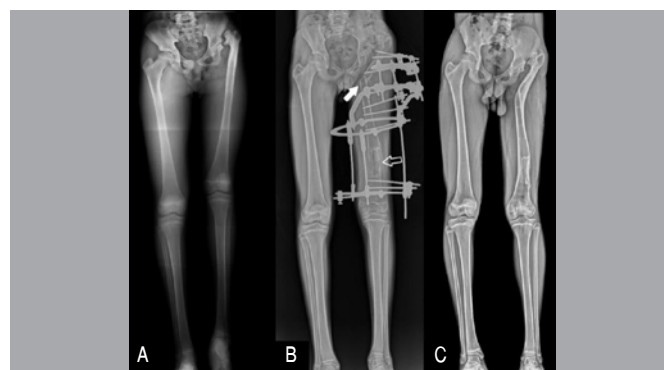


Figure 2. Sequence of radiographs illustrating the main technical steps.

A: panoramic radiographs of the lower limbs of a 13-year-old patient with childhood infectious arthritis. Preoperatively, the hip is dislocated, in adduction and great shortening of the left lower limb; B: aspect after pelvic support osteotomy and during the axis correction and limb lengthening. The full arrow shows the proximal osteotomy and the empty arrow indicates the site of distal osteotomy, as well as the segment in lengthening; C: End of treatment. There are 3 cm of shortening left that still cause pelvic inclination. A new lengthening can be planned in the distal region of the femur.

In the preoperative assessment, we observed that all patients could walk, but with an equinus foot deformity, limp or contralateral knee flexion as a compensation. The limp was caused by hip abductor insufficiency and limb shortening. The Trendelenburg test presented positive results in all cases and 10 of them (90.9%) were normalized after treatment. The discrepancy in the length of the lower limbs before treatment ranged between 2.5 and 7 cm, with a mean of 5 cm and, at the end, it was reduced to a mean of 1.9 cm (0 to 4 cm). According to the Paley classification,⁶ eight individuals presented problems (72.7%), 10 presented obstacles (90.9%) and three presented complications during limb lengthening (27.2%). The issues were: stiffness on the knee joint in one individual (9%) and infection in the external fixation pins of the apparatus of seven individuals (63.6%). These cases were treated with physical therapy and antibiotics, respectively. The obstacles found consisted of restricted range of motion of the knee, which was resolved by manipulation under anesthesia, in 10 cases (90.9%). There was one case of early consolidation of the regenerated bone, one case of recurve deformity of regenerated bone and two cases of late fracture in the proximal osteotomy (18.1%). The bone fractures were surgically resolved with open reduction and internal fixation with a molded plate according to the previous valgus-related angle osteotomy, redoing the pelvic support (Figure 3). Early consolidation was solved with osteotomy of the regenerated bone. A total of two cases (18.1%) were considered a complication, with limited range of motion on the knee, and they were not solved by manipulation under anesthesia and were treated with quadricepsplasty and recovery of part of the functional range of motion. No patient in this study presented consolidation delay, pseudoarthrosis, deep infection or neurovascular injury.



Figure 3. Illustration of complication after the treatment and its solution. A: figure of a complication with bone fracture at the site of proximal osteotomy in a 15-year-old patient; B: aspect after the pelvic support was rebuilt and fixed with low contact plate. The plate was previously angled to maintain the support achieved before the fracture.

DISCUSSION

A hip in a vicious, unstable, and painful position, due to great destruction of the joint, as in the cases presented in this report, causes several gait and posture disorders due to pelvic instability. Shortening and associated vicious contractures are also considered. As a result, the individual tries to rebalance in order to compensate some

insufficiency by making an exaggerated contralateral inclination of the trunk in the support phase of gait, associated with hyperlordosis of the lumbar spine and increased pelvic anteversion, if there is contracture in hip flexion. This process leads to muscle fatigue and great overload of the spine, which hampers the treatment of low back pain. Thus, the proximal pelvic support osteotomy aims to improve the mechanical conditions of gait and posture.^{1,9} The objective is to medialize the center of gravity as close as possible to its original position, thus reducing the mechanical lever arm and relieving the abductors.¹⁰ The osteotomy also allows the correction of hip flexion contracture, if any, which did not occur in the cases studied. For some time there was discussion whether the greatest effect of osteotomy would be by supporting the pelvis itself or by improving the strength of the gluteus medius. These questions are based on the observation that in some younger patients the angle was remodeled by age growth, but pelvic stability was maintained. Furthermore, magnetic resonance imaging showed that a significant improvement in muscle mass of the gluteus medius occurred after surgery.⁹ This muscle mass enhancement is due to the repositioning further away from the trochanter, with increased lever arm for abductors.¹ Currently, both effects are considered significant and the surgery is recommended after 12 years of age, when the ability of spontaneous osteotomy rectification is lower. The median age in our series was 15 years, and the youngest patient was 11 years old.

Currently, with the use of total hip prosthesis, these patients are treated by arthroplasty. One of critics on pelvic support osteotomy is that it can hinder the performance of an arthroplasty in the future, since the intramedullary canal of the femur will be deformed and both residual defects of the cortex and adhesions may occur.^{10,11} Another possible complication would be pain caused by the impact of the osteotomy angle on the ischium,¹² but this has not been reported in the literature.

Pain was not assessed because it was not reported in any case, perhaps due to low age. The technique is complex, involves significant risks, but we had no irreversible complications. All patients in the study presented complications during the proposed treatment, 90.9% of which required new procedures under anesthesia, such as manipulation of the knee joint and treatment of infectious processes around the fixation wires. Patients and family members should be well-guided about the length of treatment, high rate of complications and realistic expectations. An unusual complication, because we did not find reference to it in the literature, were two fractures in the proximal osteotomy region. Usually the local repair bone presents good quality when using the Ilizarov apparatus, in any condition. One possibility to avoid this complication would be prophylactic fixation of proximal osteotomy with a plate at the same surgical time as the external fixation apparatus was removed. One of the problems that we could not fully address was the shortening, whose correction was partial in some cases, due to severe limitation of knee movement. Thus, further lengthening is one possibility to complete the correction.

CONCLUSION

The double femoral osteotomy analyzed here provided good results considering the severity of the sequela and the lack of another therapeutic option. There were no major complications associated with the treatment, but there was incomplete correction of the shortening.

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QUALITY OF LIFE AND CHALLENGES OF FAMILY MEMBERS OF CHILDREN WITH MENINGOMYELOCELE

QUALIDADE DE VIDA E DESAFIOS DE FAMILIARES DE CRIANÇAS COM MIELOMENINGOCELE

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ABSTRACT

Objective: To identify the main challenges of the family of a child with meningomyelocele (MMC) and correlate the Zarit Burden Interview (ZBI) scale with the World Health Organization Quality of Life-BREF (WHOQOL – BREF). **Methods:** Questionnaires were sent through an online platform to groups of parents and caregivers of children with MMC. Four WHOQOL-BREF domains were evaluated: physical, psychological, social and environmental. **Results:** All correlations among the domains of the WHOQOL-BREF questionnaire with the Zarit Burden Interview (ZBI) scale were negative and significant with a higher magnitude value for ZBI × psychological domain with – 57.4% correlation ($p < 0.001$). **Conclusion:** The results of this study suggest the quality of life of mothers and caregivers of children with meningomyelocele is affected regarding functional capacity, emotional aspect, and mental health. Despite this, the participants present a positive view of their lives. The most common difficulties faced by caregivers were: performing bladder catheterization, providing general care, financial burden, and accessibility. **Level of Evidence V, Expert opinion.**

Keywords: Meningomyelocele. Neural Tube. Caregivers. Quality of Life.

RESUMO

Objetivo: identificar os principais desafios da família de uma criança com Mielomeningocele (MMC) e correlacionar a escala de Zarit Burden Interview (ZBI) com o WHOQOL-BREF. **Métodos:** Foram enviados questionários via plataforma on-line para grupos de pais e cuidadores de crianças com MMC. Quatro dimensões foram avaliadas: física; psicológica; relações sociais; e meio ambiente do WHOQOL-BREF. **Resultados:** Todas as correlações entre os domínios do questionário WHOQOL-BREF com a escala de Zarit Burden Interview (ZBI) foram negativas e significativas com maior magnitude de valor para ZBI × domínio psicológico com – 57,4% de correlação ($p < 0,001$). **Conclusão:** Os resultados desse estudo sugerem que a qualidade de vida das mães e cuidadores de crianças com MMC é afetada em relação a capacidade funcional, aspecto emocional e saúde mental. Apesar disso, apresentam uma visão positiva de sua vida. As dificuldades mais encontradas pelos cuidadores foram: realizar o cateterismo vesical; prestar cuidados gerais; financeira; sobrecarga de trabalho; e acessibilidade. **Nível de Evidência V, Opinião do especialista.**

Descritores: Meningomielocelo. Tubo Neural. Cuidadores. Qualidade de Vida.

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INTRODUCTION

Meningomyelocele (MMC) is a malformation of the nervous system and is considered a complex defect in the neural tube closure. This change occurs in the fourth week of embryogenesis associated with frequent and severe neurological sequelae, which can cause significant morbidity and mortality.¹

The prevalence of MMC in the world is one child per thousand live births; this is also the average incidence in the United States.

Moreover, the lower the socio-economic development of the country, the higher the meningomyelocele index, as shown by the birth defects map published by the World Health Organization.^{2,3} There are several reports on MMC prevalence, in Brazil and in Latin America in the literature. Some of the data related to it are: 1.139/1,000 live births,⁴ 5/1,000 1.2/1,000, an average of 1.01/1,000 live births.⁵

A study on the effect of folic acid before and after the pre-natal process using a historical series of data from the state of

All authors declare no potential conflict of interest related to this article.

The study was conducted at Instituto de Assistência Médica ao Servidor Público Estadual.

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São Paulo, Brazil, found that MMC prevalence decreased by 35% from 0.57 to 0.37 per thousand live births after folic acid fortification.^{6,7} When dealing with a child with MMC needs, the family has the responsibility of providing basic care for nutrition, hygiene, stimulation to growth and development, as well as specific care resulting from organic dysfunction, such as urination problems, depending on the child's neuromotor impairment. In order to properly treat and maintain the health of a child with MMC, there is a need for continuous follow-up with a multidisciplinary team consisting of pediatrician, neurosurgeon, orthopedist, urologist, geneticist, nephrologist, physical therapist, nurse, psychologist, and social worker, who must work in an integrated way, as the child needs to be assisted in various aspects.⁸

The daily life of caregivers of children and adolescents with meningomyelocele at home is full of care and undergoes profound transformations within various emotional, economic and social aspects of the family.⁹ The approach to quality of life and burden of these caregivers, as well as their main difficulties, has not yet been addressed with relevance in the literature.

The aim of this study is to identify the main challenges of the family of a child with meningomyelocele and their impact on the quality of life of these individuals.

MATERIALS AND METHODS

This is a cross-sectional study and was approved by the ethics committee of the institution.

Questionnaires were sent through an online platform. The invitations were sent via Facebook to groups of parents and caregivers of children with meningomyelocele, who participated in websites and/or social networks about the subject (Table 1).

Table 1. Reliability statistics of World Health Organization Quality of Life-BREF questionnaire and Zarit Burden Interview scale.

Methodology	Cronbach alpha	Cronbach alpha based on standard items	N of items
WHOQOL-BREF	0.932	0.935	26
Zarit Burden Interview (ZBI) scale	0.887	0.895	22

The questionnaires were answered by the person directly responsible for the care of the individual with MMC, with an informed consent form. Family caregivers of children diagnosed with MMC were included, aged 0 to 15 years.

Data collection was performed through an online platform, directed and structured in two parts: the first, consisting of socio-demographic data involving the caregivers, through questions related to their age, gender, marital status, education, family income, knowledge about pathology and care provided; the second, through two instruments: the Zarit Burden Interview (ZBI) scale¹⁰ and WHOQOL-BREF,¹¹ focused on the quality of life of caregivers and how they feel about their own quality of life, health, and other related domains.

The ZBI scale evaluated the caregiver's burden through 22 questions subdivided into items on the caregiver-patient relationship, health condition, psychological well-being, finance, and social life.

Searching for an instrument to assess the population's quality of life, the World Health Organization (WHO) created a Quality of Life Study Group (WHOQOL Group), with the purpose of studying the concept and developing measurement instruments, from a cross-cultural perspective.¹²

Statistical analysis

For the four WHOQOL-BREF dimensions evaluated: physical, psychological, social and environmental, descriptive statistics were generated such as average, standard deviation, coefficient of variation and minimum and maximum.

In order to verify the reliability of the questionnaire among the variables each response level was converted into numbers. To assess the quality of the questionnaire applied, the conventional Cronbach alpha coefficient and the standard alpha coefficient were used.

To correlate WHOQOL-BREF with the ZBI scale, Pearson's correlation was used.

RESULTS

A total of 124 questionnaires were obtained through an online platform. The conventional Cronbach alpha for WHOQOL-BREF was 0.932 (n = 26 questions) and the standard alpha was 0.935 (n = 26 questions). For the ZBI scale, the conventional Cronbach alpha was 0.887 (n = 22 questions) and the standard alpha was 0.895 (n = 22 questions) (Table 2).

Regarding the participants' profile, the average age was 34.96 ± 7.87, and 98.39% (n = 112) were female; 37.90% (n = 47) had high school + some high school and 47.58 (n = 59) had college + some college; 74.19% (n = 92) had their own housing; 68.55% (n = 85) were married; 31.45% (n = 39) had average income of 1.5 minimum wage, and 33.90% had income over three minimum wages.

Practically two-thirds of the participants (n = 81) stated they had medium knowledge about meningomyelocele and 29% affirmed they had a lot of knowledge about the illness. 44.35% (n = 55) reported no difficulties with care.

In addition, the most common difficulties encountered by family caregivers were: bladder catheterization (16.94%, n = 21), general care (16.94%, n = 21), burden (13.71%, n = 17) and accessibility (13.71%, n = 17).

A total of 39% of the participants had help from a specialist or health institution; 28.23% reported help from relatives; 4.84% from social networks; 3.23% had spiritual help. A quarter of the patients reported they had no help at all.

A total of 72.58% of the homes (n = 90) were not visited by nurses. In the visits that did occur, topics discussed were how to perform catheterization (26.47%, n = 9), general children care (8.82%, n = 3) and vaccination (5.88% n = 2). However, 51.53% (n = 17) of caregivers stated that information provided by health professionals was not clear or did not correspond to reality.

Regarding the self-referred participants' quality of life mentioned in the WHOQOL-BREF questionnaire, 66% considered it to be good or very good (Figure 1).

Table 2. Descriptive statistics of the four domains of World Health Organization Quality of Life-BREF.

Domain	Average	Standard deviation	Coefficient of variation	Minimum	Maximum	Amplitude
Physical	3.32	0.68	20%	1.43	4.57	3.14
Psychological	3.39	0.71	21%	1.50	4.67	3.17
Social	3.09	0.83	27%	1.00	4.00	3.00
Environmental	3.01	0.63	21%	1.38	4.13	2.75
Overall average	3.22	0.90	19%	1.52	4.26	2.74

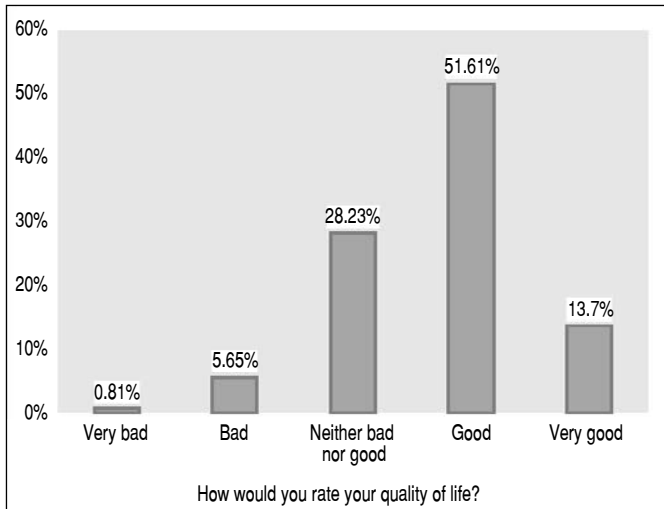


Figure 1. Quality of life profile of family members and caregivers of children with meningomyelocele.

In terms of caregivers' health satisfaction, 45.16% (n = 56) of them reported being satisfied with their health and 4.84% (n = 6) were very satisfied.

The domains of the WHOQOL-BREF questionnaire were divided into subdomains, and the domains with the lowest averages were social relationships (3) and environment (3.1). These domains presented Likert scale values below the overall average of 3.22. The subdomains with the lowest score were: participation and opportunities for recreational/leisure – environmental domain (2.5), financial resources – environmental domain (2.5) and sleep and rest – physical domain (2.9) (Figure 2).

The domains with scale above the general average were the physical and psychological. The domain with the highest variability was "social relationships" (Table 3).

All correlation among the domains of the WHOQOL-BREF questionnaire with the ZBI scale were negative and significant with similar results to those found by Caro et al. in 2018 (Table 4)

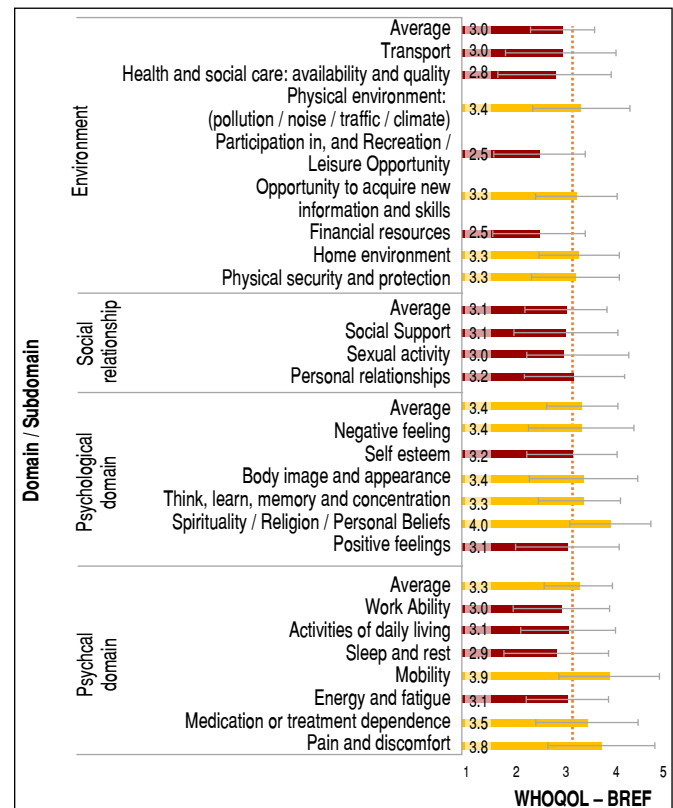


Figure 2. Domains and subdomains measured on WHOQOL-BREF scale.

Table 3. Correlation between World Health Organization Quality of Life-BREF domains with Zarit Burden Interview scale.

Domains		Physical	Psychological	Social	Environmental	Total – Zarit Burden Interview (ZBI) scale
Physical	Correlation	1	0.727*	0.613*	0.681*	- 0.567*
	P- value		< 0.0001	< 0.0001	< 0.0001	< 0.0001
	N		124	124	124	124
Psychological	Correlation		1	0.667*	0.676*	- 0.574*
	P- value			< 0.0001	< 0.0001	< 0.0001
	N			124	124	124
Social	Correlation			1	0.512*	- 0.452*
	P- value				< 0.0001	< 0.0001
	N				124	124
Environmental	Correlation				1	- 0.472*
	P- value					< 0.0001
	N					124
TOTAL – Zarit Burden Interview (ZBI) scale	Correlation					1
	P- value					
	N					

*: Correlation is significant at level 0.01 (2 ends).

Table 4. Comparison between correlations found in Zarit Burden Interview scale and World Health Organization Quality of Life-BREF.

Correlation	Current study	Caro et al. (2008)
ZBI × Physical domain	- 0.567**	- 0.394*
ZBI × Psychological domain	- 0.574**	- 0.282 ^{ns}

Table 4. Comparison between correlations found in Zarit Burden Interview scale and World Health Organization Quality of Life-BREF.

Correlation	Current study	Caro et al. (2008)
ZBI × Social domain	-0.452 ^{**}	-0.040 ^{ns}
ZBI × Environmental domain	-0.472 ^{**}	-0.470 ^{**}

ns: not significant; **: significant at 1% by t-test; *: significant at 5% by t-test.

When considering the ZBI burden classes, we noticed that 51.61% (n = 64) of caregivers fall into the moderate burden category and 13.71% (n = 17) between the moderate to severe category. One-third on average had no burden 33.87% (n = 42), and less than 1% (n = 1) had severe burden (Figure 3).

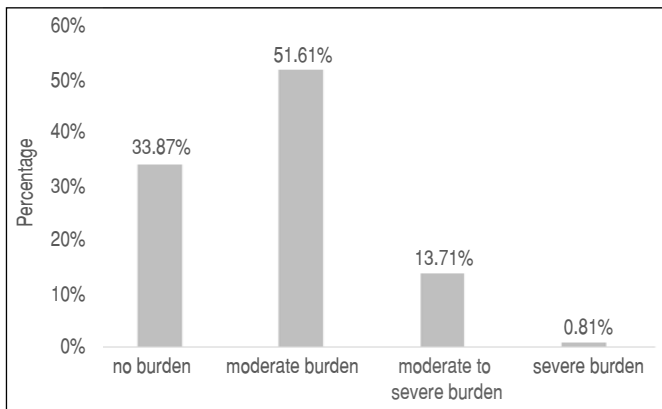


Figure 3. ZBI burden classes.

DISCUSSION

The study presented high internal consistency between responses since the alpha coefficients were 0.932 (WHOQOL-BREF) and 0.887 on the ZBI scale. In a study aimed to determine the strength of association between coping strategies and quality of life in adolescents with spina bifida using a KIDSCREEN – 52 questionnaire obtained an alpha of 0.93.¹³ In another study that evaluated the correlation between burden and quality of life of caregivers of children with meningomyelocele, the Informal Caregiver Burden Assessment Questionnaire (QASCI) was applied. The questionnaire evaluates the perception of burden in informal caregivers. In the WHOQOL-BREF questionnaire that also evaluates the perception of individuals' quality of life, the Cronbach alpha was 0.88, showing good reliability.¹⁴

Quality of life implies different forms of understanding. According to Cipriano,¹⁵ quality of life is defined by the individuals' feeling of well-being. These feelings can be measured objectively (income, employment, housing, material assets) and subjectively (security, privacy, recognition, affection, love, peace).

On average, 98.39% of responding caregivers were women (Figure 1), as well as 87.5% of volunteers from forty caregivers of patients with MMC recruited in two institutions. The predominance of women is in line with what was found in the literature, where the tradition of women is emphasized in assuming the primary responsibility of caring for children, the older population and the bedridden.¹⁴ It is emphasized that the mother was the main representative in the monitoring and care of these children as they were present in all consultations and other forms of care.

Figure 3 shows that only 5.65% had little knowledge of MMC. Although the mothers presented little or no knowledge about the child's condition until the time of diagnosis, we found that after the initial shock of the news about their child having the condition some of the mothers were in search for information about the

illness. The search for guidance and support in the process of caring for their children is a valuable resource in coping with their child's condition, as well as with other people in society. The initial denial of the illness and revolt in front of the situation changes slowly with the acquisition of information. This information can be acquired through contact with other mothers, whose children live in the same situation.¹⁶

The main difficulty in caring for children with meningomyelocele is bladder catheterization. Thus, the families of these children also learn to live with prejudices and stigmas related to motor difficulties and urinary and fecal incontinence. Both interfere with social activities. In a study investigating the thoughts and feelings of family caregivers about performing daily care in children with MMC (such as catheterization), it was suggested there should be physician participation and even the need for a psychologist to work with the interdisciplinary team, so these professionals can manage emotional difficulties with everyone involved in this exhausting procedure.¹⁷

The literature reveals that mothers of children with neurogenic bladder report attrition due to the burden or supervision required, leading to physical, psychic and social problems in their own lives. Some factors may interfere with the quality of life of caregivers of patients with MMC, such as socioeconomic status, injury site, locomotive difficulties and chronic illness associated with the caregiver.¹⁸ The long period spent and high cost involving care lead to financial difficulties.¹⁹ The visits of nursing professionals at the participants' homes are insufficient since 72.58% do not have frequent visits by professionals and when they do, it is generally to provide information on bladder catheterization (Figure 2). The absence of health professionals in the homes of children with MMC is a known issue. Unlike many health professionals, families often do not find catheterization simple. Many caregivers describe this procedure as something that binds them with the child, due to the need of the procedure to be performed several times a day.¹⁶

The quality of life profile for family caregivers of children with MMC was considered good and very good, totaling 65.31% considering the sum of both cases (Figure 1). The search for guidance and support in the process of caring for their children is a valuable resource in coping with their child's condition, as well as with other people in society. Attempting to preserve and care for the quality of life of their children, mothers put themselves behind by neglecting aspects such as vitality, mental and emotional health; as such, these results show us that the multidisciplinary team must also extend care to the families so they express their fears, anguish, and yearnings arising from physical and emotional weariness.¹⁸ In this study, the results found were different from those reported by the authors cited.

The domains and subdomains measured on the WHOQOL-BREF scale presented worse values for the environmental domain and the subdomains participation and opportunities in recreation and financial resources (Figure 2). This is probably because the caregiver is deprived of the means for leisure.

The WHOQOL-BREF method was developed collaboratively and simultaneously in several centers, including countries with different levels of industrialization, availability of health services, importance

of the family and dominant religions, among others, in addition to using an interactive data input among the researchers, at each stage of their development, allowing constant influence in the process.¹² The results found by Caro et al. (2018) aimed to identify the level of burden and quality of life of family caregivers of stroke patients and to investigate the correlation between burden and quality of life (including physical, social, psychological and environmental domains). Therefore, different correlations can be compared; the physical and environmental domains had negative and significant correlations in both studies.²⁰

On the burden index using the ZBI scale methodology the average score \pm standard deviation was 26.93 ± 13.09 (Figure 3). In a study conducted in two institutions where two different groups were evaluated (Group 1 with clean intermittent catheterization and Group 2 with use of diapers), the averages on burden were respectively 44.71 ± 10.92 and 22.94 ± 12.22 , showing a significant difference between groups ($p = 0.01$). The higher score of Group 1 can be explained by the fact that bladder catheterization takes longer to be executed, since the procedure needs to be standard at specific time intervals, and dealt with caution, as it is a clean and non-sterile technique designed to avoid any sort of infection or complications arising from the introduction of a catheter through the urethra.¹⁵

Subjectivity deals with human feelings, i.e., the qualitative perceptions of the experiences lived. Despite the difficulties presented, caregivers remain content with their quality of life and continue to break paradigms, facing often insurmountable barriers and challenges (Figure 4).¹ Many different problems may bring suffering and despair as caregivers know that treatment is a continuous process to improve the development and life of the child.

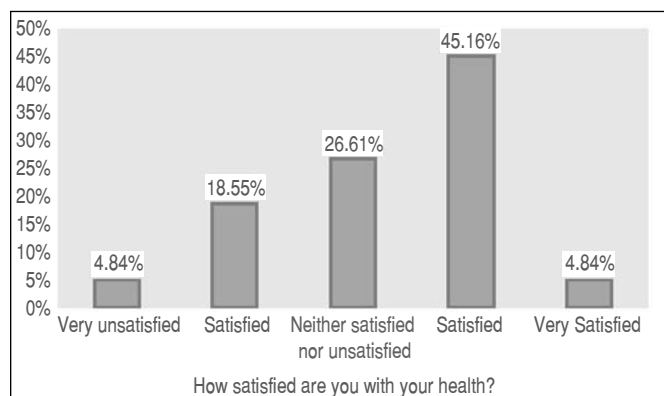


Figure 4. Profile related to health satisfaction of family members and caregivers of children with meningomyelocele.

CONCLUSION

The results of this study suggest that the quality of life of caregivers of children with meningomyelocele is affected regarding functional capacity, emotional aspect, and mental health. Despite this, the participants present a positive view of their lives. This ability to overlook problems and face difficulties is a striking feature of these families and should encourage programs to improve care and information for caregivers of children with meningomyelocele. The most common difficulties encountered by caregivers were performing bladder catheterization, providing general care, financial burden, and accessibility; however, even with these difficulties, they constantly find strength and correlate the welfare of the child to their own well-being.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. RSB: writing of the article, data analysis, interpretation, participation in the review process and approval of the final version of the manuscript to be published; MPN: design and planning of the activities that led to the study, study orientation, critical review of the intellectual content, and approval of the final version of the manuscript to be published.

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TRANSFORAMINAL INTERSOMATIC LUMBAR ARTHRODESIS: COMPARISON BETWEEN AUTOGRAFT AND CAGE IN PEEK

ARTRODESE LOMBAR INTERSOMÁTICA TRANSFORAMINAL: COMPARADO AUTOENXERTO E CAGE-PEEK

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ABSTRACT

Objective: To compare the postoperative outcomes of transforaminal intersomatic lumbar arthrodesis with structured iliac bone autograft and PEEK device. **Methods:** The total of 93 medical records of patients undergoing transforaminal intersomatic fusion between January 2012 and July 2017 with at least 1 year of postoperative follow-up, with complete medical record, containing clinical file and radiological exams, were reviewed. **Results:** From the medical records evaluated, 48 patients underwent the procedure with structured iliac autograft (group 1) and 45 with PEEK device (group 2). There was an improvement in functional capacity in both groups ($p < 0.001$), however there was no difference when comparing them ($p = 0.591$). **Conclusion:** The postoperative clinical and radiological results of lumbar arthrodesis with TLIF technique, using a structured iliac bone autograft compared to a PEEK device, were similar. **Level of Evidence II, Retrospective study.**

Keywords: Spinal Fusion. Laminectomy. Intervertebral Disc Degeneration.

RESUMO

Objetivo: Comparar os desfechos pós-operatórios da artrodese lombar intersomática transforaminal com autoenxerto ósseo ilíaco estruturado e dispositivo em poliéter-éter-cetonico-polímero (PEEK). **Métodos:** Foram revistos 93 prontuários de pacientes submetidos à fusão intersomática transforaminal entre janeiro de 2012 e julho de 2017 com pelo menos um ano de acompanhamento pós-operatório, com prontuário completo, contendo ficha clínica e exames radiológicos. **Resultados:** Dos prontuários avaliados, 48 pacientes foram submetidos ao procedimento com autoenxerto ilíaco estruturado (Grupo 1) e 45 com dispositivo em PEEK (Grupo 2). Houve melhora da capacidade funcional em ambos os grupos ($p < 0,001$), no entanto não houve diferença ao compará-los ($p = 0,591$). **Conclusão:** Os resultados clínicos e radiológicos pós-operatórios da artrodese lombar na técnica Fusão Intersomática Lombar Transforaminal (TLIF) utilizando autoenxerto ósseo ilíaco estruturado, em comparação com o uso de dispositivo em PEEK, foram semelhantes. **Nível de Evidência II, Estudo retrospectivo.**

Descritores: Fusão Vertebral. Laminectomia. Degeneração do Disco Intervertebral.

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INTRODUCTION

Spinal disorders are among the most common problems encountered in clinical practice,¹ affecting up to 80% of the population at some point in life.² Lumbar arthrodesis is used as a treatment alternative for patients with degenerative discopathies, spondylolisthesis, segmental instabilities, among others.^{1,3} It may or may not be associated with instrumentation, being subdivided depending on its approach such as: posterior fusion (PF), posterolateral fusion (PLF), anterior lumbar intersomatic fusion (ALIF), posterior lumbar intersomatic fusion (PLIF), transforaminal lumbar intersomatic fusion (TLIF) and lateral lumbar intersomatic fusion (LLIF).^{1,3}

The association of PLF with pedicular instrumentation presents consolidation levels of up to 92%.^{4,5} Including the intersomatic technique, it reaches rates of 96% in the case of PLIF associated with transpedicular fixation.⁵⁻⁷ PLIF requires major retraction of the dural sac and nerve roots, increasing the risk of dural injury and root injury.⁸ The transforaminal technique (TLIF) brought less manipulation of neural structures with unilateral access to the disc space, becoming the most used technique for lumbar degenerative disorders.⁹ The theoretical advantages of TLIF over PLF include anterior spine support, indirect foraminal decompression, removal of the disc as a pain generator, and restoration of lumbar lordosis.⁹

All authors declare no potential conflict of interest related to this article.

The study was conducted at Universidade Federal de São Paulo, Paulista School of Medicine, Sports Traumatology Center.

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To perform vertebral fusion, bone graft sums traditionally obtained from the patient's iliac crest,^{10,11} considered the gold standard, which provides mineral architecture for the orientation of bone growth and osteogenic factors.¹²

In this sense, this study aims to analyze clinical and radiographic parameters of patients submitted to lumbar arthrodesis by transforaminal technique using structured iliac autograft, as well as to compare postoperative clinical and radiographic results after lumbar intersomatic arthrodesis using structured iliac autograft and the PEEK device.

MATERIALS AND METHODS

The study was approved by the Research Ethics Committee under Protocol No. 1342, in 2017. All participants signed an informed consent form. Data from medical records from 2012 to 2016 from the database of a private hospital were included, where a search was performed for patients submitted to transforaminal intersomatic lumbar arthrodesis, of both genders, over 18 years of age, for the treatment of lumbar degenerative disease, such as spondylolisthesis, degenerative disease of the vertebral canal and spinal canal stenosis. As inclusion criteria, patients should have all been operated by the same surgical team, have intersomatic arthrodesis by transforaminal access of one or two vertebral levels, complete follow-up with medical records, imaging exams and questionnaires routinely applied by the group before and after the surgical procedure. Lumbar arthrodesis is indicated by the group in the presence of degenerative disease of the lumbar spine with segmental instability, previously submitted to clinical treatment for at least six months in the absence of neurological urgency. The medical records of individuals with active neoplastic or infectious disease, scoliosis with angulation greater than 15° and surgeries of three or more lumbar levels were excluded.

The patients were grouped as follows: Group 1 (structured iliac bone autograft, Figure 1) and Group 2 (PEEK device, Figure 2) according to the description of the surgical technique.

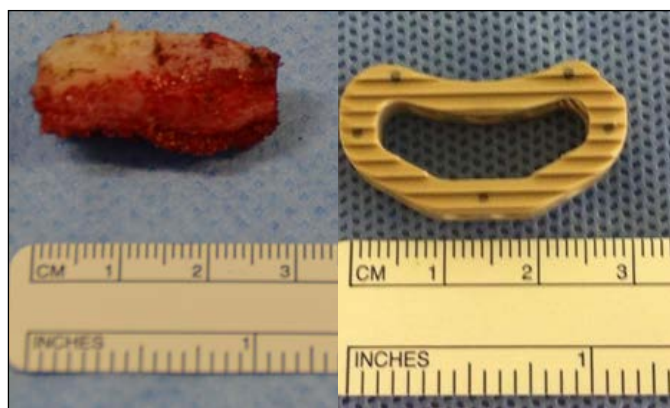


Figure 1. Photographs of the structured iliac graft and the spacer in polyether-ether-ketone polymer, demonstrating measurement of the laterolateral diameter, 2016.

All patients were submitted to antibiotic prophylaxis, performed according to the Hospital Infection Control Service (SCIH). Analgesia and postoperative standard rehabilitation.

All participants completed a socio-demographic and clinical form (age, gender, morbidity, smoking habit, time of clinical treatment, work activity, sports practice and time away from work), and completed the Oswestry Disability Index (ODI) dysfunction questionnaire in the version validated for Portuguese before and after 12 months of the surgical procedure.¹³



Figure 2. Photographs of the structured iliac graft and spacer in polyether-ether-ketone polymer, demonstrating measurement of the anteroposterior diameter, 2016.

Before surgery, patients underwent simple radiographs and MRI scans in the anteroposterior and lateral positions, as well as the lateral position with maximum flexion and extension. The scale of Pfirrmann et al.¹⁴ was used for classification of disc degeneration. The determination of muscle strength was according to the Medical Research Council scale for manual motor tests.¹⁵ Radiological measurements were carried out before the surgery and one-year after it, through the Software Surgimap® and Easy Pixel Tool® version 1.1 (for OS X 10.8 processor or later 64-bit). For the height of the intervertebral disc, the modified Farfan classification was used.¹⁶ The angle of the intervertebral disc and lumbar lordosis were measured according to Cobb's method (1948).¹⁷ For radiographic evaluation of fusion, criteria of the Food and Drug Administration Center for Devices and Radiological Health (FDA) were used, in which fusion is defined as angular motion smaller than five degrees and sagittal movement on dynamic radiographs less than three millimeters.¹⁸

Surgical technique

Performed by paramedian surgical access.¹⁹⁻²¹ Single incision in the skin, subcutaneous divulsion, removal of iliac bone graft including the anterior-superior iliac spine (right or left) totaling 2 or 2.5 cm of craniocaudal extension. The latero-medial size was the thickness of the iliac of the patient and a depth of 0.5 cm, so that muscle disinsertion was not performed, and the limits of the sacroiliac joint were respected. Removal of iliac spongy graft. The back-loin fascia was sutured along with the subcutaneous. We carried out the incision of two access routes in the back plate fascia, as well as muscle digitodivulsion, installation of polyaxial pedicular screws in L4 to S1 or L5-S1, hemyloaminectomy(s) of the most symptomatic side and facetectomies, transforaminal access to the disc, preparation of terminal plates and partial filling of the disc space (anterior to the intersomatic device) with iliac spongy bone graft.

Group 1: Manual preparation of the iliac bone autograft structured by additional osteotomies with a gouge, respecting the height of the disc space observed intraoperatively. Introduction by annulotomy by intersomatic positioning in the middle third of the vertebral bodies under traction, without intersomatic compression before torque in the fixation system.

Group 2: Measurement of the height of the intraoperative disc space under traction of the screws to determine the size of the

device. Introduction by annulotomy by positioning it intersomatic in the middle third of the vertebral bodies under traction, without intersomatic compression before torque in the fixation system. As shown in Figure 3:

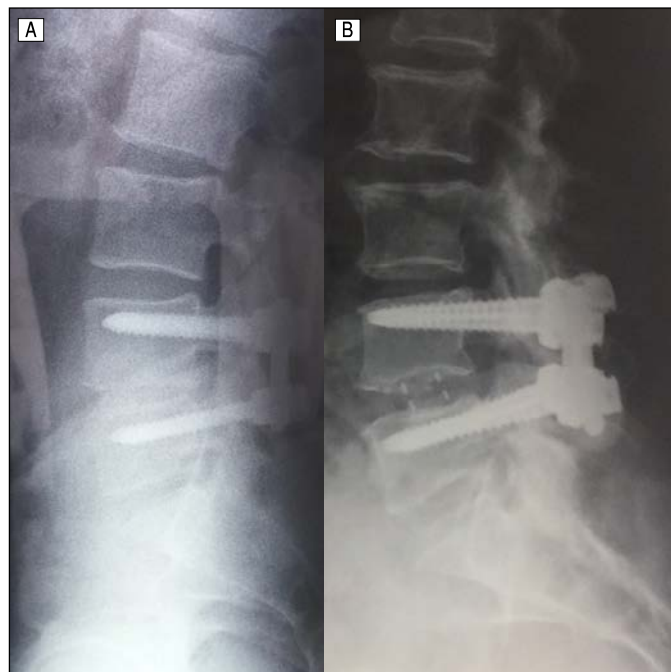


Figure 3. X-ray images of the lumbosacral spine in orthostatic profile illustrating intersomatic arthrodesis with structured iliac auto graft (A) and intersomatic device in PEEK (B), 2016.

Statistical analysis

Qualitative variables were presented by absolute and relative frequencies, while quantitative variables were presented by measures of central tendency and respective confidence intervals of 95%. To analyze the adherence of the data to the normal distribution, the Shapiro-Wilk test was used. In the associations between the qualitative variables, the chi-square test with Yates correction was used. For the analysis of the magnitude of the associations, we used Poisson regression with robust variance, estimating the prevalence ratio and respective confidence intervals of 95%, adjusted for the variables that presented association.

The quantitative variables with symmetric distribution were compared by Student's t-test for independent samples. The Mann-Whitney test was used for variables without normal distribution. To compare the differences in the pre- and postoperative moments, Student's t-test was used for paired samples. Linear Regression was used to estimate the effects of surgical techniques on height and disc angulation and lumbar lordosis between the groups at the moments studied. For all analyses, a 5% significance level was adopted. The program used was Stata® (StataCorp., LC) 11.0

RESULTS

After establishment of the inclusion criteria, we selected 93 patients treated with intersomatic arthrodesis of the lumbar spine by structured iliac bone autograft or peek device and their medical records were reviewed. Sociodemographic and clinical characteristics are described in Table 1.

Table 1. Characterization of patients treated with lumbar arthrodesis using transforaminal lumbar intersomatic fusion in polyether-ether-ketone polymer and structured iliac bone autograft, São Paulo, Brazil, 2012-2016.

Variables	N	%
Gender		
Female	40	43
Male	53	57
Number of Affected Locations		
1 location	63	67.7
2 locations	30	32.3
Comorbidities		
Smoking habit	26	28.3.
Physical Activity		
Preoperative	37	40.2
Post-operative	48	52.2
Employment	83	90.2
Pfirschmann		
III	7	5.4
IV	116	89.9
V	6	4.7
Pathologies		
Degenerative discopathy with compression	58	62.4
Degenerative discopathy without compression	6	6.3
Spondylolisthesis	18	19.4.
Central stenosis	1	1.1
Pseudoarthrosis	9	9.7
Synovial cyst	1	1.1
Strength deficit	59	63.4
Operated level		
L3-L4		
L4-L5	15	16.1
L5-S1	28	30.1
L3-L4 + L4-L5	6	6.5
L4-L5 + L5-S1	44	47.3
Reoperation due to mis-positioning	1	1.1
	Mean (SD)	(min-max)
Age	43.7 (9.0)	27-68
Time of prior treatment	16.4 (11.2)	4 – 48
ODI	31.5 (8.3)	10 – 50

SD: standard deviation; min-max.: minimum and maximum values, respectively.

Table 2 compares the preoperative sociodemographic and clinical characteristics of Groups 1 and 2, demonstrating homogeneity, except that physical activity is higher in the group treated with preoperative PEEK device ($p = 0.037$) and the presence of degenerative discopathy with compression is higher in the group where the autograft was used ($p = 0.016$).

The preoperative clinical and radiographic characteristics of patients in both groups were similar in terms of the presence of sciatica ($p = 0.683$), strength deficit ($p = 0.126$), site of injury (L3-S1) ($p = 0.630$), functional capacity ($p = 0.310$), lumbar lordosis ($p = 0.763$) and Pfirschmann radiological classification ($p = 0.617$), disc height at both level L4-L5 ($p = 0.139$) and L5-S1 ($p = 0.791$) and disc angulation ($p = 0.283$ and $p = 0.719$). These data showed that there were no differences between the groups for all variables in the preoperative moment (Table 3).

Table 2. Comparison of sociodemographic and preoperative clinical characteristics of patients treated with lumbar arthrodesis using structured iliac bone autograft and polyether-ether-ketone polymer device.

Variables	N 93 (100%)	Graft (n = 48; 51.6%)	PEEK (n = 45; 48.4%)	p*
		n (%)		
Male	40 (43.0)	27 (56.2)	26 (57.8)	0.882
More than one affected location	30 (67.7)	13 (27.1)	17 (37.8)	0.270
Comorbidities	5 (18.5)	4 (8.3)	1 (2.2)	0.192
Smoking habit	26 (29.3)	14 (29.8)	12 (26.7)	0.740
Preoperative Physical Activity	37 (40.2)	14 (29.8)	23 (51.1)	0.037
Employment	83 (90.2)	44 (93.6)	39 (86.7)	0.262
Pathologies, n (%)				
DD with compression	58	32 (66.7)	26 (57.8)	0.016
DD without compression	6	6 (12.5)	0 (0.0)	
Spondylolisthesis	18	9 (18.8)	9 (20.0)	
Central stenosis	1	0 (0)	1 (2.2)	
Pseudoarthrosis	9	1 (2.1)	8 (17.8)	
Synovial cyst	1	0 (0)	1 (2.2)	
	Mean	Median (95%CI)		p**
Age (years)	43.7	42.5 (39.7; 46.3)	42.0 (39.0; 47.2)	0.895
Duration of pre-operative treatment (months)	16.4	12.0 (9.0 – 18.0)	12.0 (12.0 – 18.0)	0.668

DD: Degenerative discopathy; 95%CI: 95% Confidence Interval; *: Chi-square with Yates correction; **: Mann-Whitney.

Table 3. Comparison of sociodemographic and preoperative clinical characteristics of patients treated with lumbar arthrodesis using structured iliac bone autograft and polyether-ether-ketone polymer device.

Variables	Graft (51.6%; n = 48)	PEEK (48.4%; n = 45)	p*
Sciatica, n (%)	39 (81.3)	38 (84.4)	0.683
Strength deficit, n (%)	34 (70.8)	25 (55.6)	0.126
Lesion site, n (%)			
L3-L4	2 (4.2)	1 (1.8)	0.63
L4-L5	21 (43.7)	29 (50.9)	
L5-S1	25 (52.1)	27 (47.3)	
Pfirrmann			
III	3 (4.5)	4 (6.0)	0.617
IV	59 (89.4)	57 (83.8)	
V	4 (6.1)	7 (10.2)	
Oswestry (Disability classification), n (%)			
Minimal disability (0 – 20)	0 (0.0)	1 (2.2)	0.31
Moderate disability (21 – 40)	1 (2.1)	4 (8.9)	
Severe disability (41 – 60)	21 (44.7)	18 (40.0)	
Crippled (61 – 80)	15 (31.9)	17 (37.8)	
Bed-bound or exaggerating symptoms (80 – 100)	10 (21.3)	5 (11.1)	

Table 3. Comparison of sociodemographic and preoperative clinical characteristics of patients treated with lumbar arthrodesis using structured iliac bone autograft and polyether-ether-ketone polymer device.

Variables	Graft (51.6%; n = 48)	PEEK (48.4%; n = 45)	p*
	Median (95%CI)		p**
Lumbar lordosis in degrees of angulation, mean (95%CI)	53.0 (48.6; 57.5)	54.1 (48.8; 59.3)	0.763
Height of discs in pixels, average (95%CI)			
L3-L4	19.1 (14.6; 23.5)	27.5***	-
L4-L5	22.2 (17.6; 26.8)	26.3 (22.8; 28.9)	0.139
L5-S1	25.1 (20.6; 29.6)	24.4 (20.8; 27.9)	0.791
Disc angulation, mean (95%CI)			
L3-L4	6.1 (- 30.7; 42.9)	0,2***	-
L4-L5	6.8 (4.7; 8.2)	5.3 (3.4; 7.2)	0.283
L5-S1	7.4 (5.4; 9.4)	7.9 (5.9; 9.9)	0.719

95%CI: 95% Confidence Interval; *: Chi-square with Yates correction; **: Student's t-test; ***: Just one participant.

The postoperative comparison is shown in Table 4. There was no significant difference between the groups in relation to sciatica ($p = 0.547$), improvement of muscle strength ($p = 0.0820$), return to work ($p = 0.472$), physical activity ($p = 0.292$) and months of absence from social insurance ($p = 0.889$).

Table 4. Comparison of postoperative clinical criteria of patients treated with lumbar arthrodesis with structured iliac bone autograft and the polyether-ether-ketone polymer device.

Variables	Graft (51.6%; n = 48)	PEEK (48.4%; n = 45)	p*
Sciatica, n (%)			
Stable	9 (18.8)	7 (15.6)	0.547
Improvement	39 (81.2)	37 (82.2)	
Worsening	0 (0)	1 (2.2)	
Analysis of muscle strength, n (%)	34 (70.8)	24 (53.3)	0.082
Return to work, n (%)	37 (78.7)	32 (71.1)	0.472
Practice of physical activity, n (%)	22 (46.8)	26 (57.8)	0.292
			p**
Months of absence, median and 95%CI	7.0 (6.0; 9.0)	7.0 (6.0; 10.8)	0.889

*: Chi-square with Yates correction; **: * Mann-Whitney Test.

Table 5 shows that the two groups showed significant improvement in the Oswestry index after arthrodesis ($p < 0.001$), and there was no difference when comparing the two techniques ($p > 0.05$). Regarding radiological parameters, there was no significant difference when comparing lordosis, height and pre- and postoperative disc angulation in both groups ($p > 0.05$).

Figure 4 shows the reduction of functional disability of patients one year after surgery, with no pre- and postoperative differences between them. There was a gain of 81.8% in patients operated using the technique with structured iliac bone autograft and 75.6% in patients with the PEEK device.

Table 5. Clinical and radiological characteristics in the pre- and postoperative period of patients treated with lumbar arthrodesis using structured iliac bone autograft compared to the polyether-ether-ketone polymer device.

Variables	Graft (51.6%; n = 48)				PEEK (48.4%; n = 45)				Postoperative Difference	p**
	Preoperative	Postoperative	Difference	p*	Preoperative	Postoperative	Difference	p*		
Oswestry (score in % mean, 95%CI)	64.7 (60.1; 69.3)	20 (13.9; 26.1)	-44.7 (-50.8; 38.6)	< 0.001	61.2 (55.9; 66.4)	22.3 (16.4; 28.1)	-38.9 (-45.0; 32.7)	< 0.001	5.0 (-0.08; 10.1)	0.060
Lumbar lordosis (mean angulation, 95%CI)	53.5 (48.8; 58.2)	52.9 (48.3; 57.5)	-0.58 (-4.6; 3.5)	0.769	53.6 (48.3; 58.9)	54.1 (50.1; 58.0)	0.48 (-2.5; 3.5)	0.747	2.4 (-3.2; 8.0)	0.388
Disc height (average pixel count, 95%CI)										
L3-L4***	19.1 (14.6; 23.5)	13 (-7.0; 33.0)	-6.1 (-30.5; 18.4)	0.195	27.4	39.3	-11.8	-	17.9	-
L4-L5	22.2 (17.6; 26.8)	20.5 (15.8; 25.3)	-1.6 (-4.4; 1.2)	0.242	27 (23.3; 30.6)	26.5 (22.7; 30.2)	-0.5 (-3.2; 2.2)	0.724	1.2 (-2.9; 0.9)	0.548
L5-S1	24.5 (10.1; 28.8)	22.6 (19.1; 26.2)	-1.8 (-5.3; 1.7)	0.29	25 (21.3; 28.7)	23.1 (19.1; 27.1)	-1.9 (-4.5; 0.7)	0.148	-0.07 (-4.3; 4.1)	0.970
Disc angulation (mean in degrees, 95%CI)										
L3-L4***	6.1 (-30.7; 42.9)	5.2 (-10.0; 20.4)	-0.9 (-53.0; 51.2)	0.862	0.2	1.5	1.3	-	-2.2	-
L4-L5	6.9 (4.7; 9.0)	7.3 (5.7; 8.8)	0.4 (-0.9; 1.7)	0.533	5.3 (3.4; 7.2)	6.8 (5.8; 7.8)	1.5 (-0.1; 3.1)	0.059	1.01 (-0.94; 3.2)	0.285
L5-S1	7.6 (5.5; 9.6)	9.2 (7.6; 10.7)	1.6 (-0.14; 3.3)	0.07	7.4 (5.6; 9.1)	7.6 (6.0; 9.2)	0.2 (-1.6; 2.0)	0.807	-1.4 (-3.9; 1.1)	0.269

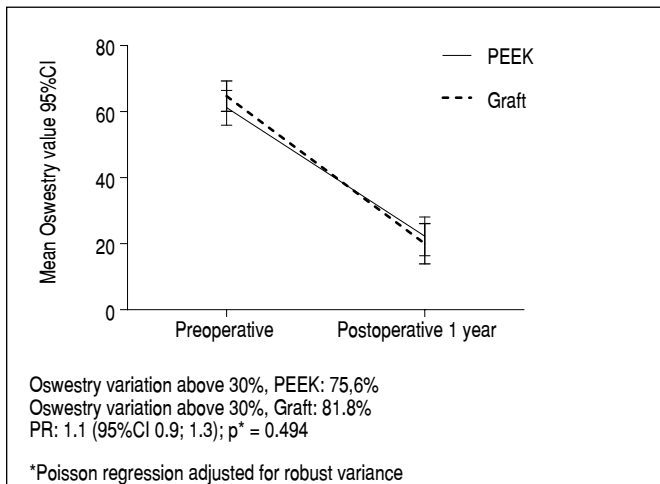


Figure 4. Comparison of differences in the percentage of improvement of the Oswestry Disability index of patients in the pre- and postoperative times (one year) treated with lumbar arthrodesis using structured iliac bone autograft and the polyether-ether-ketone polymer device.

DISCUSSION

The use of the intersomatic device in PEEK in lumbar arthrodesis is related to good results of gain of disc height, lumbar lordosis, improvement of functional capacity and indirect foraminal decompression. However, the main disadvantage is the high cost of the devices, especially for patients from developing countries and regions.²²⁻²⁴

In vertebral fusion surgery, the bone graft favors consolidation. Traditionally obtained from the iliac crest of the patient, it provides mineral architecture for bone growth guidance and osteogenic factors.^{11,12} The autograft of the iliac crest is considered the gold standard for spinal surgery.¹³ The osteoconductive and osteoinductive properties

of the iliac autograft allow excellent fusion rates, in addition to low surgical cost.²⁵⁻²⁹ However, postoperative complications may occur in the place of collection, mainly pain, infection and bleeding.²⁸ Postoperative pain at the site of bone graft collection is reported in 6% to 39% of cases. Many patients who have not undergone iliac bone graft collection may present pain in the vicinity of the posterosuperior iliac spine after the surgery, overestimating the true incidence of pain from bone graft collection.²⁹ There is no consensus in the literature on the prevalence of pain at the collection site compared to residual low back pain in the patient, favoring the use of autologous bone graft, which is a low-cost and effective option for vertebral arthrodesis.²⁹

In the present study, pain in the collection site of bone graft was not a limiting factor. We believe that the performance of minimal muscle disinsertion in the site of graft collection, performed in all patients, contributed to the reduction of pain. Park et al.³⁰ reaffirmed that the iliac bone graft has properties of osteoconduction, osteoinduction and osteogenicity, having the chemistry, structure and porosity for bone formation due to the presence of active and latent osteoblasts. Spongy bones are easily revascularized and quickly incorporated, with no concerns about disease transmission and no risk of immunogenicity. Its use brings fusion rates of 80-93% according to the aforementioned author.

Intersomatic fusion can be performed using allograft, iliac autograft, impacted local autograft, carbon fiber cage, titanium cage, PEEK cage, among others.³¹ Buttermann et al.²⁵ compared clinically and radiographically the results of lumbar arthrodesis using femoral ring allograft and iliac crest autograft. They observed a pseudoarthrosis rate of 6% in cases where allografts were used and no pseudoarthrosis when the autograft was used. We believe that careful dissection, as well as sensible preparation of terminal plates and use of iliac autograft favored the intervertebral fusion index for both groups of our study.

Autologous bone fragments obtained at laminectomy (local autograft) are often used and have similar fusion rates but are not always available in sufficient quantity.³¹⁻³⁵

Martinelli et al.²² evaluated the disc height and lumbar lordosis comparing the TLIF and PLIF techniques in a retrospective study, concluding that both techniques showed benefits, with no significant difference when comparing them. In the present study, lumbar lordosis and pre- and postoperative disc height were compared. There were no statistically significant differences comparing within or between the two groups.

Ly et al.²³ compared the TLIF technique with cage and impacted local autograft and concluded that there were no significant differences in clinical (ODI) and radiological (disc height and vertebral fusion) results. In addition, they concluded that the procedure without the cage has lower cost and thus the impacted bone graft is a good option for cases of single-level TLIF, especially in less developed regions. Zhang et al.³² studied spondylolisthesis in two lumbar segments operated through the PLIF technique and compared the group with cage and the group with local autograft. They observed that there was a high degree of loss in disc height in the local autograft group, concluding that the use of the cage is better for height maintenance of the intervertebral disc. The present study demonstrated divergent results since no significant differences were found in disc height between the groups. This can be explained by the fact that we used structured iliac autograft made in the form of a cage, a factor that may have contributed to the maintenance of disc height, considering that in most cases the removed local graft is fragmented and does not provide support.

Wang et al.³³ compared results of the posterior arch autograft associated with a facet joint as a spacer and another group treated with a PEEK cage filled with autograft in the treatment of lumbar isthmic spondylolisthesis in adults and obtained similar clinical and radiographic results in both groups. The use of an intersomatic

device in PEEK increases its cost, so a local autograft using the facet joint for intersomatic fusion was effective and accessible in the treatment of lumbar isthmic spondylolisthesis.

Wu et al.³⁴ studied a new intersomatic allograft device designed for TLIF, using ODI, the Visual Analogue Scale, disc height and vertebral fusion with 1-year follow-up, and concluded that there was no statistical difference in relation to disc height compared to PEEK, reaching consolidation levels of 98.2%.

Studies on device sinking in vertebral bodies conducted by Choi et al.³⁵ and Marino³⁶ concluded that small loss of disc height and lumbar lordosis are expected in intersomatic arthrodesis and that they do not affect clinical outcomes. Le et al.³⁷ e Kim et al.³⁸ concluded that loss of disc height and lumbar lordosis are related to the consolidation and accommodation of the sagittal balance of the spine, to the realization of direct decompression of the nerve root or the *cauda equina* and especially to the excessive sinking of the intersomatic device in the terminal plates. In our study there were no differences in relation to lumbar lordosis and disc height within or between the groups, both before and after the surgery. The limitations of the study are related to retrospective design as well as data surveying and collection. The inconsistency of data in medical records can be considered a form of measurement bias in retrospective cohort studies. Furthermore, the tests and reports in the database do not always present quality of completion and information.

CONCLUSION

We observed that the TLIF technique using structured iliac autograft may be a good option as it presents low cost and good clinical results, comparable to the synthetic intersomatic spacer.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article: RSS: performed surgeries, data analysis, writing, review and intellectual concept of the article; DEM: data analysis and writing of the article; MK: data analysis and writing of the article; ICES: data analysis and writing of the article; NA: intellectual concept and critical review of the article; MW: intellectual concept and critical review of the article. All authors approved the final version of the manuscript.

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DETERMINANTS OF RETURN TO PLAY AFTER ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION

DETERMINANTES DO RETORNO AO ESPORTE APÓS RECONSTRUÇÃO DO LIGAMENTO CRUZADO ANTERIOR

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ABSTRACT

Objective: To systematically review and meta-analyze the performance of return to play (RTP) and non-RTP patients in different assessment tools after anterior cruciate ligament reconstructions (ACLR). **Methods:** Out of 182 studies searched on PubMed, 11 presented RTP and non-RTP groups assessing the performance of young individuals, practitioners of different sports, with different tools. **Results:** There was higher limb symmetry (7.13% [95%CI 4.55; 9.70], $p < 0.001$), Tegner activity scale (2.41 [95%CI 0.18; 4.64], $p = 0.03$), functional scores such as International Knee Documentation Committee (x7.44 [95%CI 4.69; 10.19], $p < 0.001$), Knee Osteoarthritis Outcome score for quality of life (14.75 [95%CI 10.96; 18.54], $p < 0.001$) and for sports/recreation (11.86 [95%CI 8.87; 14.86], $p < 0.001$); and lower knee laxity (-0.25 mm [95%CI -0.36; -0.14], $p < 0.001$) in RTP compared to non-RTP patients following ACLR. **Conclusion:** We confirmed that these different tools can differentiate RTP for non-RTP patients, which may contribute to the physician's decision about the ideal time for RTP. **Level of Evidence III, Systematic review of Level III studies.**

Keywords: Anterior Cruciate Ligament Reconstruction. Sports. Arthroplasty. Knee.

RESUMO

Objetivo: Revisar sistematicamente e meta-analisar o desempenho de atletas que retornaram (RTP) e não retornaram (não RTP) ao esporte em diferentes ferramentas de avaliação após cirurgia de ligamento cruzado anterior (RLCA). **Métodos:** De 182 estudos pesquisados no PubMed, 11 tiveram grupos RTP e não RTP avaliando a performance de jovens, praticantes de distintas modalidades esportivas, em diferentes ferramentas. **Resultados:** Houve melhor simetria dos membros (7,13% [95%IC 4,55; 9,70], $p < 0,0001$), escala de atividade de Tegner (2,41 [95%IC 0,18; 4,64], $p = 0,03$), escores funcionais como o International Knee Documentation Committee (7,44 [95%IC 4,69; 10,19], $p < 0,001$), Knee Osteoarthritis Outcome Score para qualidade de vida (14,75 [95%IC 10,96; 18,54], $p < 0,001$) e esportes/recreação (11,86 [95%IC 8,87; 14,86], $p < 0,001$); e frouxidão ligamentar do joelho (-0,25 mm [95%IC -0,36; -0,14], $p < 0,001$) em RTP comparados com pacientes não RTP após RLCA. **Conclusão:** Concluímos que essas ferramentas conseguem diferenciar pacientes RTP de não RTP, o que deverá contribuir com a decisão de médicos sobre o momento ideal de retorno ao esporte. **Nível de Evidência III, Revisão sistemática de Estudos de Nível III.**

Descritores: Reconstrução do Ligamento Cruzado Anterior. Esportes. Artroplastia. Joelho.

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INTRODUCTION

Although advancements has occurred in the last years regarding anterior cruciate ligament reconstructions (ACLR), some athletes cannot return to play (RTP). There is no consensus to indicate a precise criterion to release athletes and sports practitioners to RTP after ACLR. A systematic review, showed that 40% of 264 studies failed to provide any criteria for RTP, whereas most studies apply post-operative time as the sole criteria,¹ and only few studies applied criteria as muscle strength, range of motion, stability measurements, and questionnaires.¹ Although some associations of these criteria with poor prognostic in ACLR patients has been shown,^{2,3} we are not aware of a consensus

confirming whether these scores really differ in RTP and non-RTP patients. A few modifiable risk factors have been combined as a functional testing algorithm to support the decision for a rehabilitation treatment for RTP;⁴ however, one must consider, non-modifiable risk factors, such as age, gender or time post ACLR to RTP could determine RTP success.^{5,6}

This systematic review and meta-analysis aims to compare Limb Symmetry Indexes (LSI), Tegner activity scale, knee laxity, and functional scores such as International Knee Documentation Committee (IKDC), Knee Osteoarthritis Outcome score for quality of life (KOOS-QOL), and Sports/Recreation (KOOS-Sports) between RTP

All authors declare no potential conflict of interest related to this article.

The study was conducted at Universidade de Campinas

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and non-RTP patients after ACLR. The effects between RTP and non-RTP will support the decision-making process of physicians, physical therapists, athletic trainers, and coaches about treatments and facilitate the decision of ideal time for RTP.

MATERIALS AND METHODS

Study search and selection

We conducted a systematic search on MEDLINE with the last update on November 2018. The search included "anterior cruciate ligament reconstruction" as a MeSh term and "return to sport" as MeSh term or "Return to Play" in title and abstracts. The flowchart of the study is detailed in Figure 1. We selected the studies comparing surgery success of RTP individuals and non-RTP individuals after ACLR. Six patient-oriented outcome measures were chosen due to their applicability in clinical practice as well as the prevalence of these outcomes on the studies included. Thus, we included in the systematic review studies reporting measures for at least one of the selected outcomes: LSI, Tegner activity scale, knee laxity, IKDC, KOOS-QOL and KOOS-Sports.

Studies were selected independently by two investigators. After overall screening, 11 studies were included and each RTP group within studies were treated as a separated study using non-RTP as control group for meta-analyses. Different time points of assessment were also considered different studies for meta-analyses.

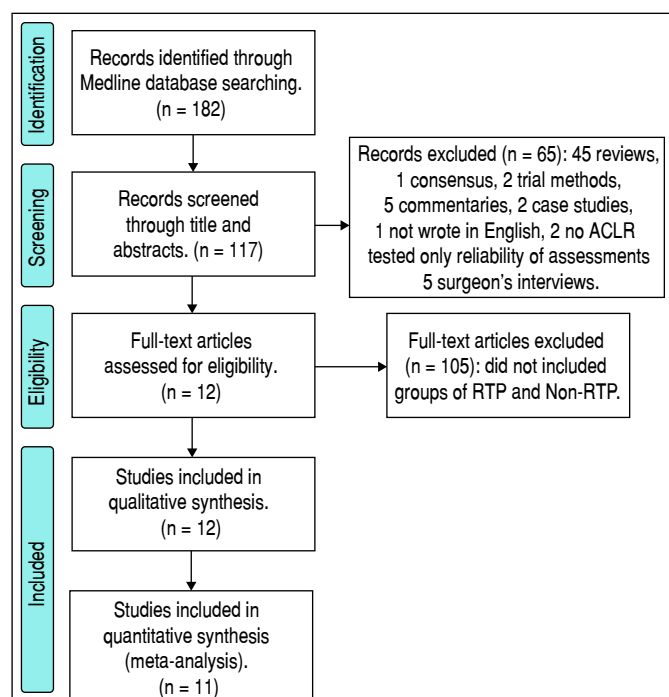


Figure 1. Flowchart of the studies selection.

Caption: ACLR: anterior cruciate ligament reconstruction; RTP: return to play; Non-RTP: non return to play.

Outcomes

LSI. Functional performance was assessed by dynamometer strength or hop tests and Limb Symmetry Indexes (LSI) was estimated based on the equation: $LSI\% = \left[\frac{\text{strength of involved limb}}{\text{strength of uninjured limb}} \right] * 100$, for each participant.⁷ Protocols using dynamometer included isometric and isokinetic evaluation for knee extension with 60 °/s, 180 °/s and 300 °/s. Hop tests included were single hop, crossover hop, square hop, triple hop, 6-m timed hop. Higher values of LSI represent better functional performance,

considering the injured limb (involved) reached more similar strength than the non-injured limb (uninvolved).

Tegner activity scale. Tegner activity scale is graded between 0 (do not walk on even ground) and 10 (elite national/international soccer player), embracing different activities in daily life, as well as recreational and competitive sports. Activities resulting in score between 5 and 10 can only be achieved by recreational or competitive sport practitioners.⁸ Thus, the higher score for Tegner activity scale means the higher level of activity.

Knee laxity. Knee laxity is measured by an arthrometer. The arthrometer was developed to compare anterior tibial translation between non-injured knee and injured (reconstructed knee). The measures are taken from both knees and the mean displacement recorded in millimeters. The side-to-side difference is recorded as the injured knee score minus the non-injured knee score, to confirm normal knee laxity after surgery.⁹ Thus, higher values for knee laxity mean worst results.

IKDC. The International Knee Documentation Committee (IKDC) is a form composed of nine subjective questions evaluating Knee symptoms, function, and sports activity, regardless of a specific disease.¹⁰ IKDC has been widely used for ACLR evaluation and the higher IKDC values (scale from 0 to 100 points) the better the results. **KOOS-QOL and KOOS-Sports.** The Knee injury and Osteoarthritis Outcome Score (KOOS) is an extension of the WOMAC Osteoarthritis Index aimed at assessing symptoms and function in subjects with knee injury and osteoarthritis. Despite KOOS holds five separately scored subscales, in this study only those more prevalent subscales among the studies were included, the knee-related Quality of Life (QOL) and Function in Sport and Recreation (Sport/Rec). This questionnaire has been specifically validated for anterior cruciate ligament reconstruction¹¹ and it is a valid, reliable, and responsive self-administered instrument.¹² The higher KOOS values (scale from 0 to 100 points) the better the results.

Data extraction

Mean, standard deviation (SD), and sample size (n) were used for analysis. Standard error (SE) was converted into SD by the equation $SD = SE \times (\sqrt{n})$, if SD was not provided in the original study. Furthermore, median and interquartile range (IQR) were replaced by mean and SD ($SD = (IQR / 1.35)$).¹³ One of the studies presented the Knee laxity for each leg separately.⁶ Thus, the ratio of injured limb/non-injured limb was estimated to obtain the same scores presented by the other studies for knee laxity. One study presented data only on box plots,¹⁴ thus we extracted median and IQR from the figures using the online software WebPlotDigitizer before conversion into mean and SD. Characteristics of study populations, ACLR, and RTP were clustered for further sub-group analysis.

Statistical analyses

The six meta-analyses were performed using Comprehensive Meta-Analysis (CMA) software, version 3.3.070. The effect was estimated based on the difference between RTP and non-RTP groups or between RTP group limbs difference and non-RTP groups limbs difference for LSI. We used raw mean difference (RMD) and 95% confidence interval for all 6 meta-analyses, considering that variables were presented by the same unit of measurements among all studies. When no statistical significance was presented for heterogeneity, fixed effect models were selected for analyses (KOOS-Sport and Knee laxity) and when statistical significance was presented for heterogeneity, randomized effect models were selected for analyses (LSI, Tegner, IKDC and KOOS-QOL). Conservative pre-post correlations of 0.5 were assumed.¹⁵ Egger's tests were performed to check the risk of publication bias in each meta-analysis.

Sub-group analyses were planned to run for gender, age, and time to RTP for all variables. However, due to the low number of groups in each category for most variables only age (adolescents versus young patients) were analyzed for LSI and a comparison between the assessment by dynamometer and hop tests was also analyzed for LSI.

RESULTS

Table 1 shows details of the studies included. There was no risk of publication bias for Tegner activity scale, IKDC, KOOS-QOL, KOOS-Sports, and knee laxity considering $p > 0.05$ for Egger tests; however, risk of bias was significant for LSI ($p = 0.01$).

LSI was measured by dynamometer (only knee extension strength assessments were included) or hop tests and the final

score represents the percentage of strength of the injured limb compared to non-injured limb. Studies reporting only the mean group strength in each limb without showing the proportion of injured limb to the uninjured limb were not included in this analysis, considering there was no reliable way to estimate LSI.^{6,16} Figure 2 shows that LSI was higher for RTP than non-RTP (RMD = 7.13%, $p < 0.001$), that is, individuals able to return to play had a mean of 7.13% higher symmetry between their injured and non-injured limbs. Regarding subgroup analysis, Table 2 shows, LSI difference between RTP and non-RTP was higher when assessed by dynamometer compared to hop tests. LSI difference between RTP and non-RTP was higher for adolescents compared to young individuals.

Table 1. Characteristics of studies included.

First author, year (subgroup)	Gender. Group age (y). Level of play before injury. Time to RTP	Graft type	Exclusion criteria	RTP criteria
Burland et al. ¹⁷	Both. 15.9 ± 1.8 (non-RTP 15.6 ± 1.9). NR. Time to RTP: 7.4 ± 1.9 mo.	Hamstrings autograft.	≥ 19 y of age. Failed to follow up. Had a previous surgery on the contralateral knee. Had reconstructive surgery with a bonepatellar tendon-bone graft. Underwent a revision surgery. Sustained a multiligamentous injury.	Full pain-free range of motion; resolution of joint effusion; an LSI of 80% for quadriceps isometric and isokinetic testing at $180^\circ/s$; and a satisfactory score on the Noyes hop test.
Fältström et al. ¹⁸	Women. 20.1 ± 2.3 (non-RTP 20.8 ± 3.0). Elite; Sub-elite; Recreational level. Time to RTP: 6 to 36 mo.	Hamstrings; patellar tendon; others.	Had returned to football but were not currently playing. Just played football at the injury occasion. Have never played football. Bilateral ACL injury. Re-rupture or revision ACLR. Still under rehabilitation.	Currently playing football after ACLR (training with the team) and currently playing at any level at the time of follow-up (current players).
Takazawa et al. ¹⁹	Both. 24.0 ± 4.0 (non-RTP 27.1 ± 6.7). NR. Time to RTP: 38.2 ± 10.2 mo.	Primary ACLR: Hamstring-single bundle; Hamstring-double bundle; Iliotibial tract; and Artificial. Revision ACLR: BPTB patellar tendon autografts.	History of previous revision reconstruction. Reason not otherwise described, including not using BTPB grafts. High tibial osteotomy was needed after surgery. Tegner activity scale was less than 4.	Full postoperative rehabilitation program had been completed, and the patients had achieved a full range of knee motion and adequate knee stability.
Hamrin Senorski et al. ¹⁶ (Men)	Men. 23.7 ± 4.5 (non-RTP 23.3 ± 4.2). Knee-strenuous sports. Time to RTP: 10.2 ± 3.1 mo (non-RTP 9.8 ± 3.4 mo).	NR	Follow up other than 6-18 months. Tegner Activity Scale < 6 . Still in rehabilitation.	Patients who had returned to their pre-injury level Tegner ± 1 but a minimum of Tegner 6, and two, patients who had returned to a Tegner of 6 or higher.
Hamrin Senorski et al. ¹⁶ (Women)	Women. 20.8 ± 3.0 (non-RTP 21.4 ± 3.8). Knee-strenuous sports. Time to RTP: 10.1 ± 3.1 mo (*non-RTP 10.8 ± 3.7 mo).	NR	Follow up other than 6-18 months. Tegner Activity Scale < 6 . Still in rehabilitation.	Patients who had returned to their pre-injury level Tegner ± 1 but a minimum of Tegner 6, and two, patients who had returned to a Tegner of 6 or higher.
McCullough et al. ²⁰ (High School)	NR	Autograft, allograft.	Multi-ligament injuries.	NR
McCullough et al. ²⁰ (College)	NR	Autograft, allograft.	Multi-ligament injuries.	NR
Müller et al. ²¹	Both. 31.4 ± 10.3 (non-RTP 33.0 ± 10.5). Level I or level II recreational sports. Time to RTP: 9.2 ± 3.1 wk (*non-RTP: 10.8 ± 4.1 wk)	Hamstring graft.	Concomitant injuries, such as injuries involving lateral ligaments or menisci, adjacent joints (hip or foot) or the contralateral leg. Patients with other orthopaedic, internal, neurological or psychiatric diseases, as well as pregnant women.	At the 6-month surgeon's examination, the operated knee joint had to be free of pain, without irritation, and it had passively full range of motion. The Lachman and Pivot Shift Test had to be positive. The patients had to be able to stand and hop on the operated leg and did not report a subjective feeling of instability. They had to be able to perform level III activities without symptoms.
Rodríguez-Roiz, 2015 ²² (RTP-SL)	Both. 30 (14 to 52). Recreational sports. Time to RTP: until 36 mo.	Hamstring graft.	Multiple ligament injury. Chondral lesions above 1 square cm. History of previous surgery on the same knee. ACL revision surgery. Bilateral ACL injury.	NR

Table 1. Characteristics of studies included.

Rodríguez-Roiz et al. ²² (RTP-LL)	Both. 30 (14 to 52). Recreational sports. Time to RTP: until 36 mo.	Hamstring graft.	Multiple ligament injury. Chondral lesions above 1 square cm. History of previous surgery on the same knee. ACL revision surgery. Bilateral ACL injury.	NR
Sandon et al. ⁶	Both. 23.9 ± 8.3 (non-RTP 25.5 ± 9). Time to RTP: 6 mo.	Hamstrings, patellar tendon.		NR
Sonesson et al. ²³ (4mo)	NR. 22: 15 to 41 (non-RTP 23: 16 to 44). Elite; competitive, recreation; and none. Time to RTP: 4 mo.	Hamstring graft.	Previous ACL reconstruction (to either knee). Other major injuries to either knee (i.e. grade III collateral ligament injury, PCL injury, or grade III articular cartilage injury).	NR
Sonesson et al. ²³ (13mo)	NR. 22: 15 to 41 (non-RTP 23: 16 to 44). Elite; competitive, recreation; and none. Time to RTP: 13 mo.	Hamstring graft.	Previous ACL reconstruction (to either knee). Other major injuries to either knee (i.e. grade III collateral ligament injury, PCL injury, or grade III articular cartilage injury).	NR
Webster et al. ⁵	Both. 26 ± 9 (non-RTP 28 ± 10). NR. Time to RTP: 14 (12 to 20) mo.	Autograft, allograft.	Bilateral ACL injuries, who received a double-bundle reconstruction between 2007 and 2010. Does not practice any sport. Underwent further surgery within the first 12 months after their ACL reconstruction.	NR
Werner et al. ¹⁴	Both. 23 ± 11 (non-RTP 23 ± 11). NR. Time to RTP: 04.02 ± 3.20y (*non-RTP 3.68 ± 2.71y).	Hamstrings, Quadriceps tendon and Ipsilateral patelar tendon autograft and allograft.	Posterior cruciate ligament tear. Any history of previous surgery to or injury of the contralateral lower extremity in the 6 months before the study. ACLR revision, fracture, or knee dislocation.	RTP individuals were required to have returned to at least 1 of the cutting or landing sports in which they were participating before ACL injury. Individuals who changed to a non-cutting sport, such as running, were not considered RTP.

Caption: Data was presented as mean ± standard deviation; NR: not reported in the original paper; y: years; mo: months; wk: weeks; RTP-SL: return to play at same level RTP-LL: return to play at lower level; BPTB: bone–patellar-tendon–bone; ACLR: anterior cruciate ligament reconstruction; *Time to RTP for non-RTP group refers to time point assessments in this group.

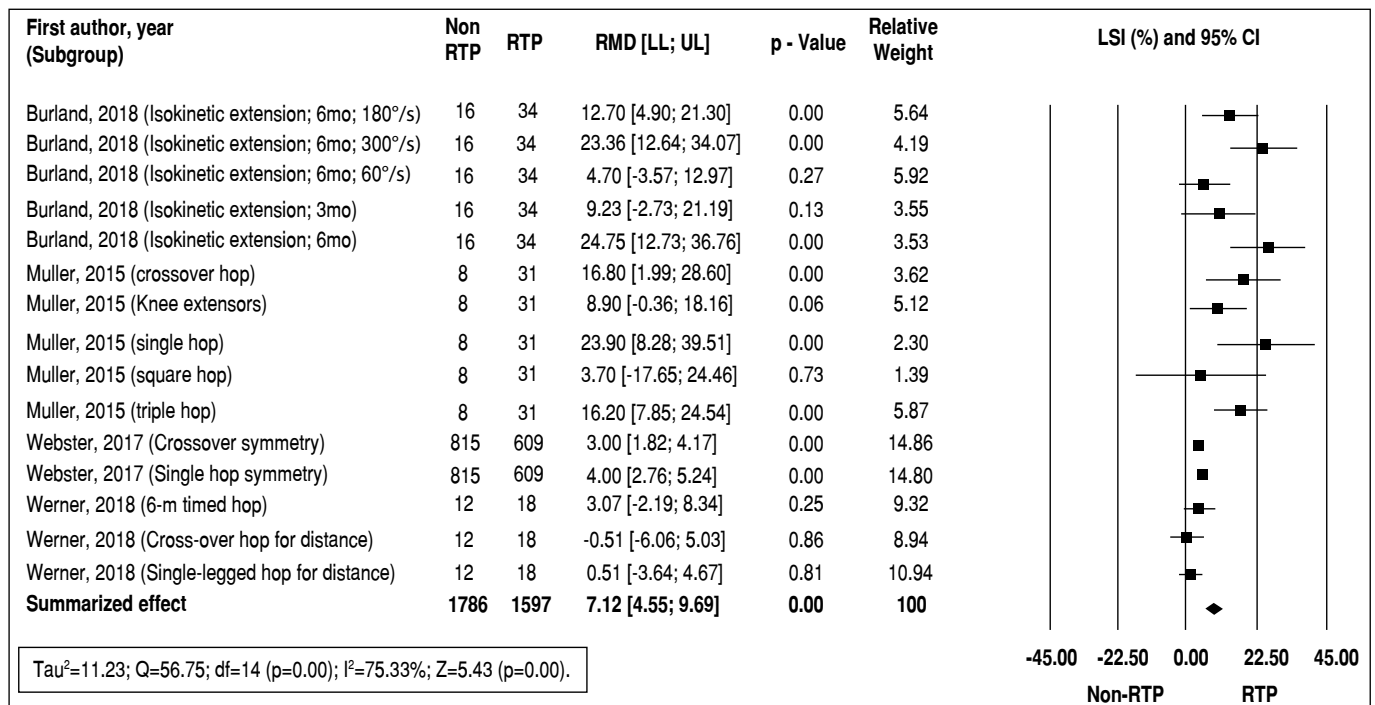


Figure 1. Flowchart of the studies selection.

Activity score assessed by Tegner was significantly higher (RMD = 2.41 [0.18; 4.64], $p = 0.03$) for RTP than non-RTP (Figure 3). Regarding functional scales, RTP presented higher IKDC (RMD = 7.44 [4.69; 10.19], $p < 0.001$), KOOS-QOL (RMD = 14.75 [10.96; 18.54],

$p < 0.001$) and KOOS-Sports (RMD = 11.86 [8.87; 14.86], $p < 0.001$) than non-RTP (Figures 4, 5, and 6). Figure 7 shows knee laxity was lower in RTP (RMD = -0.25 [-0.36; -0.14], $p < 0.001$).

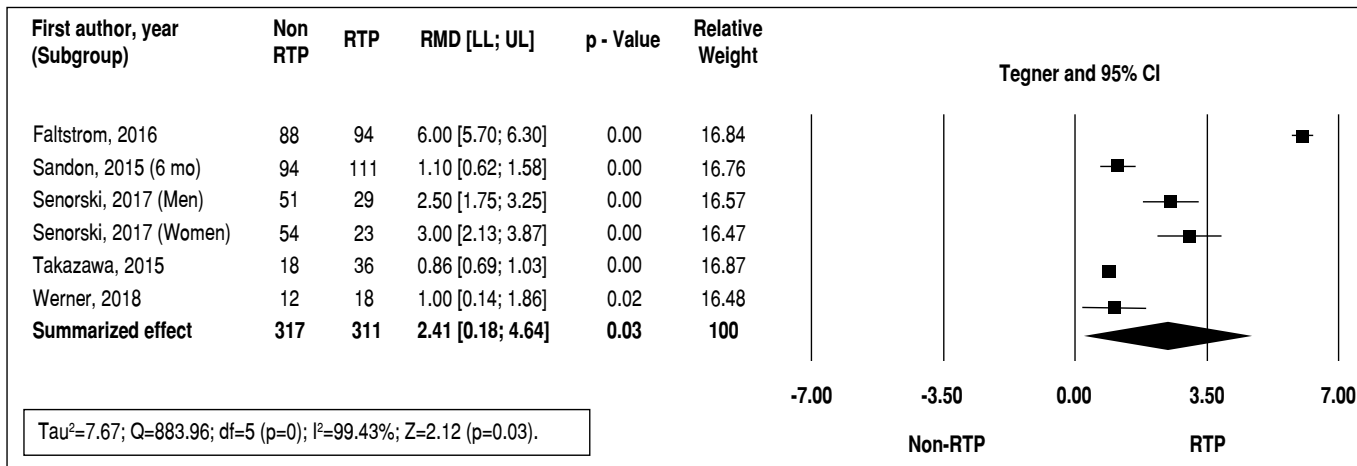


Figure 3. Forest Plot of raw mean difference (RMD) of Tegner between RTP and non-RTP.

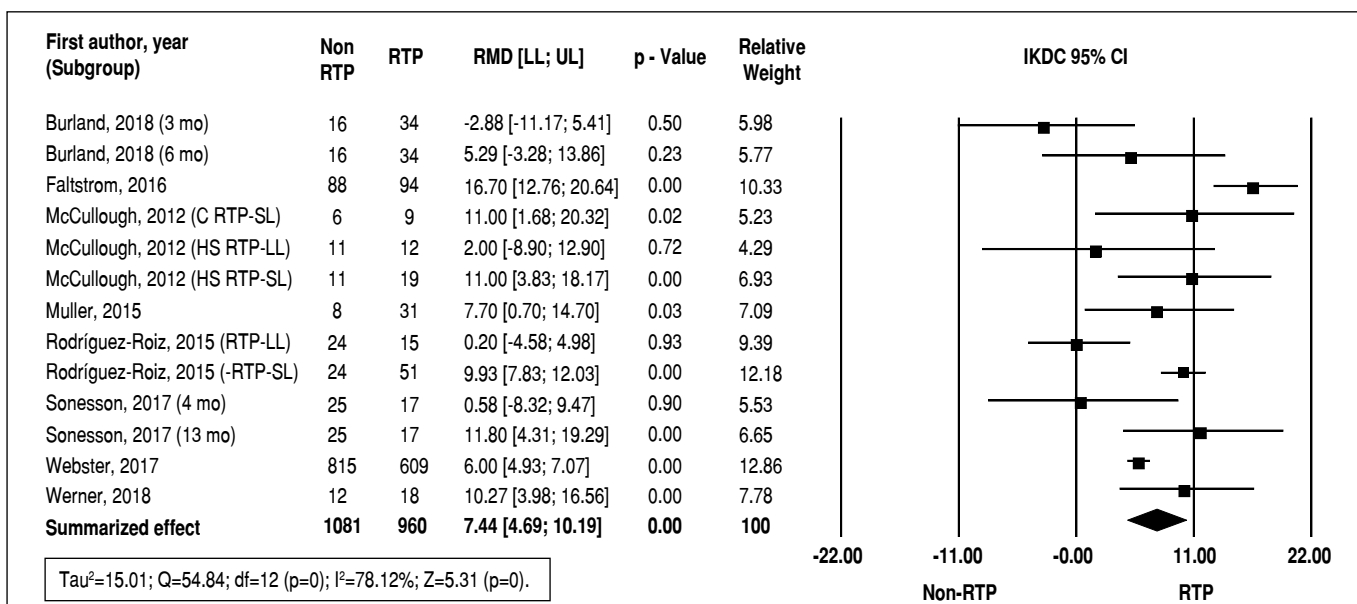


Figure 4. Forest Plot of raw mean difference (RMD) of IKDC between RTP and non-RTP.

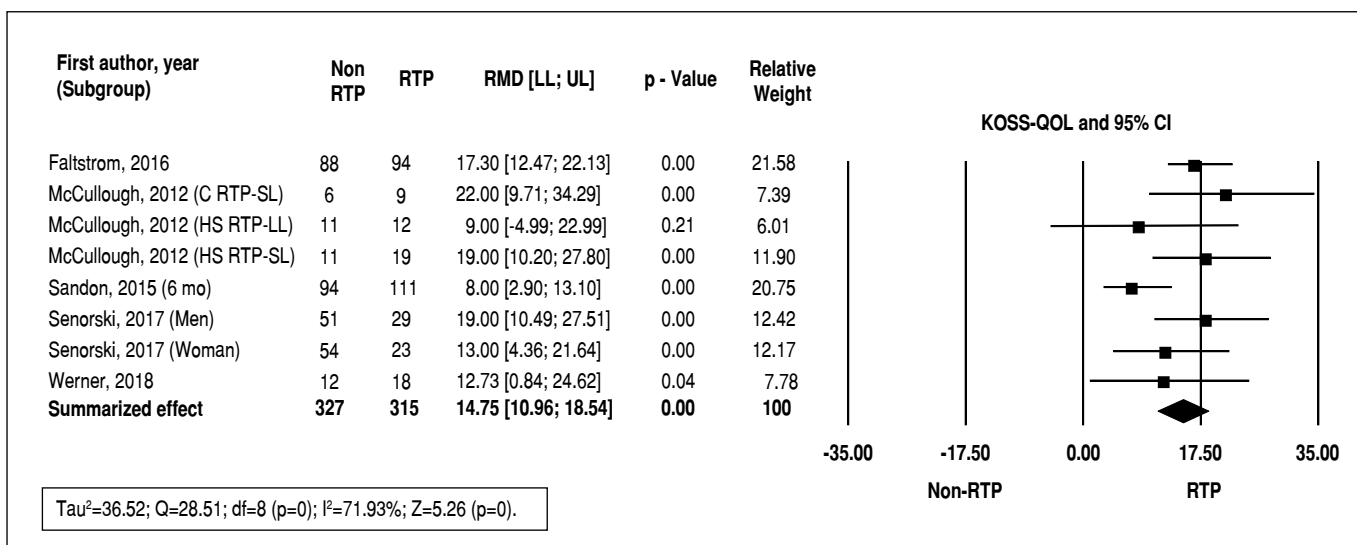


Figure 5. Forest Plot of raw mean difference (RMD) of KOOS-QOL between RTP and non-RTP.

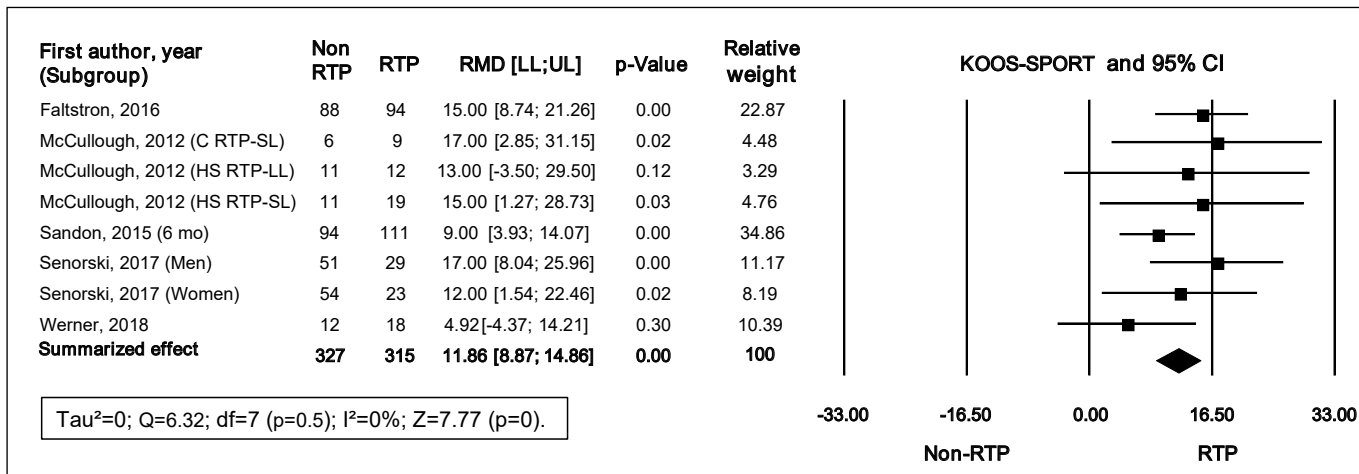


Figure 6. Forest Plot of raw mean difference (RMD) of KOOS-Sport between RTP and non- RTP.

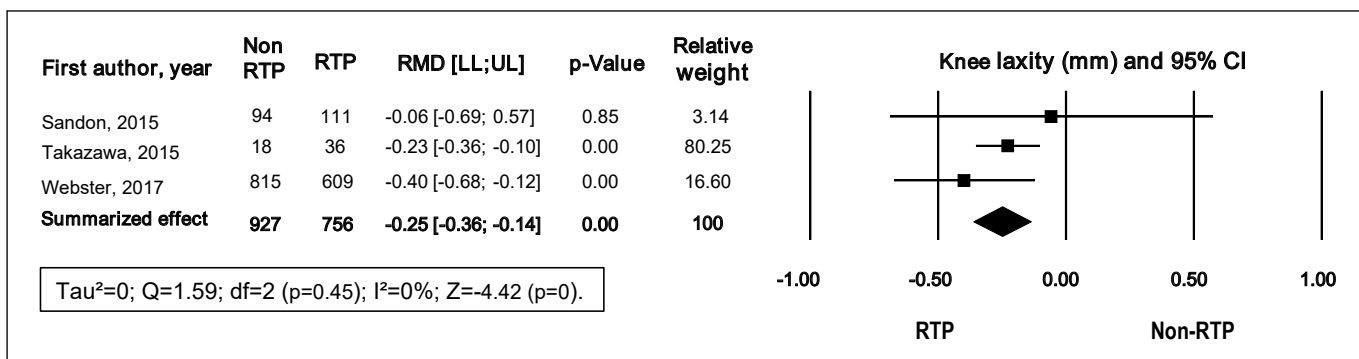


Figure 7. Forest Plot of raw mean difference (RMD) of knee laxity between RTP and non- RTP.

Table 2. Subgroup analysis of raw mean difference (RMD) of LSI between RTP and non-RTP.

Test	K	References	RMD (95%CI)	P value	P difference
Dynamometer	6	17,21	13.37 (7.01; 19.73)	< 0.001	< 0.001
Hop tests	9	5,14,21	4.21 (3.11; 7.46)	< 0.001	
Age	K		RMD (95%CI)	P value	P difference
Adolescents	5	17	14.45 (6.77; 22.12)	< 0.001	0.014
Young	10	5,14,21	4.44 (2.18; 6.694)	< 0.001	

Caption: K: number of RCTs; RMD: raw mean difference; CI: confidence interval.

DISCUSSION

In total, 11 studies assessing RTPC parameters in adolescents or young patients, athletes or recreational sports practitioners from different modalities were included. Table 1 shows characteristics such as gender, age, level of play before injury, time to RTP, graft type, exclusion criteria, and RTP criteria.

Our meta-analyses show that all RTPC parameters tested were able to differentiate RTP to non-RTP patients. LSI, Tegner activity scale, IKDC, KOOS-QOL, and KOOS-Sports were higher, whereas knee laxity was lower in RTP patients. The higher number of studies using LSI, enabled further sub-group analysis. Thus, other significant factors to be discussed in the next paragraphs were identified.

LSI assessed by dynamometer better differentiate RTP from non-RTP patients compared to hop tests. Our findings combined with the risk of knee overload or injury during hop tests²⁴ suggest, if available, the use of a dynamometer for LSI.

Regarding the effect of age, the studies included in the systematic review were homogeneous, comparing patients younger than 30 years old. Among adolescents, the LSI difference between RTP and non-RTP (RMD = 14.45 [95%CI 6.77; 22.13] $p < 0.001$) is even higher than young patients (RMD = 4.44 [95%CI 2.19; 6.70] $p < 0.001$). On the other hand, McCullough et al.²⁵ comparing college and high school athletes did not find difference for KOOS-QOL, KOOS-Sport, and IKDC scores between RTP and non-RTP. This finding suggests that age could have higher effect for differentiate RTP and non-RTP patients when LSI is used instead of KOOS-QOL, KOOS-Sport, and IKDC. We expect younger individuals to undergo better recovery after surgery, however, it is known that younger individuals undergo higher chance of ACL revision.²⁵ McCullough et al.²⁰ and Rodríguez-Roiz et al.²² brought an excellent information regarding different types of RTP. For example, RTP

patients could return to the same level they used to play or lower levels after ACLR. Thus, based on the effects of these studies in our analyses, we noticed only RTP patients returned to the same levels, showing significantly higher IKDC, KOOS-QOL, and KOOS-Sports than non-RTP patients (Figures 4, 5, and 6), whereas RTP patients returning to lower levels did not differ from non-RTP in these RTPC parameters.

Regarding gender comparisons only three studies had their samples exclusively composed of men or women, whereas the others presented mixed gender samples, precluding sub-group analysis for this variable. Nevertheless, Hamrin Senorski et al.¹⁶ compared men and women in their study. They found higher Tegner activity scale, KOOS-QOL, and KOOS-Sports scores for RTP than non-RTP for both men and women groups.

Time after ACLR might influence RTP. Among patients returning to play 9 months after ACLR, higher LSI occurred simultaneously with reduced knee injury rate.³ Burland et al.¹⁷ directly tested the difference on RTPC between RTP and non-RTP 3 and 6 months after ACLR. They analyzed athletes from different modalities, and they found IKDC and LSI were not different between RTP and non-RTP at 3 months, however LSI became higher in RTP than non-RTP after 6 months. Although IKDC seems to be higher after 6 months, it was also higher in non-RTP patients, leading to similar values between RTP and non-RTP also at 6 months.

Although we did not include psychological factors that might influence RTP in the present meta-analyses, Sonesson et al.,²³ assessing athletes from different sports modalities, found RTP patients were more motivated during rehabilitation to chase their pre-injury level and were more satisfied with their activity level and knee function one year after ACLR. Fältström et al.¹⁸ also found higher motivation in RTP female soccer players. Despite the higher chance of RTP for athletes undergoing ACLR sooner after injury, RTP soccer players also presented significant higher ratings for

psychological readiness to return to sport. Nevertheless, the benefits of psychological factors over RTP in both studies aforementioned happened simultaneously with other functional improvements that might affect RTP as well, precluding the isolated understanding of psychological factors influence on RTP.

Note that most evaluations analyzed herein are commonly used by physicians in clinical practice as part of the criteria to release patients to play and they could be a cause of the differences we found between RTP and non-RTP. However, as we showed in Table 1, they were not consistent among studies and many protocols of release to RTP were not described. The expected higher values for Tegner Activity in RTP could be a confounding factor, considering that patients returning to play could reach higher scores. Still, this study shows the difference between RTP and non-RTP for most used RTPC.

The significant risk of publication bias for LSI is a limitation of the literature. Studies identifying higher LSI for RTP than non-RTP might be more likely to be published in indexed journals or it could just be a coincidence, considering LSI was the parameter commonly used by the included papers.

CONCLUSION

In fact, after pooled analyses the selected RTPC parameters were determinant to differentiate RTP for non-RTP patients. Our findings support that therapies following ACLR might target higher LSI, Tegner activity scale, IKDC, KOOS-QOL, KOOS-Sport and lower knee laxity to reach the same level RTP in patients on different modalities. Moreover, LSI assessed by dynamometer performed better than hop test to differentiate RTP from non-RTP. Furthermore, the narrow age range of young patients of the studies included in our systematic review limits the applicability of our findings to older patients.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. ALLA: development of the research project, writing, and review; AVS: writing and statistical analysis; BL: overall concept of the study and review; WDB: overall intellectual concept of the study and review.

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NEW GENERATION NAIL VS. PLATE IN THE TREATMENT OF UNSTABLE INTERTROCHANTERIC FEMORAL FRACTURE

PREGOS DE NOVA GERAÇÃO CONTRA A PLACA NO TRATAMENTO DE FRATURAS DE FÊMUR INTERTROCANTÉRICAS INSTÁVEIS

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ABSTRACT

Objective: To compare antirotator proximal femoral nail (A-PFN) with antirotator dynamic hip screw (A-DHS). **Methods:** Fourteen proximal femur models with type 31/A2 fracture, according to the AO Foundation/Orthopaedic Trauma Association (AO/OTA) classification, were separated into two groups. Group 1 bones (n = 7) were fixed with A-PFN and Group 2 (n = 7) with A-DHS. A 5 mm/min axial load was applied to femur heads using a testing device. **Results:** Two of the seven models in the A-PFN group fractured at the proximal, and the other five at distal locking screw level. All models in the A-DHS group fractured at the tightened distal screw region. The median fracture load for the A-PFN group was 132.1 N (97.1-173.69 N range), and for the A-DHS group it was 81.7 N (75.15-89.12 N range). **Conclusion:** A-PFN-treated unstable intertrochanteric fractured models resisted to higher levels of axial load than the A-DHS-treated group, with statistically significant difference. However, clinical studies are required to support these results. **Level of Evidence V, Biomechanical study.**

Keywords: Femoral fracture. Fracture fixation. Intramedullary and plate.

RESUMO

Objetivo: O objetivo deste estudo foi comparar a haste do fêmur anti-rotador (A-PFN) com o parafuso dinâmico do quadril anti-rotador (A-DHS). **Métodos:** Este estudo envolveu dois grupos de quatorze modelos de fêmur proximal, tipo fratura 31/A2, de acordo com a classificação The AO Foundation/Orthopaedic Trauma Association (AO/OTA). Os ossos do grupo 1 (n = 7) foram fixados com A-PFN, enquanto o grupo 2 (n = 7) foi fixado com A-DHS. Um dispositivo de teste foi utilizado para aplicar força axial de 5 mm/min nas cabeças do fêmur. **Resultados:** Dos sete modelos do grupo A-PFN, dois foram rompidos na proximal e o restante no nível do parafuso de travamento distal. Todos os modelos no grupo A-DHS foram quebrados a partir da região do parafuso distal apertado. Os modelos ósseos no grupo A-PFN foram quebrados a uma força mediana de 132,1 N (variação de 97,1-173,69 N). No grupo A-DHS, a força de fratura dos modelos ósseos foi mediana de 81,7 N (variação de 75,15-89,12 N). **Conclusão:** Neste estudo, modelos ósseos fraturados intertrocantéricos instáveis tratados com A-PFN foram resistentes a um nível mais alto de forças de pressão axial, em contraste com o grupo tratado com A-DHS, e a diferença foi estatisticamente significativa. No entanto, há uma necessidade de estudos clínicos para apoiar esses resultados. **Nível de Evidência V, Estudo biomecânico.**

Descritores: Fratura femoral. Fixação de fratura. Intramedular e placa.

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INTRODUCTION

Trochanteric fractures of the proximal femur are very common among older adults. Surgical treatment and fracture fixation are the preferred treatment for preventing life-threatening complications and assisting bone healing.¹ Although a range of implant designs

have been proposed for managing these fractures,^{1,2} selecting the ideal implant for treatment is still a controversial issue. This study compares two new designs of implant models that recently became widely used in the surgical treatment of intertrochanteric femoral fractures: A-PFN and A-DHS.

All authors declare no potential conflict of interest related to this article.

The study was conducted at the Istanbul Medeniyet University.

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MATERIALS AND METHODS

Twenty synthetic third-generation femur models (Synbone AG indust. Switzeland®, model 2420) initially composed our sample. However, due to the breakage of three models from each group during the study, evaluations were completed with fourteen. Each bone model had 135 mm collum-diaphyseal angle, 15 mm anteversion angle, 337 mm length, 48 mm femoral head diameter, and 10 mm diaphysis diameter. A type 31/A2 fracture was created in each model, according to AO/OTA classification (Figures 1 and 2), and the fourteen synthetic models were separated into two groups of seven. Fractures were fixed with antirotator proximal femoral nail (A-PFN) in Group 1, and with antirotator dynamic hip screw (A-DHS) in Group 2.



Figure 1. A and B: fracture model fixed with antirotator proximal femoral nail; C and D: fixation under image intensifier.

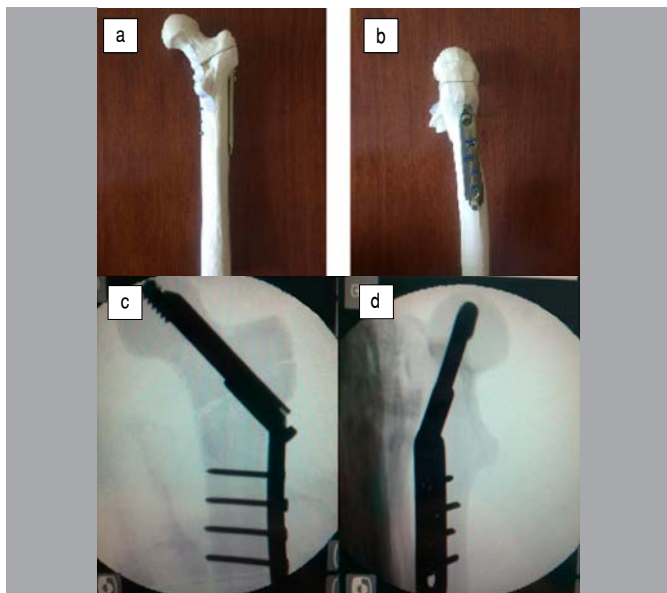


Figure 2. A and B: fracture model fixed with antirotator dynamic hip screw; B and C: fixation under image intensifier.

Characteristics of Implants

A-PFN (TST Industries Istanbul – Turkey®) is available in two lengths: 160 and 220 mm. Proximal nail diameter is 15 mm, and it has a 6° valgus angle (mediolateral curvature) in the nail upper third. This nail presents four options of diameter – 9, 10, 11, and 12, – a lag screw compressing fracture fragments, and a wedge block improving rotational stability for femoral fractures. The lag screw has a 10 mm-width thread and a 125° angle, compatible with the collum-diaphyseal angle. The wedge block lies on the groove, located at the inferior region of the lag screw. The nail distal features two locking holes, suitable for either dynamic or static fixations.

A-DHS (TST Indust. Istanbul – Turkey®) consists of four parts: the plate, lag screw, compression screw, and antirotation wedge. The lag screw not only enables a controlled dynamic sliding of the femoral head, but also improves anti-rotational stability together with the wedge block. The wedge block lies in the groove located at the inferior region of the screw. Plate is 8 mm thick and 19 mm wide, and holes are 16 mm distant. The lag screw on the plate is positioned 135° to the femoral head and its length may range from 60 mm to 120 mm, whereas the plate ranges from 73 mm to 207 mm.

Group 1 bone models were fixed with 220 mm A-PFN. After drilling the due point of the major trochanter tip, proximal femoral nail was applied with the help of the guide. A Kirschner wire guided lag screw placement, and femoral head was drilled inside out to verify centralization. After correction, the lag screw of correct size was applied, followed by anti-rotation wedge and distal locking screw (Figure 1).

Group 2 models were fixed with A-DHS. First, a Kirschner wire with a 135° angled guide was used for placing the lag screw. Once centralization was corrected and K-wire inserted, the lag screw was placed with the dynamic plate seated on it. Then antirotator wedge block was applied, followed by five cortical screws, inserted bicortically (Figure 2).

All models were tested under compressive axial load using the Shimadzu Autograph AGS. For applying physiological load, models were placed into the device with a 15° valgus angle (Figure 3). An axial load was applied to femoral heads at a constant speed of 5 mm/min, according to the femoral mechanical axis, until implant or model failure. After all bone models were evaluated, data from the testing device were recorded and failure type was observed.



Figure 3. Placement of the fracture model into the Shimadzu Autograph AGS compression device.

Obtained data were statistically analyzed using SPSS Statistics V.22.0 software. Results are presented in mean \pm standard deviation, median, minimum and maximum values, absolute numbers, and percentages. Variables distribution was analyzed using the Kolmogorov-Smirnov test. The Mann-Whitney U test was used to compare quantitative data. A p value < 0.05 was considered statistically significant.

RESULTS

After axial loading, two of the seven bone models fixed with A-PFN fractured from the proximal part and five from distal locking screw. In models fractured proximally, we observed a new fracture line from the nail entry point to the fracture line (Figure 4a and 4b). Among models fractured distally, three fractured with a butterfly fragment and two with a new oblique fracture line (Figure 4c and 4d). Table 1 shows the loads causing the new fracture line.

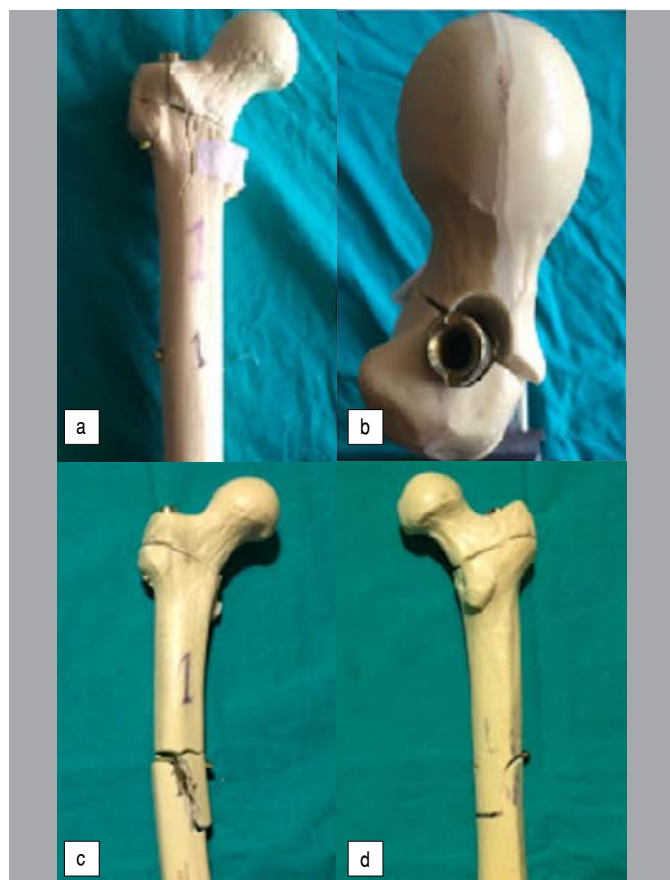


Figure 4. Fracture patterns in the antirotator proximal femoral nail group after testing. A: new fracture line from the entry point, anterior view; B: new fracture line from the entry point, axial view; C: butterfly fragment and new oblique fracture line, anterior view; D: butterfly fragment and new oblique fracture line, lateral view.

Table 1. Loads causing new fracture line in Group 1.

No.	Group	Failure time (sec)	Load (N)
1	1	170.30	1736.9
2	1	191.80	1549.5
3	1	196.00	971.0
4	1	196.30	1557.6
5	1	201.90	1599.3
6	1	216.10	1670.0
7	1	232.20	1643.5

As for models fixed with A-DHS, all seven presented a nearly transverse new fracture line from the distal locking screw (Figure 5). Table 2 shows the load causing the new fracture line.

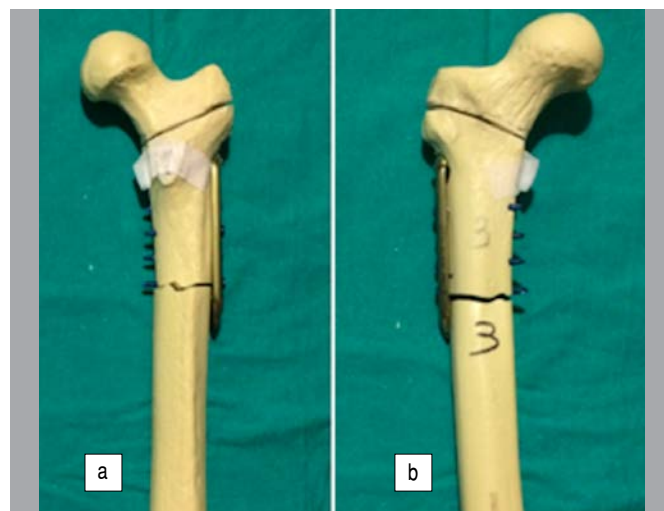


Figure 5. Fracture patterns in the antirotator dynamic hip screw group after testing. A: transverse fracture, anterior view; B: transverse fracture, posterior view.

Table 2. Loads causing new fracture line in Group 2.

No.	Group	Failure time (sec)	Load (N)
1	2	93.85	796.5
2	2	109.25	859.25
3	2	90.25	891.2
4	2	87.50	841.5
5	2	87.00	751.5
6	2	80.85	753.2
7	2	53.05	826.6

In the A-PFN group, models fractured under a minimum load of 971 N and maximum 1736.9 N, according to test results, resulting in a median fracture load of 1599 N (Figure 6). As for the A-DHS group, minimum fracture load was 751.5 N and maximum 891.2 N, resulting in a median value of 817 N (Figure 7).

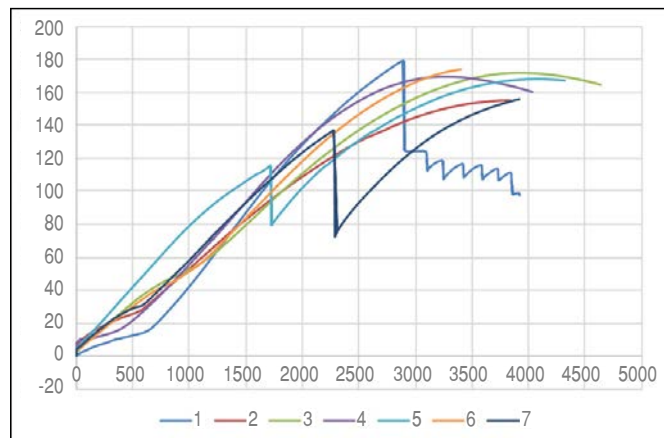


Figure 6. Antirotator proximal femoral nail group load (N) \times 10/time.

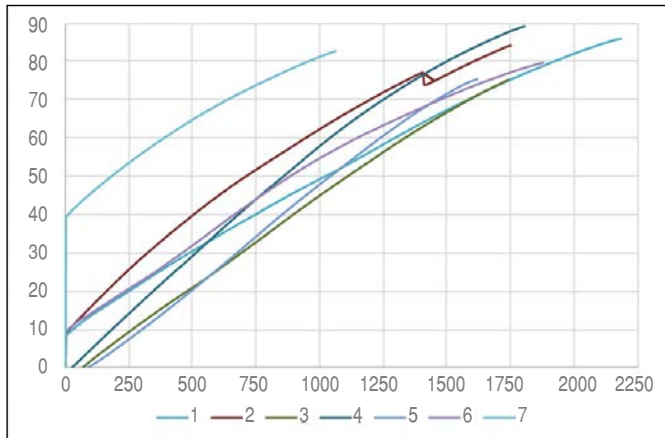


Figure 7. Antirotator dynamic hip screw group load (N) \times 10/time.

DISCUSSION

Trochanteric femur fractures are one of the most common fractures among older adults.² In young patients, they occur after high-energy trauma, but in older patients they may occur even after a low-energy trauma due to osteoporosis.³ Hip fractures are a leading cause of morbidity and mortality among older patients.¹

Biomechanical studies have shown that intramedullary devices are more stable than others (plate, dynamic hip screw ([DHS]) due to their shorter lever arm. However, differences in intramedullary implants design, incorrect surgical procedure, and non-anatomic reduction may lead to considerably high failure rates.² Despite the technical advances in implants for trochanteric fractures fixation, morbidity and mortality rates are still high in older patients after hip fracture. Several studies are under progress worldwide to determine the most appropriate treatment.^{2,4}

Intramedullary implants may be more suitable for older patients because its fixation technique is less invasive than that of extramedullary implants. Closed reduction facilitates fracture healing by protecting hematoma containing osteogenic cells and preventing excessive soft tissue dissection. This would possibly decrease infection rates, postoperative complications, and blood loss.⁵ Many studies compare extramedullary and intramedullary implants. Two prospective randomized trials comparing patients with intertrochanteric femoral fractures treated with gamma nail and dynamic hip screw (DHS) found no statistically significant difference between mortality rates. However, the rate of iatrogenic femoral shaft fracture was higher in gamma nail-treated patients, due to its design, than in those treated with DHS. Consequently, DHS was recommended for treating intertrochanteric femoral fractures.^{6,7} Although five of the seven models fixed with A-PFN in our study fractured at the distal lock screw level, bone models

pertaining to this group can overall withstand higher loads than the A-DHS group.

Mechanical problems such as cut-out, varus deformity, Z-effect, and reverse Z-effect have been reported in patients treated with proximal femoral nail (PFN).^{3,5} Third -generation nails were developed to reduce these complications.⁸ A study showed that a single screw inserted in a central location could prevent lag screw early cut-out.⁹ Subsequently, a study performing a biomechanical comparison reported that A-PFN reduced lag screw cut-out issues.¹⁰ In our study, both A-PFN and A-DHS have a single lag screw, the additional wedge with rail system ensures anti-rotation, and the system entails three different compression parts.

Proximal femoral nail antirotation (PFNA), a third generation nail, contains a helical head that increases trabecular bone volumetric compression in osteoporotic fractures, decreasing cut-out rate.¹¹ Many studies reported that PFNA is a good alternative for osteoporotic bones.^{2,4,11-17} However, PFNA has some disadvantages in relation to telescopic nails, as lag screw lateral migration and inadequate compression.^{18,19}

According to the literature, new lag screw system with A-PFN nail and A-DHS plate were designed to mitigate such problems – their main goal is to increase rotational stability with three different compression sites. Increasing lag screw diameter provides not only resistance to cut-out, but also extra compression force by threads on the lag screw. A wedge, located at the inferior region of the screw, compresses trabecular bone and, consequently, increases resistance to rotational forces. The locking mechanism also increases resistance against lateral migration.

We found no lag screw cut-out and lateral migration for the A-PFN nor for the A-DHS group – which may occur in DHS plate new generation and femoral nails third generation. A-PFN-fixed bone models showed no femoral shaft fracture and distal screw failure. The synthetic bone models used in this study were also used in the aforementioned biomechanical studies. However, studies conducted with more samples of cadaver bones may help reaching more definitive results. We also have not applied all forces acting on the hip in daily life, posing another limitation for this study. We encourage the development of further multicentric, randomized controlled clinical trials to support these findings and contribute to the literature.

CONCLUSION

The results showed that the A-PFN group could withstand significantly higher loads than the A-DHS group, due to the shorter lever arm and the ability to transfer forces applied into the models. We found no lag screw cut-out or lateral migration in either group. This biomechanical study findings may guide new clinical trials approaching the fixation of unstable intertrochanteric femoral fractures using A-PFN and A-DHS.

AUTHORS' CONTRIBUTIONS: BO: correspondence author, data collection, study standardization, and biomechanical work; SE: biomechanical work and data collection; TTO: biomechanical work; KO: consultant.

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ACHILES: AN IMORTAL EPONYMOUS

AQUILES: UM EPÔNIMO IMORTAL

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ABSTRACT

The conditions affecting the calcaneal tendon remain extremely prevalent in the clinical practice. The search for information about these diseases in national and international scientific databases are commonly hampered in the use of search tools, requiring the use of an eponym in the strategy. Achilles, in reference to the hero of the Greek mythology, is often used by several authors in scientific publications despite the new Nomenclature Anatomica. Objective: This article intends to recover the history behind the use of this term, which heroically resists in the clinical discussions of everyday life in articles and textbooks. **Level of Evidence V, Literature Review.**

Keywords: Achilles Tendon. History of Medicine. Terminology. Anatomy.

RESUMO

As afecções que afetam o tendão calcâneo permanecem extremamente prevalentes na prática clínica. A busca por informações sobre essas doenças na produção científica nacional e internacional comumente esbarra em uma dificuldade na utilização das ferramentas de procura e na necessidade de acrescentar um epônimo na estratégia. Aquiles, em referência ao herói da mitologia grega, é frequentemente empregado por diversos autores em suas publicações científicas a despeito da nova nomenclatura anatômica. Objetivo: Esse artigo busca resgatar a história da utilização desse termo, que resiste heroicamente tanto nas discussões clínicas do cotidiano quanto nos artigos e livros-texto. **Nível de Evidência V, Revisão da Literatura.**

Descritores: Tendão do Calcâneo. História da Medicina. Terminologia. Anatomia.

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Achilles turned his back to Troy and raised his hand in triumph. Seeing his chance, Paris let fly his arrow. It flew as a hawk flies to make its kill – remorseless, eager, unchangeable. Then, it began to dip toward the ground and lose power. Yet, still flew straight and deadly. Achilles had been protected from the weapons of men since his mother dipped him in the dark waters of the River Styx. Now, the arrow found the only place that Thetis' fingers covered, letting it untouched by the turbulent waters. The arrow stroked hard Achilles' heel, killing him.
Iliad, Homer.¹

The calcaneal tendon is the strongest and thickest tendon unit in the human body. It is also called Achilles in reference to the Greek mythological hero who, according to the authors of antiquity, was held by this anatomical region when being dipped in the River Styx. Thetis, his mother, trying to make her son immortal by submerging him, would have left that part vulnerable. Achilles was killed by Paris with a poisoned arrow right at that region. This mythological passage rose the expression "Achilles' heel" widely used when referring to the weak point of a person or object.^{2,3} Homer, around the 8th century BC, writes *Iliad*, one of the epic poems of ancient Greece, in which he narrates the events of the 51 last days of the Trojan War. In this part of the epic, he

introduces the warrior Achilles, Greek hero and protagonist of the play. *Iliad* deals with the wrath of Achilles. Such wrath is caused by a dispute between him and Agamemnon, commander of the Greek armies in Troy, and it is consummated with the death of the Trojan hero Hector. Achilles, betrayed by Agamemnon, decides to abandon the war, but returns to battle after his great friend Patroclus is killed by Hector. The hero avenges his colleague by murdering Hector.¹ The word Achilles is originated from the combination of the expressions "grief or pain" (*achos*) and "people" (*laos*), which can be interpreted as an embodiment of the suffering of people. It became a common name in antiquity, frequent in mythological stories. The hero Achilles appears in several literary works after the *Iliad*, mainly in later centuries, becoming a figure of numerous frescoes, sculptures, and plastic productions in the three millennia following his original appearance. Achilles is a character widely manifested nowadays, as a highlight of ancestral and contemporary culture.⁴ Statius, around the year 1 AD, writes *The Achilleid* and addresses the birth of the hero, giving rise to the myth of his vulnerable spot. His mother, Thetis, shortly after the birth of her son, would have plunged him into the River Styx in an attempt to make him immortal. However, she had held the child by his heel, a region that was not submerged, thus, this place became his zone of weakness. According to Statius, the hero would later be killed with a poisoned arrow thrown at his heel by Paris. The myth of the unbeatable warrior

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shot down with a vulnerable spot gained intensity over the course of human history, classically referred to as the fragility zone of an individual or item.⁵

The omnipresence of Achilles in popular folklore reached medicine, and the warrior became eponymous of the posterior and distal topography of the leg, particularly the tendon that connects the calf muscle to the heel bone. This nickname was attributed by Philip Verheyen, flamenco surgeon, who, in 1693, published the book *Corporis Humani Anatomia* and associated this structure with the mythological hero in the 13th chapter of its second edition. Unofficial sources also indicate that this attribution was carried out by Verheyen (1699) after dissecting his own leg amputated due to gangrene. Jean-Louis Petit, in 1705, connects the terms “tendon” and “Achilles” in his work *L'art de Guérir les Maladies des Os*. Lorenz Heister, in his *Compendium Anatomicum*, from 1717, uses the Latin expression *tendo Achillis* for the first time in history when describing the insertion of the calcaneal tendon. The author uses the term again in a case report of an Achilles tendon suture.⁶⁻¹⁰

Thus, this nomina was widely used in the 18th century by several anatomists. In the subsequent century, virtually all previous denominations were abandoned, increasing the use of *tendo Achillis*. However, it was only after the creation of the Anatomical Society in 1895 that this terminology was proclaimed at the *Basiliensis Nomina Anatomica congress*. Following some minor changes over the decades, the historical term was finally deconsecrated, in 1998, by the Anatomical Terminology, and it was replaced by *tendo calcaneus*. According to the Committee, the use of the cultural reference Achilles should be done exclusively on an unofficial

level. Despite the norm, the term “Achilles tendon” remains in the modern medical and orthopedic literature, being found routinely in scientific articles and books.^{9,11,12}

Hippocrates (460-377 BC) may have been the first in history to refer to the calcaneal tendon as *neura megala*. *Neuron* was used to describe both tendons and nerves as commonly occurred in ancient Greece. The translation of Greek into Latin incorporated the concept of *nervus*, and this tendon was described by Ruphus (60-120 AD) as *nervus latus* or *nervus crassus*. Avicenna (980-1037 A.D.), by the translations of Cremonensis (1114-1187 AD), uses the term *chorda magna Hippocratis*, an expression shared with the one from Ruphus in the following centuries. It was only with Vesalius, in his work *De Corporis Humani Fabrica Libri Septem*, 1543, that the term tendon (*tendo*) designates tendon structures. Paré, in 1579, uses the term *tendon du talon* and Verheyen in 1693, creates *chorda Achillis*, being followed by the others, as previously reported in this chapter. The word calcaneal is originated from the Latin word *calx*, which can be translated as limestone. It was used for the probable similarity of the bone to this ore, sometimes being designated as posterior projection or spur of the foot.^{9,13-18}

Although the term “calcaneal tendon” is supported by the official anatomical norm, the official name of this structure is not the most used either at the formal or informal level. This practice might be attributed to the necessity professionals have to differentiate the calcaneus bone from the Achilles tendon in daily practice. Still, the tradition of using eponyms and the attractive historical rescue brought by the use of this mythological reference still greatly influence its utilization. Nevertheless, it is still interesting to observe the evolution of its nomenclature and how much it survives in modern times. Achilles still lives.

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HALLUX PROXIMAL PHALANX FRACTURE IN ADULTS: AN OVERLOOKED DIAGNOSIS

FRATURA DA FALANGE PROXIMAL DO HÁLUX EM ADULTOS: UM DIAGNÓSTICO ESQUECIDO

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ABSTRACT

Objectives: To describe the surgical treatment of fractures that involves the hallux interphalangeal joint, current indications and management options. **Methods:** we performed a literature review of relevant clinical studies in multiple databases, including PubMed, MedLine and Scopus, from January 1989 to October 2020. **Results:** There is consensus for surgical treatment of intra-articular fractures with a deviation greater than 2 mm, metadiaphyseal fractures with malrotation and/or malangulation, open fractures and unstable fractures. **Conclusion:** The use of more rigid implants allow alignment maintenance during healing process and lower risk of reduction loss. Valgus deformity and interphalangeal joint osteoarthritis are possible complications that must be avoided. **Level of Evidence III, Systematic review of Level III studies.**

Keywords: Hallux. Fracture Fixation. Treatment Outcome.

RESUMO

Objetivos: destacar o tratamento cirúrgico das fraturas que envolvem a articulação interfalangeana do hálux, suas indicações atuais e as opções de tratamento. **Métodos:** Realizamos uma revisão da literatura de estudos clínicos relevantes em múltiplas bases de dados, incluindo PubMed, MedLine e Scopus, de janeiro de 1989 a outubro de 2020. **Resultados:** Há consenso para o tratamento cirúrgico de fraturas intra-articulares com desvio superior a 2 mm, fraturas metadiafisárias com má rotação e/ou malangulação, fraturas expostas e fraturas instáveis. **Conclusão:** O uso de implantes mais rígidos permite a manutenção do alinhamento durante o processo de consolidação e menor risco de perda da redução. As complicações que devem ser evitadas são a deformidade em valgo e a osteoartrite da articulação interfalangeana. **Nível de Evidência III, Revisão sistemática de Estudos de Nível III.**

Descritores: Hallux. Fixação de Fratura. Resultado do Tratamento.

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INTRODUCTION

Phalanx fractures of the toes are common.¹ Hallux phalanx fractures represent the largest proportion of all toes phalanx fractures.² However, hallux proximal phalanx fracture in adults has rarely been reported.³⁻⁶ Fractures of the hallux require surgical treatment much more often than other toe fractures due to the role of the first toe in weight bearing, balance, and pedal motion.⁷ Diaphyseal and articular fractures of the hallux proximal phalanx tend to consolidate in a good position with an appropriate initial treatment. When the principles of treatment for diaphyseal and intra-articular fractures are not respected, complications such as

valgus deformity, decreased range of motion and interphalangeal joint (IPJ) osteoarthritis can lead to significant functional loss.⁸⁻¹⁰ The objective of our review is to describe the surgical treatment of fractures that involve the hallux interphalangeal joint, current indications and management options.

MATERIALS AND METHODS

We searched for relevant scientific literature from 1992 to 2019 in Electronic databases, such as PubMed, MedLine and Scopus. The keywords used are shown in Table 1.

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Table 1. Keywords used to search the PUBMED, MedLine and Scopus database.

Keywords for main PUBMED, MedLine and Scopus literature search		
Hallux	Trauma	Phalanx
Incidence	Fracture	Adults
Prevalence	Fixation	Great toe
Subheadings used for PUBMED, MedLine and Scopus literature search		
Complications	Lag screw	Radiology
Outcome	Interphalangeal joint	Sports
Plate	Diagnosis	Foot
K-wire	Trauma mechanism	Injuries

We included case-control studies, cohort studies, epidemiological studies, and case reports, written in or translated into English, which described hallux phalanx fractures, treatment and complications.

Any available reports of hallux phalanx fractures we considered eligible. Studies that did not focus on this subject were excluded. The studies selected were read by the authors and judged on their contribution to the body of knowledge of this topic. The conduct and validity of any clinical studies was carefully considered, and the outcomes of management protocols were carefully scrutinized.

Other relevant case reports mentioning a specific association with the condition were also included. Only papers that made a significant contribution to the understanding of this condition were included in the review.

In total, 49 abstracts were selected, 31 of which were directly related to the hallux phalanx fractures.

Epidemiology

Understanding the epidemiology of fractures seems to be a challenge since the classic paper from Buhr et al.¹¹

Epidemiological data on the foot and ankle injuries were obtained by authors who studied trauma-mechanism or site-specific epidemiology,^{12,13} and others who examined population-specific epidemiology.¹⁴⁻¹⁹

An epidemiological study showed that 92.74% of all foot fractures were not work-related, 53.49% occurred outdoors and 26.12% occurred at patient's household.¹

Shibuya et al.¹ use the National Trauma Data Bank set from 2007 to 2011 to analyze the frequency and proportion of each fracture in the foot and ankle in major trauma hospitals in the United States. The authors found 280,933 foot and ankle fractures. Of those, 15,432 were phalanx fractures, which represent 5.49% of all foot and ankle fractures. Although metatarsal fractures were more common than phalangeal fractures, this study showed that the proportion of phalangeal open fractures was significantly higher than that of metatarsal fractures (33% and 16%, respectively). Moreover, approximately 20% of all phalanx fractures were open.¹ In a study conducted in the United Kingdom, the authors observed 5,953 inpatient and outpatient fractures, of which 3.56% presented phalanx fractures (mean age: 35.3 years old). In fact, the hallux is the most fractured toe, representing the greatest proportion of all toe phalangeal fractures (38 – 56%).^{20,21} In another study with 512,187 individuals who participated in the China National Fracture Survey, the authors found an incidence rate of foot fractures of 39.2/100000/year (95%CI: 33.8-44.7), 50.8/100000/year among men and 27.3/100000/year among women.²² Missed injuries and delayed diagnosis are some reasons for limited outcome of multiple trauma patients, in which foot injuries are often neglected. Fitschen-Oestern et al.²³ observed 6.6% of missed/delayed toes fractures in 34,091 polytrauma patients.

Classification System

The AO Foundation/Orthopaedic Trauma Association (AO/OTA) classification updated in 2018 is the most useful classification system. This coding system is well established, allowing a universal language standardization.²⁴ In this system, the bone location should be determined first and the foot designation is 8. Then in the subdivisions, phalanx fractures are designated as 88. Toe identifiers are numerically determined as hallux:1, second toe:2, etc. The bone segments are numbered as proximal end segment = 1, diaphyseal segment = 2, and distal end segment = 3.²⁵ The universal modifiers are descriptive terms of fracture morphology, displacement, associated injury, or location that are common to most fractures (Figure 1). They are generically divided in morphology of the diaphyseal fracture and morphology for the end segment fractures using letters (A, B, or C).²⁵ As an example, great toe, proximal phalanx, distal end segment, partial articular fracture is classified as AO/OTA type 8811.3.B.²⁴

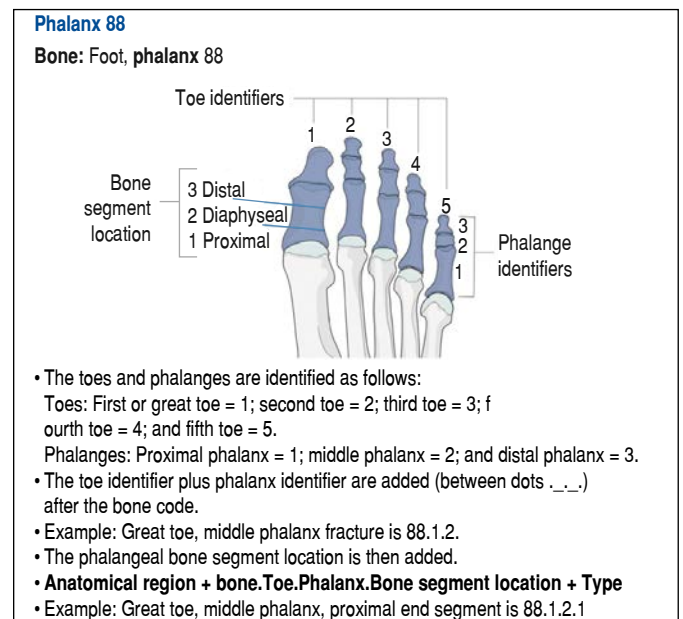


Figure 1. AO Foundation/Orthopaedic Trauma Association coding classification system forefoot.

Source: <https://surgeryreference.aofoundation.org/orthopedic-trauma/adult-trauma/foot-phalanges>.

Trauma mechanism

A knowledge of the trauma mechanism is useful in understanding both the classification and the appropriate treatment. The three most common trauma mechanism patterns are twisting of the forefoot, axial trauma, and crushing. The forces producing these injuries are either direct (crush) or indirect (twist and axial). Specifically in hallux phalanx fractures, the two mechanisms commonly involved are axial trauma and crushing.⁴

Hallux fractures can occur to the distal phalanx and proximal phalanx with or without intra-articular involvement into the interphalangeal joint. A direct axial injury to the tip or tuft of the great toe usually lead to distal phalanx injury, whereas a crushing type of injury can lead to both proximal and distal phalanx injury.

Surgical treatment indications, approaches and fixation options

In general, closed reduction is acceptable for treating hallux proximal phalanx diaphyseal fractures, being uncommon a surgical treatment.⁵ The main *indications* for the surgical treatment of the hallux proximal phalanx are:

- Intra-articular fractures with a deviation greater than 2mm;
- Metadiaphyseal fractures with malrotation;

- Metadiaphyseal fractures with malangulation;
- Open fractures; and
- Unstable fractures.

The case reports of operative management show improved outcomes considering range of motion, pain, and deformity compared to nonoperative management.²⁶⁻²⁸

The recommendation of an operative approach and method fixation is usually based on the surgeon experience, fracture pattern, and size of fragments; they have been addressed in few studies.^{5,6,9,10}

Medial longitudinal approach

This classic approach is recommended for fractures of the two phalanx of the hallux with or without joint involvement. However, this approach can also be used for open reduction and internal fixation (ORIF) of the medial sesamoid bone and distal fractures of the first metatarsal, as well as for treating complications. The skin incision starts at the mid-point of the phalanx base and runs distally towards the mid-diaphysis of the distal phalanx.

Some anatomical structures are at risk, such as the proximal phalanx, which receives its blood supply from an artery that enters the base, the dorsomedial (collateral) digital nerve (mostly a branch of the deep fibular nerve), which innervates the dorsal half of the medial side, and the medial plantar hallux nerve, which, in turn, innervates its plantar aspect.²⁴

Dorsomedial approach

Surgical treatment for ORIF with this approach is mostly recommended for treating the displaced bicondylar fractures of the proximal phalanx of the hallux (> 2 mm). It could also be recommended for the treatment of displaced unicondylar or diaphyseal fractures of the proximal phalanx of the hallux.⁶ Dorsomedial approach presents the same structures at risk as the medial longitudinal approach.

Dorsolateral approach

This approach is recommended for treating the supra-intercondylar fracture of the proximal phalanx of the hallux with instability, malangulation, and malrotation, especially fractures with lateral displacement, which require implant on the lateral side of the proximal phalanx. It is performed medial to the vessels and lateral nerves of the hallux and no ligament or tendon detachment is necessary.²⁹

Both dorsomedial and dorsolateral approach using L-shaped incision present higher risk for soft tissue blood supply compared to other approaches using straight incisions.^{6,9}

Direct reduction should be performed using a periosteal elevator as a lever to reduce the fracture. Anatomical restoration of the articular surface is mandatory, with correction of axial rotation, length, and angulation. It is useful to apply a small pointed reduction clamp to temporarily compress the articular fracture fragments. Once the fracture is adequately reduced, a Kirschner wire (K-wire) is used, so the clamp can be removed, thus facilitating plate positioning.^{5,6,9,29} (Figure 2)

Implants options

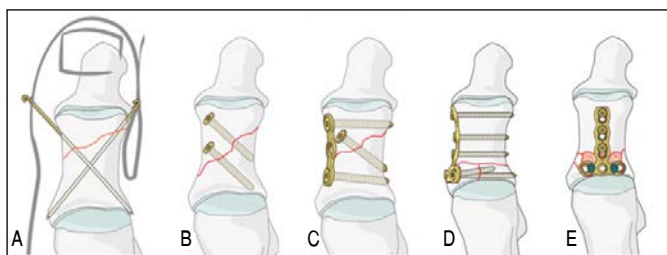


Figure 2. A: crossed K-wires; B: lag screws; C: lag screw and neutralization plate; D: neutralization plate and lag screw through plate; and E: "T" dorsal plate.

Source: <https://surgeryreference.aofoundation.org/orthopedic-trauma/adult-trauma/foot-phalanges>.

K-wires: when choosing closed reduction, the fixation with two or more K-wires may be performed. This fixation may be recommended for patients with poor soft tissue envelope or severe medical comorbidities.

Lag screw with 2.0 mm or 2.3 mm screws: recommended for simple fractures (spiral, oblique and transverse), extra-articular fractures, partial articular fractures, and complete articular fractures, which have inherent stability, thus making lag screw fixation sufficient. A plate to protect the lag screw fixation is rarely necessary.

Locking plate with 2.0 mm or 2.3 mm screws: recommended for wedge and multifragmentary fractures, or when a neutralization plate is needed. This plate enhances the degree of fixation and permits a greater degree of weight bearing, which facilitates functional rehabilitation. A lag screw may be used through the plate, since this combination increases the fixation strength.

The plate must be adequately molded and to cut it in an appropriate length. If necessary, the plate can be bended and twisted to contour the bone (Figure 3).

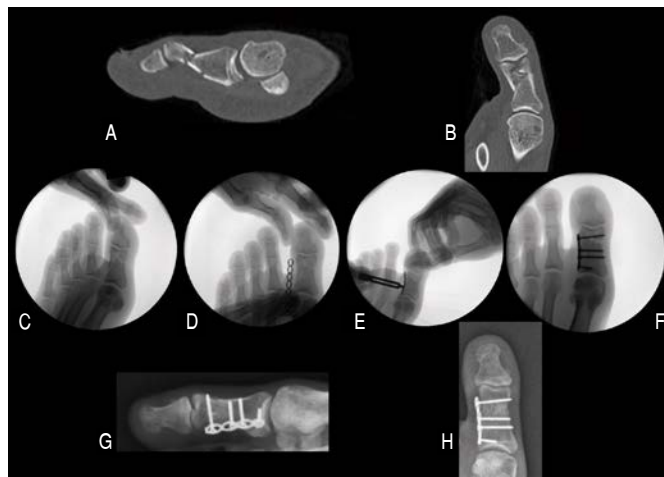


Figure 3. A and B: preoperative CT sagittal and axial view; C: intra-operative hallux distraction; D, E and F: plate cutting in an appropriate length, molding and bending to contour it to the bone; G and H: postoperative oblique and anteroposterior conventional radiographic images of hallux proximal phalanx fracture.

The plate should be applied to the tension side of the fracture to act as a tension band during plantar support. Moreover, the plate should have a low profile to reduce soft tissue irritation.²⁹

Complications

Subungueal/nail hematoma can lead to potentially serious complications if not immediately identified and treated. It is more related with distal phalanx fracture than proximal phalanx fracture.^{5,30}

A significant hematoma is defined as covering more than 50% of the nailbed surface beneath the nail plate.

- Type I injuries are described as relatively clean nail bed lacerations with less than 1 cm in length;
- Type II injuries are described as moderately contaminated nailbed lacerations without extensive soft tissue damage greater than 1 cm in length,
- Type III injuries are described as highly contaminated nailbed lacerations with extensive soft tissue damage to muscle, skin, and neurovascular structures.

Antibiotic administration and drainage are based on the type of injury. Partial nail plate avulsion should be treated non-surgically.

If a laceration of nail plate is evident, then the nailbed should be completely cleaned up. Contour of the nailbed should be maintained for preventing onychodystrophy. Nonadherent sterile gauze should be used as a template and inserted into the proximal nail fold.³⁰

Valgus deformity

Patients with a fracture of proximal phalanx of the great toe complain more about valgus deformity than about severe pain.¹⁰ Valgus deformity progresses gradually and can result in hallux valgus and interphalangeal hallux valgus according to the fracture site. Interphalangeal hallux valgus is defined as the angular relationship between the longitudinal axes of the proximal and distal phalanges. Normal values range from an average of 9° in the unshod to 13.4° in a shoe-wearing population.⁹

Fracture of the lateral side of the proximal phalanx head and/or diaphysis, and the medial side of the proximal phalanx base can result in valgus deformity.¹⁰

Treatment can be performed with arthrodesis or corrective osteotomy, depending on the degree of joint degeneration of the interphalangeal joint (IPJ).

Hallux interphalangeal joint osteoarthritis

Degenerative arthritis of the hallux IPJ may occur following hallux proximal phalanx fracture, more frequent in the proximal phalanx head and/or diaphysis.^{9,10}

IPJ osteoarthritis is grading by radiographic system.³¹

- Grade I shows no degenerative change;
- Grade II shows mild degenerative changes with less than 1 mm of chondrolysis;

- Grade III shows moderate degenerative change with 1 mm to 2 mm of chondrolysis,
- Grade IV shows severe degenerative changes with joint destruction, cysts, or malalignment.

Arthrodesis of the IPJ of the hallux is performed for pain, deformity, or dysfunction secondary to hallux fracture.

Multiple approaches have been described, including longitudinal linear, transverse semi-elliptical, curvilinear, or L-shaped.³² Fixation used included single linear or multiple crossed K-wires (44% non-union), intramedullary compression screw (10% non-union) or 2.7-mm cortical lag screw.^{32,33}

The optimal position in the sagittal plane has been reported to be from neutral to 5 or 10 degrees of plantar flexion to permit weight bearing on the toe pad.³³

CONCLUSION

Fractures of the hallux and lesser toes phalanges are frequent injuries. Hallux phalanx fracture correspond to about 5.5% of foot and ankle fractures. The most frequent trauma mechanism is axial trauma. Foot trauma is often neglected in polytrauma patients. AO/OTA coding classification system allows a universal language standardization.

There is consensus for surgical treatment of intra-articular fractures with a deviation greater than 2mm, metadiaphyseal fractures with malrotation and/or malangulation, open fractures and unstable fractures. A surgery can be performed through medial longitudinal, dorsomedial and dorsolateral using L-shaped incision or straight incisions. The use of more rigid implants allow alignment maintenance during the healing process and lower risk of reduction loss. Valgus deformity and interphalangeal joint osteoarthritis are possible complications that must be avoided.

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EFFECT OF PKP ON SERUM SOST IN PATIENTS WITH VERTEBRAL COMPRESSION FRACTURES

EFEITO DE PKP EM SOST SORO EM PACIENTES COM FRATURAS DE COMPRESSÃO VERTEBRAL

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ABSTRACT

Objective: This study sought to determine serum sclerostin (SOST) expression in patients with osteoporotic thoracolumbar vertebral compression fractures before and after percutaneous kyphoplasty (PKP). **Methods:** Serum SOST levels were quantified with a sandwich enzyme-linked immunosorbent assay (ELISA) preoperatively and six months postoperatively. Anterior vertebral height, kyphotic angles, and Visual Analogue Scale (VAS) scores were also recorded. **Results:** Serum SOST was highly expressed in patients and remained negatively correlated with bone mineral density (BMD). Vertebral heights, local kyphotic angles, and VAS scores were all significantly improved after PKP. However, serum SOST was positively correlated with BMD six months after surgery. **Conclusion:** PKP was an effective treatment strategy for osteoporotic thoracolumbar vertebral compression fractures, improving BMD and decreasing serum SOST levels. **Level of Evidence II, Prospective comparative study.**

Keywords: Bone Density. Kyphoplasty. Osteoporosis.

RESUMO

Objetivo: Este estudo teve por objetivo determinar a expressão de esclerostina (SOST) em pacientes com fraturas vertebrais osteoporóticas por compressão na coluna toracolombar antes e depois da Cifoplastia Percutânea (PKP). **Métodos:** Os níveis de SOST no soro foram quantificados por meio de um Ensaio de Imunoadsorção Ligado à Enzima (ELISA) sanduíche, realizado no pré-operatório e aos seis meses pós-operatório. Foram também registrados a altura do corpo vertebral anterior, os ângulos cifóticos, e os valores obtidos na escala analógica visual (VAS). **Resultados:** O nível de SOST no soro foi altamente expresso nos pacientes, e permaneceu correlacionado negativamente com a densidade mineral óssea (DMO). As alturas vertebrais, os ângulos cifóticos locais, e as pontuações obtidas na escala VAS foram significativamente melhores após o PKP. No entanto, o SOST foi correlacionado positivamente com a DMO aos seis meses pós-operatório. **Conclusão:** O PKP foi uma estratégia eficaz para o tratamento de fraturas vertebrais osteoporóticas por compressão na coluna toracolombar, melhorando os níveis de DMO e diminuindo os níveis de SOST no soro. **Nível de Evidência II, Estudo prospectivo comparativo.**

Descritores: Densidade Óssea. Cifoplastia. Osteoporse.

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INTRODUCTION

Osteoporosis is a common skeletal disease characterized by low bone mass, impaired bone mechanical functions, and increased bone fragility. It has become a major cause of disability and death among older adults, leading to an increased fracture risk.¹ Vertebral fracture is the most common outcome of osteoporosis, especially osteoporotic vertebral compression fractures (OVCF), which

frequently occur at the thoracolumbar segment.² Patients with that type of fracture usually suffer from low back and lumbosacral pain that is aggravated by activities.

We believe osteoporotic fracture is traditionally treated with bed rest and analgesics. However, long-term bed rest might result in potential complications such as pulmonary infection, atelectasis, thrombosis, and pulmonary embolism.³ Open surgery and minimally

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invasive surgery are well documented alternative methods for the operative treatment of OVCF. Open surgeries, such as laminectomy and internal fixation, are appropriate for patients who present signs of neurological deficits, or those with space-occupying lesions in spinal canal and spinal cord compression, based on nerve computed tomography (CT) and magnetic resonance imaging (MRI) scans. However, open surgery entails two major disadvantages: greater blood loss and high failure rate.⁴

Percutaneous kyphoplasty (PKP) is a vertebroplasty-modified minimally invasive procedure that may effectively recover height and reduce bone cement leakage.⁵ Up to now, few studies evaluated PKP efficacy in the treatment of osteoporotic thoracolumbar vertebral compression fractures.⁶⁻⁸

Sclerostin (SOST) is an important osteocyte-derived glycoprotein that functions as a negative regulator of bone formation by inhibiting Wnt/ β -catenin signaling to promote osteogenic differentiation.⁹ SOST-KO mice showed to enhance bone defects healing¹⁰ and highly expressed serum SOST is associated with fracture healing.¹¹ SOST functions as a therapeutic target for treating osteoporotic fracture.¹² However, the influence of PKP treatment on SOST expression remained unclear. Considering that, this study sought to analyze the serum SOST expression among patients with osteoporotic thoracolumbar vertebral compression fractures and their response to PKP treatment.

MATERIALS AND METHODS

Chart 1. Highlights.

Serum SOST was highly expressed in patients with osteoporotic thoracolumbar vertebral compression fractures.

Vertebral heights, Cobb's angles, and VAS scores were significantly improved after PKP

Postoperative SOST was positively correlated with BMD during 6 months follow-up

Study population

From January 2017 to June 2018, 150 patients with osteoporotic fractures examined by computed tomography (CT) or magnetic resonance imaging (MRI) of the thoracolumbar spine were evaluated. Of these, sixty cases of thoracolumbar vertebral compression fractures were included in the study. Patients with severe heart and lung disease and coagulation disorders were excluded. Our study group included 33 women and 27 men with body mass index (BMI) ranging from 22 to 28 kg/m³. Average age at surgery was 69 years (range: 44 to 78 years) and average duration of symptoms was eight weeks (range: 2 to 24 weeks). Sixty gender- and age-matched individuals with normal bone mineral density (BMD), confirmed by physical examination during the same period, composed the control group. A written informed consent form was obtained from each participant. All experimental protocols for this study were approved by the Ethics Committee of Ningbo Women and Children's Hospital.

Surgical procedure

Percutaneous kyphoplasty (PKP) was performed under general anesthesia in prone position, as previously described.¹³ Bone marrow biopsy needle was percutaneously inserted under C-arm fluoroscopy guidance (BAITENG Medical, Shanghai, China) into the fractured vertebra body through pedicle. Then a balloon was inserted into the vertebra to restore vertebral body height and create a cavity for bone cement injection. Bone cement introducer was removed after the cement was well diffused. The same surgeons performed all operations, and no bone cement leakage and balloon rupture occurred during operation.

Enzyme-linked immunosorbent assay

Fasting blood samples containing anticoagulant were collected from patients with thoracolumbar vertebral compression fractures and healthy volunteers and centrifuged at 3000 rpm for twenty minutes. Serum specimens were then stored at -80 °C until analysis. Serum sclerostin (SOST) protein levels in serum were measured using the Human SOST ELISA kit (Boster, Wuhan, China), according to manufacturer's instruction.

Clinical and radiographic examinations

Values of bone mineral density (BMD), visual analogue scale (VAS), anterior vertebral body height of the fractured level (AVHF), and Cobb's angle were investigated to evaluate improvement in patients' pain and outcomes. BMD was measured by dual energy X-ray absorptiometry using the QDR-2000 (Hologic Inc., Waltham, MA, USA). Clinical evaluation of pain employed the VAS score, ranging from 0 (no pain) to 10 (severe pain). X-ray examination was obtained preoperatively and one-week postoperatively. Cobb's angle was measured between the superior vertebral endplate, one level above the treated vertebra, and the inferior vertebral body endplate, one level below the treated vertebra. Anterior height was determined by measuring the length between the superior endplate most antero-superior point and the inferior endplate most antero-inferior point of the fractured vertebra body.

Statistical analysis

Data were expressed as mean \pm standard deviation (SD) and analyzed using SPSS version 22.0 (SPSS, Chicago, IL, USA). Statistical differences were assessed using two-sided Student's *t* test or analysis of variance, and *p* value < 0.05 was considered significantly different. Spearman's rank correlation coefficient was used to analyze the correlation between serum SOST and BMD.

RESULTS

SOST and BMD association in patients with osteoporotic thoracolumbar vertebral compression fractures

Patients with osteoporotic thoracolumbar vertebral compression fractures showed higher serum SOST (Figure 1A, *p* < 0.05) and lower BMD (Figure 1B, *p* < 0.05) than healthy controls. We found a significant negative correlation between serum SOST and BMD, according to Spearman's correlation coefficient (Figure 1C, *r* = 0.5345, *p* < 0.001).

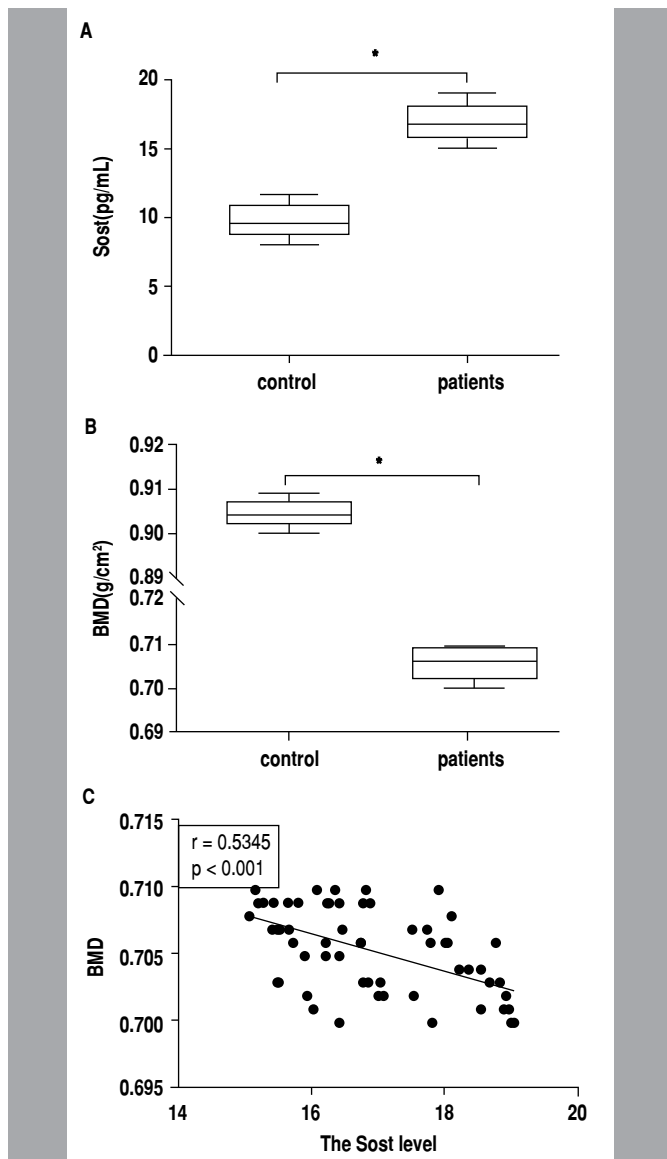


Figure 1. Sclerostin expression in patients with osteoporotic thoracolumbar vertebral compression fractures and its correlation with bone mineral density. $p < 0.05$ vs. control group.

A: serum SOST levels; B: BMD in patients with osteoporotic thoracolumbar vertebral compression fractures and healthy controls; and C: correlation analysis between serum SOST and BMD in patients with osteoporotic thoracolumbar vertebral compression fractures.

Pre- and postoperative outcomes comparisons

All patients underwent successful surgery. Mean operative time was seventy minutes (range 45–120 minutes). Intraoperative blood loss ranged from 8 to 14 mL, with an average of 10 mL. All patients were able to get out of bed within 3 to 5 days after surgery. Forty-six cases reported complete pain relief, 12 partial relief, and two no relief; complete remission rate was 96.60%. Patients developed no complications such as constipation, pneumonia, and lower extremities deep venous thrombosis.

As presented in Table 1, the average preoperative pain based on VAS was 7.24 (SD = 0.29) and the average postoperative VAS was 2.24 (SD = 0.14), suggesting pain relief one week after PKP. We also observed postoperative improvement in the anterior vertebral height and a significant decrease in the average vertebral Cobb's angle when compared to preoperative values (all, $p < 0.05$).

Table 1. Pre- and postoperative Visual Analogue Scale, anterior vertebral height, and Cobb's angle.

Group	VAS	anterior vertebral height (mm)	Cobb's angle (°)
preoperative	7.24 ± 0.29	18.47 ± 0.82	23.72 ± 1.15
postoperative	2.24 ± 0.14*	24.38 ± 1.62*	8.84 ± 1.42*

VAS: Visual Analog Scale.

Postoperative SOST expression in patients and its correlation with BMD

To better understand the efficacy of PKP for treating thoracolumbar vertebral compression fractures and its effect on SOST expression, we compared serum SOST levels and BMD before and after surgery. Figure 2 shows that serum SOST was markedly downregulated (Figure 2A) while BMD shows an upward trend (Figure 2B) at one, three and six months postoperatively in comparison to preoperative values (all, $p < 0.05$). We found a positive correlation between serum SOST level and BMD within six-month postoperative (Table 2, $p < 0.05$).

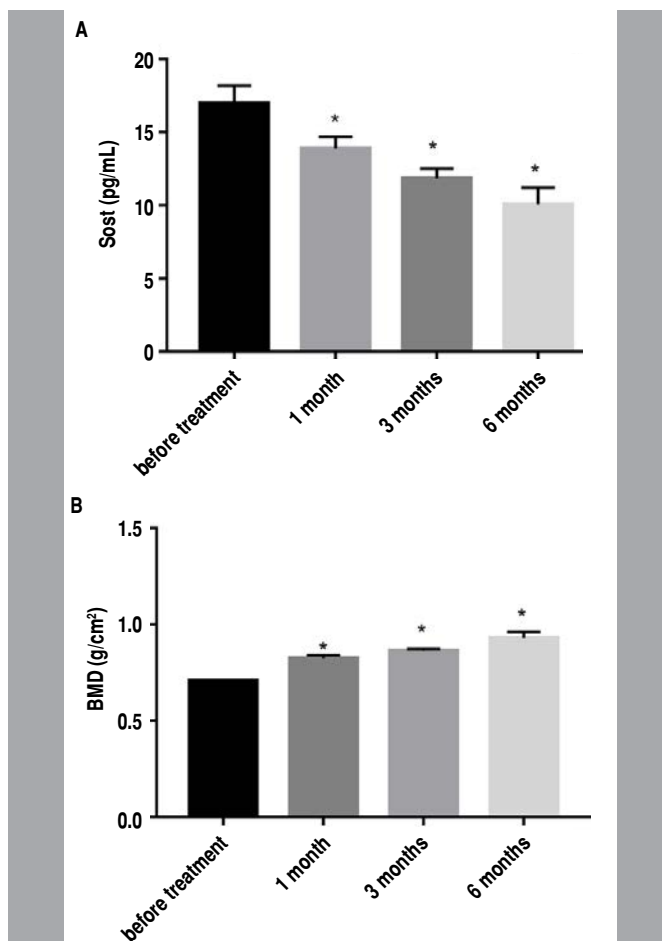


Figure 2. Changes of serum sclerostin and bone mineral density after percutaneous kyphoplasty.

A: serum SOST levels; and B: BMD before surgery and at one, three and six months postoperatively.

Table 2. Correlation between serum sclerostin and postoperative bone mineral density.

Postoperative	r	P
one month	0.269	0.037
three months	0.621	0.000
six months	0.629	0.000

DISCUSSION

Osteoporosis vertebral compression fracture (OVCF), a common complication of osteoporosis, may lead to severe lower back pain, limited movement, and spinal and kyphotic deformity.¹⁴ Bone remodeling mainly relies on the activity of two major cells types – bone-forming osteoblasts and bone-resorbing osteoclasts. Recently, accumulating evidence strongly implied that Wnt/ β -catenin signaling plays an important role in controlling bone mass, increasing proliferation and differentiation of osteoblastic precursor cells and improving bone mineral density (BMD).¹⁵ In mammalian cells, Serum sclerostin (SOST) inhibits Wnt signaling by binding to Wnt receptors extracellular domain.¹⁶ Thus, SOST is increasingly recognized as a vital negative regulator of bone formation.¹⁷ SOST deficiency-induced diseases in humans are characterized by increased bone mass.¹⁸ Gaudio and colleagues¹⁹ found high SOST serum levels expression in patients with immobilization-induced bone loss. According to Shen et al.,²⁰ anti-SOST is a potential therapy for osteoporosis. In our study, SOST serum levels were significantly higher in patients with osteoporotic thoracolumbar vertebral compression fractures when compared with healthy controls. More importantly, serum SOST was negatively correlated with BMD.

With the continuous socioeconomic development and the improvement in medical technology, several surgical methods are used for treating thoracolumbar fractures.^{21,22} Percutaneous kyphoplasty (PKP) is a minimally invasive, safe, and effective treatment for OVCF that can effectively and quickly relieve pain, improve functional capacity, reduce the incidence of complications, increase vertebral strength, avoid postoperative vertebral height loss, and prevent secondary fractures.²³ Sun et al.²⁴ reported low-viscosity for PKP results in the restoration of middle vertebral height for treating OVCF. Zhao et al.²⁵ found PKP to be also associated with a significantly longer operation time and a lower risk of cement leakage. In our study, all patients showed significant improvement in VAS score, anterior vertebral height, and Cobb's angle within one week after operation compared with values before operation. PKP surgery also resulted in serum SOST downregulation and BMD increase at 6-month follow-up. SOST was positively correlated with BMD after PKP treatment.

CONCLUSION

In conclusion, PKP treatment may not only restore compressed vertebral body height and correct kyphosis, but also reduce SOST expression to achieve an effective treatment of patients with osteoporotic thoracolumbar vertebral compression fractures.

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