TRATAMENTO DAS FRATURAS DO TERÇO MÉDIO DA CLAVÍCULA: OSTEOSSÍNTES COM PLACA X IMOBILIZAÇÃO EM OITO. Ensaio clínico randomizado.

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UNIVERSIDADE FEDERAL DE SÃO PAULO
ESCOLA PAULISTA DE MEDICINA

2017

Relatório Final de Estágio de Pós-Doutorado

Programa de Pós-Graduação em Cirurgia Translacional
Coordenador: Prof. Dr. Miguel Sabino Neto
Supervisor do Pós-Doutorado: Prof. João Carlos Belloti

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2017

RELATÓRIO FINAL

Nome: Marcel Jun Sugawara Tamaoki

Área de Concentração: *Qualidade Como Método de Avaliação*

Linha de Pesquisa: *Medicina Baseada em Evidências*

Período: junho de 2012 a agosto de 2017

Instituição: Escola Paulista de Medicina - Universidade Federal de São Paulo

Supervisor: Prof. João Carlos Belloti

TRATAMENTO DAS FRATURAS DO TERÇO MÉDIO DA CLAVÍCULA: OSTEOSSÍNTES COM PLACA X IMOBILIZAÇÃO EM OITO. Ensaio clínico randomizado

O cerne de nosso projeto, sobre o controverso tema do Tratamento das Fraturas Desviadas da Clavícula foi terminado, e teve uma conclusão importante, a de que não houve diferença quanto aos resultados funcionais, entre o tratamento não cirúrgico (com imobilizador em 8) e o cirúrgico (uso da placa anteroinferior), mas, quando considerado o desfecho de complicações e, em particular, as pseudartroses e o encurtamento residual da clavícula, o resultado foi favorável para tratamento cirúrgico. Com isso, nosso ensaio clínico randomizado fornece mais uma informação para a elaboração de uma evidência conclusiva sobre o assunto.

Este projeto, inicialmente, foi contemplado com a Bolsa do Programa de Reestruturação e Expansão das Universidades Federais (REUNI) em 2012, o qual teve como objetivo a melhoria e a inovação do ensino de graduação e sua integração com a pós-graduação nas Universidades Federais. Também foi subsidiado com Auxílio Pesquisa Regular da Fapesp (processo número 11/21611-2, com vigência entre 01/maio/2012 e 30 de abril de 2014, tendo como beneficiário o prof. João Carlos Belloti).

No contexto da proposta REUNI, as melhorias na integração entre a graduação e pós-graduação, a nossa atuação foi focada nos alunos da Liga de Traumatologia Ortopédica (que inclui, atualmente, alunos do 2º., 3º., 4º. e 5º. anos da Escola Paulista de Medicina).

No Programa da Pós-graduação em Cirurgia Translacional (PPG-CT), em que, atualmente, atuo como Professor Orientador – credenciamento em 2015, participaram do processo de integração, tanto alunos em nível de mestrado, quanto do doutorado, inseridos em nossa Linha de Pesquisa (LP) e participando de projetos de revisões sistemáticas e ensaios clínicos.

Basicamente, os alunos da graduação, bem como aqueles inscritos na Liga Acadêmica, tem como foco o atendimento e tratamento das afecções ortopédicas, ou seja, relacionadas às atividades práticas-assistênciais. Além disso, foram desenvolvidas atividades de educação para promover as necessárias habilidades de aprendizagem e prática da medicina baseada em evidências, por meio de todos os seus passos, utilizando os melhores métodos educacionais para este propósito, e o desenvolvimento das melhores e mais adequadas técnicas para aplicar essas evidências encontradas na prática clínica, ou seja, nos pacientes.

Para tanto, fizeram parte do ensino a disseminação de diretrizes baseadas em evidências, fontes eletrônicas com conhecimento científico e já criticamente avaliadas, de fácil acesso e compreensão, como *Best Evidence, POEMS, CATs, Cochrane Library* e, com esse objetivo, foi disponibilizado na Disciplina de Cirurgia da Mão e Membro Superior do Departamento de Ortopedia e Traumatologia (DOT), todos os recursos e equipamentos necessários, como computadores, acesso à INTERNET, e acesso a periódicos.

A atividade prática de aplicação da medicina baseada em evidência (MBE), foi tanto na sua concepção, com o desenvolvimento de ensaios clínicos randomizados e revisões sistemáticas e metanálises, quanto na sua aplicação em um ambulatório específico para o atendimento de pacientes com afecções de

membro superior e, durante as cirurgias, por meio de questionamentos e discussões sobre determinada técnica empregada.

Assim, os graduandos, que participaram deste projeto, puderam aprender e utilizar os princípios da MBE durante a prática, e desenvolver hábitos de criar suas próprias questões clínicas, buscando na literatura, respostas para as mesmas. Então, de posse dessa informação, poderão avaliá-la criticamente, e aplicá-la a situação desejada, melhorando o processo de tomada de decisão e mantendo-os atualizados.

Em relação ao desenvolvimento da pesquisa dentro da Linha de Pesquisa de medicina baseada em evidências (MBE), apesar do desenvolvimento anterior de outros ensaios clínicos randomizados, este foi o primeiro realizado de maneira multicêntrica, o que apresenta dificuldades técnicas e metodológicas para coordenação e desenvolvimento da pesquisa.

Os principais desafios vencidos foram coordenar centros distintos, e coletar e estabelecer protocolos da aplicação das intervenções e aferições de desfechos. A sede organizacional foi definida em nossa Universidade (UNIFESP), onde concentrou todos os dados referentes a randomização e coleta de dados, além de local das reuniões mensais, onde discutia-se o seu desenvolvimento, mensalmente.

Este projeto gerou duas publicações (Qualis A1 e B1):

1. Tamaoki MJS, Matsunaga FT, Costa ARFD, Netto NA, Matsumoto MH, Belloti JC. Treatment of Displaced Midshaft Clavicle Fractures: Figure-of-Eight Harness Versus Anterior Plate Osteosynthesis: A Randomized Controlled Trial. J Bone Joint Surg Am. 2017 Jul 19;99(14):1159-1165. (ANEXO 1)

2. Figueiredo GS, Tamaoki MJ, Dragone B, Utino AY, Netto NA, Matsumoto MH, Matsunaga FT. Correlation of the degree of clavicle shortening after non-surgical treatment of midshaft fractures with upper limb function. BMC Musculoskelet Disord. 2015 Jun 17;16:151. (ANEXO 2)

Além disso, houve divulgação da pesquisa nos congressos:

1. Tamaoki MJ; REZENDE, AG ; Belloti, JC ; NETTO, NA ; MATSUMOTO,MH Intervenção Cirúrgica X Não Cirúrgica para as Fraturas do Terço Médio da Clavícula em Adultos. Ensaio Clínico Randomizado – Resultados Preliminares. In: 43o Congresso Brasileiro de Ortopedia e Traumatologia, 2011, São Paulo. Programa Oficial - 43o Congresso de Ortopedia e Traumatologia, 2011. v. 1. p. 61-61.

2. Tamaoki MJ, Utino AY, Figueiredo GS. Correlation of the degree of clavicle shortening after non-surgical treatment of midshaft fractures with upper limb function 2015. Baltimore, Maryland, EUA. 4th International Conference on Orthopedics & Rheumatology.

Por fim, como fruto deste trabalho inicial e experiências deste projeto, multicêntrico, podemos elaborar dois outros ensaios clínicos randomizados, com estes refinamentos, sendo um concluído:

1. Matsunaga FT, Tamaoki MJ, Matsumoto MH, Netto NA, Faloppa F, Belloti JC. Minimally Invasive Osteosynthesis with a Bridge Plate Versus a Functional Brace for Humeral Shaft Fractures: A Randomized Controlled Trial. J Bone Joint Surg Am. 2017 Apr 5;99(7):583-592. doi: 10.2106/JBJS.16.00628, que gerou duas publicações uma do protocolo (B2 – ANEXO 3) e outra do trabalho final (A1 – ANEXO 4).

E outro, em andamento:

2. Mansur NS, Faloppa F, Belloti JC, Ingham SJ, Matsunaga FT, Santos PR, Santos BS, Carrazzone OL, Peixoto G, Aoyama BT, Tamaoki MJ. Shock wave therapy associated with eccentric strengthening versus isolated eccentric strengthening for Achilles insertional tendinopathy treatment: a double-blinded randomised clinical trial protocol. BMJ Open. 2017 Jan 27;7(1):e013332, publicado o protocolo qualis B1 (ANEXO 5).

O primeiro se referiu ao projeto de doutorado desenvolvido em nosso PPG-CT (coorientação), e o segundo, trata-se do projeto de mestrado de outro pós-graduando (orientação).

Também iniciamos dois novos projetos, multicêntricos, de acurácia. Ambos sob minha orientação, matriculados regularmente no PPG-CT. Inseridos nos dois projetos, dois alunos de iniciação científica:

1. Acurácia dos testes clínicos do ombro no diagnóstico das lesões do tendão do supraespinal;

2. Acurácia dos testes clínicos do ombro e ultrassonografia no diagnóstico nas lesões do subescapular.

A iniciativa do REUNI foi um ótimo incentivo para a integração da graduação com a pós graduação e, proporcionou, uma experiência única, permitindo a transmissão do conhecimento e contato do graduando com a pesquisa, que tem a capacidade de despertar o interesse e apresenta suporte para a concepção de ideias e metodologias, e assim, criar uma visão mais global de todo processo, de seu desenvolvimento e sua condução para criação de novos conhecimentos em pesquisa clínica. Estimula e envolve, de maneira recíproca, o pesquisador.

ANEXO 6

PROGRAMA DE PÓS-DOUTORADO DA UNIVERSIDADE FEDERAL DE SÃO PAULO, CAMPUS SÃO PAULO

FORMULÁRIO PARA ENCERRAMENTO DO ESTÁGIO

I – Dados do Pós-Doutorando

Nome (completo): MARCEL JUN SUGAWARA TAMAOKI

II – Dados do Supervisor

Nome (completo): JOÃO CARLOS BELLOTI

III – Dados do Programa – PPG CIRURGIA TRANSLACIONAL

Título do Projeto: **TRATAMENTO DAS FRATURAS DO TERÇO MÉDIO DA CLAVÍCULA: OSTEOSSÍNTES COM PLACA X IMOBILIZAÇÃO EM OITO. Ensaio clínico randomizado**

Período do Relatório: junho de 2012 a agosto de 2017.

Resumo sucinto das atividades desenvolvidas no período (até 10 linhas):

Inicialmente, foi contemplado com a Bolsa do Programa de Reestruturação e Expansão das Universidades Federais (REUNI) em 2012 (relatório aprovado) e Auxílio Regular a Pesquisa da Fapesp. No Programa da Pós-graduação em Cirurgia Translacional (PPG-CT), Professor Orientador (2015), participando do processo de integração, alunos em nível de mestrado e doutorado, inseridos na LP - projetos de revisões sistemáticas e ensaios clínicos. Este projeto gerou duas publicações (*Estratos* A1 e B1, MEDICINA III), com divulgação nos congressos da área. Elaboramos dois outros ensaios clínicos randomizados, com refinamentos obtidos com esta primeira experiência, sendo um concluído e outro, em andamento. Iniciamos dois novos projetos, multicêntricos, de acurácia, ambos sob minha orientação (nível de Doutorado) matriculados regularmente no PPG-CT, com a participação de dois alunos de iniciação científica. (Relatório Final, anexo).

Local e Data.....

Assinatura do Pós-Doutorando: .....

Assinatura do Supervisor: .....

Para aprovação pela Câmara de Pós-Graduação e Pesquisa anexar:

Com bolsa: Cópia do parecer sobre Relatório Final de pesquisa pela assessoria científica.

Sem bolsa: Cópia do Relatório Final de Pesquisa para ser analisado por assessor indicado pela Câmara de Pós-Graduação e Pesquisa.

HOSPITAL SANTA PAULA

(Preencher os dados quando não houver etiqueta)
Nome do Paciente:_____
Data de nascimento: _____/_____/_____

TERMO DE CONSENTIMENTO INFORMADO PARA PROCEDIMENTO CIRURGICO

O presente Termo de Consentimento Informado tem o objetivo de informar ao paciente e/ou responsável, quanto aos principais aspectos relacionados ao Procedimento Cirúrgico ao qual será submetido, complementando as informações prestadas pelo seu médico e pela equipe de profissionais e prestadores de serviços do Hospital Santa Paula.

Os campos abaixo deverão ser preenchidos pelo médico

Confirmo que expliquei detalhadamente para o paciente e/ou responsável o propósito, os benefícios, os riscos e as alternativas para o procedimento cirúrgico proposto.

Procedimento proposto:_____

Os principais riscos associados especificamente a este procedimento são: _____

_____

O paciente e/ou responsável demonstrou entender o que foi explicado.

Nome do médico:_____

Assinatura:_____CRM:_____

São Paulo, _____ de _____ de 20_____ Horário ____:____

Os campos abaixo deverão ser preenchidos pelo paciente e/ou responsável

Eu,_____, inscrito no RG sob o nº _____ ( ) paciente/ ( ) responsável declaro que:

1. Fui informado que as avaliações e exames realizados revelaram alteração de meu estado de saúde, com indicação de realização do procedimento cirúrgico descrito acima.
2. Recebi todas as informações necessárias quanto aos riscos, benefícios e alternativas do procedimento proposto.
3. Compreendo que durante o procedimento poderão apresentar-se outras situações ainda não diagnosticadas, assim como também poderão ocorrer situações imprevisíveis ou fortuitas.
4. Estou ciente que em procedimentos médicos invasivos, como o proposto, podem ocorrer complicações gerais como sangramento, infecção, problemas cardiovasculares e respiratórios.
5. Estou ciente de que para realizar o(s) procedimento(s) proposto (s), será necessário o emprego de anestesia, cujos métodos, as técnicas e os fármacos serão indicados pelo médico anestesista, estando também ciente dos riscos e benefícios e alternativa.
6. Autorizo o médico acima citado, bem como seus assistentes e/ou outros profissionais por ele selecionados a intervir no procedimento.
7. Autorizo qualquer outro procedimento, exame, tratamento e/ou cirurgia, incluindo transfusão de sangue, em situações imprevistas que possam ocorrer e necessitem de cuidados diferentes daqueles inicialmente propostos.
8. Confirmo que recebi explicações, li, compreendo e concordo com tudo que me foi esclarecido e que me foi concedido a oportunidade de anular, questionar, alterar qualquer espaço, parágrafo ou palavras com as quais não concordasse. Tive a oportunidade de fazer perguntas que me foram respondidas satisfatoriamente. Assim, tendo conhecimento, autorizo a realização do procedimento proposto.

Assinatura do paciente e/ou responsável: _____ Grau parentesco:_____

Universidade Federal de São Paulo - UNIFESP/ Hospital São Paulo

PROJETO DE PESQUISA

Título: Tratamento das fraturas do terço médio da clavícula: osteossínese com placa X imobilização em 8. Ensaio clínico randomizado.

Área Temática:

Pesquisador: MARCEL JUN SUGAWARA TAMAOKI **Versão:** 1

Instituição: Universidade Federal de São Paulo - UNIFESP/EPM **CAAE:** 03763112.0.0000.5505

PARECER CONSUBSTANCIADO DO CEP

Número do Parecer: 32911

Data da Relatoria: 18/06/2012

Apresentação do Projeto:

O tratamento das fraturas do terço médio da clavícula é controverso, classicamente seu tratamento é não cirúrgico com imobilizador, contudo atualmente tem se questionado este tratamento pois os paciente adultos apresentam até 15% de não consolidação com este método. Alguns autores propõe o tratamento cirúrgico como forma de diminuir esta taxa de não consolidação, no entanto, este médoto também tem suas complicações como infecção, lesão neurolófica, cicatriz hipertrófica. Para avaliar qual o método mais efetivo para o tratamento destas fraturas em adultos nos propusermos a desenvolver este estudo. Estudo de ensaio clínico randomizado conduzido na Disciplina de Mão e Membro Superior da Escola Paulista de Medicina - UNIFESP e foi aprovado no Comitê em Ética de Pesquisa (CEP 0891/08).
Foram incluídos pacientes adultos (>18 anos), que tenham assinado e concordado com termo de consentimento e com fratura isolada do terço médio da clavícula com desvio(2B de Robinson 1998), considerando translação entre os fragmentos principais igual ou maior que 100%
em pelo menos uma das incidências radiográficas ou sem contato entre os fragmentos e com fragmentos medial e lateral que permitam a fixação mínima com 3 parafusos. Os 101 pacientes foram randomizados para um dos dois grupos : tratamento conservador com imobilização em oito ou tratamento cirúrgico com redução e fixação das fraturas com placa e parafusos.
Intervenções: O atendimento inicial será realizado com exame clínico e radiográfico dos pacientes. As radiografias serão realizadas nas incidências anteroposterior com inclinação de 45 graus caudal, 45 graus de inclinação cefálica(16) e radiografia em anteroposterior incluindo os dois ombros. Após avaliação quanto aos critérios de inclusão e exclusão do estudo os pacientes, serão esclarecidos sobre a natureza e objetivo do estudo mediante a leitura do Termo de Consentimento Livre e Esclarecido e após a assinatura do mesmo serão cadastrados recebendo um número de ordem seqüencial do protocolo do estudo. Junto ao prontuário foi anexado um envelope opaco e selado, dentro do qual haverá o procedimento a ser seguido, ou seja tratamento conservador ou tratamento cirúrgico, previamente randomizado. Apos isso, era iniciado o preechimento da ficha de extração. O tratamento conservador consistiu de imobilizador em oito pré-fabricado durante sua colocação o paciente foi orientado quanto a correta manutenção da tensão do dispositivo e cuidados de assepsia da região axilar. Os pacientes foram também orientados a evitar esforço com o
membro durante o período de imobilização, ou seja, durante 6 semanas. Durante o período de tratamento os pacientes retornaram semanalmente para controle clínico e radiológico das fraturas e para reavaliação do dispositivos de imobilização. No grupo cirúrgico, os pacientes serão submetidos a avaliação pré-anestesica. A intervenção será realizada no centro cirúrgico. Participarão do estudo 6 cirurgiões previamente definidos e familiarizados com a técnica cirúrgica utilizada no estudo. A técnica anestésica utilizada será a do bloqueio do plexo braquial supraclavicular com o uso de eletroestimulador. Na anestesia serão utilizados 30 ml de anestésico em partes iguais sendo 15 ml de ropivacaina 0,5% e 15ml de lidocaina 1% associada a anestesia geral inalatória após profilaxia com 2g de cefazolina endovenosa.O paciente será colocado na mesa cirúrgica em posição de cadeira de praia e após assepsia, será realizada incisão oblíqua de aproximadamente 10 cm, será realizado a dissecção por planos e o foco da fratura e identificado, reduzido e fixado com uma placa de reconstrução de pequenos fragmentos de 3,5 mm na superfície anteroinferior. Essa fixação será de no mínimo seis corticais no fragmento medial. Mascaramento: Os desfechos serão realizados por profissionais não ligados diretamente ao estudo. O seguimento pós-operatório e pós-imobilização serão acompanhados semanalmente até a sexta semana e após 3, 6 e 12 meses, para avaliação clínica, radiológica e aplicação dos questionários de avaliação. Serão avaliados os desfechos clínico primário,

a satisfação do paciente com o método empregado, utilizando o questionário DASH, validado para o Brasil. Quanto aos desfechos secundários, serão avaliados o arco de movimento e a dor, utilizando a Escala da dor.

Objetivo da Pesquisa:

Avaliar a efetividade do tratamento cirúrgico em comparação ao não cirúrgico nas fraturas desviadas da clavícula.

Avaliação dos Riscos e Benefícios:

Risco médio, desconforto mínimo com procedimento cirúrgico.

Comentários e Considerações sobre a Pesquisa:

Estudo clínico com intervenção terapêutica (fixação com placa e parafusos) randomizado com controle da intervenção (imobilizador em 8). Estudo analisado e aprovado pelo CEP em 2008, submetido para inclusão na PB para acompanhamento do estudo. (CEP 891/08)

Considerações sobre os Termos de apresentação obrigatória:

Folha de rosto e TCLE apresentados adequamente

Recomendações:

Nada consta

Conclusões ou Pendências e Lista de Inadequações:

Sem inadequações, projeto aprovado previamente pelo CEP-Unifesp.

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

Considerações Finais a critério do CEP:

O colegiado acata o parecer do relator
PROJETO APROVADO

SAO PAULO, 06 de Junho de 2012

Assinado por:
José Osmar Medina Pestana

A commentary by David S. Ruch, MD, is linked to the online version of this article at jbjs.org.

Minimally Invasive Osteosynthesis with a Bridge Plate Versus a Functional Brace for Humeral Shaft Fractures

A Randomized Controlled Trial

Fabio Teruo Matsunaga, MD, PhD, Marcel Jun Sugawara Tamaoki, MD, PhD, Marcelo Hide Matsumoto, MD, PhD, Nicola Archetti Netto, MD, PhD, Flavio Faloppa, MD, PhD, and Joao Carlos Belloti, MD, PhD

Investigation performed at the Division of Hand and Upper Limb Surgery, Department of Orthopedics and Traumatology, Universidade Federal de São Paulo-Escola Paulista de Medicina (Unifesp-EPM), São Paulo, Brazil

Background: Nonoperative treatment has historically been considered the standard for fractures of the shaft of the humerus. Minimally invasive bridge-plate osteosynthesis for isolated humeral shaft fractures has been proven to be a safe technique, with good and reproducible results. This study was designed to compare clinical and radiographic outcomes between patients who had been treated with bridge plate osteosynthesis and those who had been managed nonoperatively with a functional brace.

Methods: A prospective randomized trial was designed and included 110 patients allocated to 1 of 2 groups: surgery with a bridge plate or nonoperative treatment with a functional brace. The primary outcome was the Disabilities of the Arm, Shoulder and Hand (DASH) score at 6 months. The score on the Short Form-36 (SF-36) life-quality questionnaire, complications of treatment, Constant-Murley score for the shoulder, pain level, and radiographic results were assessed as secondary outcomes. Participants were assessed at 2 weeks; 1, 2, and 6 months; and 1 year after the interventions.

Results: The mean DASH score of the bridge plate group was statistically superior to that of the functional brace group (mean scores, 10.9 and 16.9, respectively; $p = 0.046$) only at 6 months. The bridge plate group also had a significantly more favorable nonunion rate (0% versus 15%) and less mean residual angular displacement seen on the anteroposterior radiograph (2.0° versus 10.5°) (both $p < 0.05$). No difference between the groups was detected with regard to the SF-36 score, pain level, Constant-Murley score, or angular displacement seen on the lateral radiograph.

Conclusions: This trial demonstrates that, compared with functional bracing, surgical treatment with a bridge plate has a statistically significant advantage, of uncertain clinical benefit, with respect to self-reported outcome (DASH score) at 6 months, nonunion rate, and residual deformity in the coronal plane as seen on radiographs.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

Peer Review: This article was reviewed by the Editor-in-Chief and one Deputy Editor, and it underwent blinded review by two or more outside experts. It was also reviewed by an expert in methodology and statistics. The Deputy Editor reviewed each revision of the article, and it underwent a final review by the Editor-in-Chief prior to publication. Final corrections and clarifications occurred during one or more exchanges between the author(s) and copyeditors.

Historically, nonoperative treatment with a functional brace has been the most popular choice of orthopaedic surgeons for acute, isolated, closed humeral shaft fractures[1]. However, this method can lead to unsatisfactory results, including malunion, nonunion, and limb impairment[2,3]. It also may present more difficulties for obese patients and those with large breasts[4].

Surgical treatment for humeral shaft fractures is usually recommended for patients with associated neurovascular

Disclosure: This project was funded by a government-based noncommercial agency: FAPESP (Fundação de Amparo a Pesquisa do Estado de Sao Paulo). The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (http://links.lww.com/JBJS/B601).

injury, an open fracture, associated elbow and forearm fractures, and polytrauma[5-7], but Level-I evidence regarding the treatment of isolated closed humeral shaft fractures is lacking[8].

Recently, a minimally invasive surgical technique with 2 small anterior approaches and use of a bridge plate—based on the relative stabilization concept—was described for these fractures[9]. This new method has been shown to be a safe technique, with good results reported in cohort studies[10-12].

This randomized controlled trial was designed to compare the effectiveness of bridge plate surgery with that of nonoperative treatment (functional bracing) for displaced humeral shaft fractures in adults. The outcomes that we considered included upper-limb functional limitation, pain, quality of life, shoulder function, complications, and radiographic outcomes.

Materials and Methods

This randomized controlled trial was approved by our Institutional Research Ethical Committee, and its protocol was registered in ISRCTN (number 24835397). The protocol of this clinical trial with details of its methodology was published previously[13].

From May 2012 to February 2015, consecutive patients with a displaced humeral shaft fracture were included in the study. All subjects were recruited, treated, and assessed in a specialized, referenced upper-limb surgery center of the Department of Orthopedics and Traumatology at the Universidade Federal de São Paulo.

Inclusion Criteria

Inclusion criteria were (1) an age of 18 years or older, (2) an isolated closed displaced fracture of the humeral shaft located in an area limited to 4 cm distal to the surgical neck and 4 cm proximal to the upper border of the olecranon fossa, (3) fewer than 21 days between the trauma and study enrollment, (4) no pathological fracture, (5) no associated neurovascular injury, (6) no contraindications to general anesthesia, (7) no previous impairment of the shoulder or elbow joint, (8) no cognitive impairment, and (9) the patient's agreement to participate and sign the written informed consent form.

Sample Size

A sample size of 50 patients in each group was previously calculated on the basis of a significance level of 0.05, a power of 90%, a standard deviation (SD) of 15 for the Disabilities of the Arm, Shoulder and Hand (DASH) score, and a minimal clinically important difference in the DASH score of 10 points between the groups[14]. Anticipating a loss to follow-up, we planned to recruit a total of 110 patients.

Randomization and Allocation

A randomization sequence was generated by computer software (http://www.randomizer.org). A list from 1 to 110 was created, with each number indicating 1 of the 2 methods of treatment: nonoperative treatment with a functional brace or surgical treatment with a bridge plate. The numbers were placed in 110 individual opaque sealed envelopes. The randomization was unrestricted.

Allocation was performed after the protocol was explained and both of the procedures were described to the potential participants. After they agreed to take part in the study and signed the informed consent form, an independent person opened the envelope to assign the intervention.

Nonoperative Treatment with Functional Brace

Patients were initially managed with closed reduction and immobilization with a coaptation U-splint[15] from the axilla to the elbow, ending at the shoulder. After 2 weeks, the splint was replaced by a functional brace[1] (Fig. 1) that allowed movement of the shoulder and elbow. The brace was worn until there was clinical and radiographic evidence of fracture consolidation.

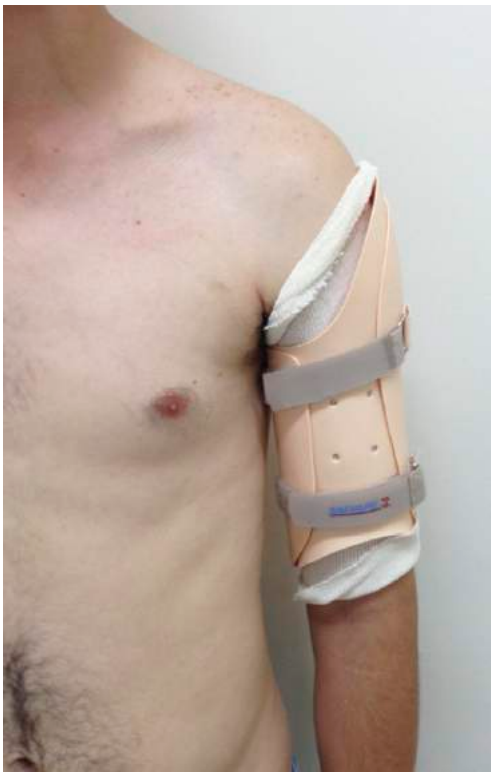

Fig. 1

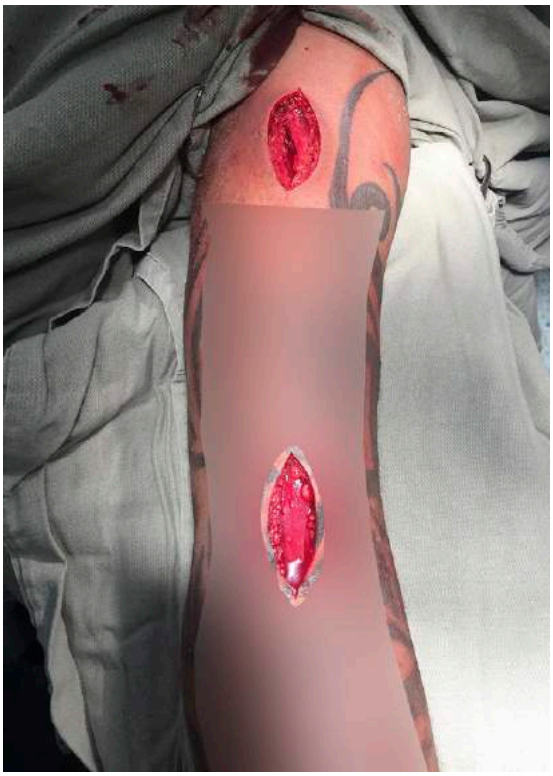

Fig. 2

Fig. 1 Functional brace. **Fig. 2** Surgical incisions for minimally invasive bridge plate osteosynthesis.

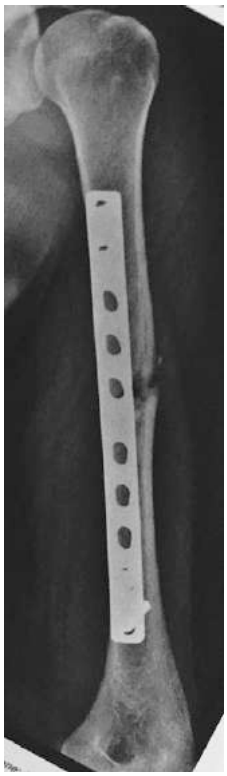

Fig. 3-A

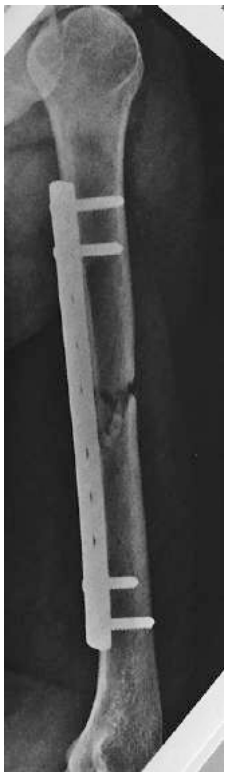

Fig. 3-B

Figs. 3-A and 3-B Postoperative radiographs.

Surgical Treatment with Bridge Plate

From the time of the initial recruitment to the surgical procedure, the upper limb was immobilized with a coaptation splint. Four previously assigned surgeons, who were experienced with the surgical technique of anterior-access bridge plate osteosynthesis, performed the surgical procedures. After the administration of the anesthetic and prophylactic antibiotics, the patient was placed in the horizontal dorsal decubitus position and 2 incisions were made in the arm; surgical access was obtained according to the originally described technique[9] (Fig. 2). The radial nerve did not have to be dissected once it was protected by the lateral part of brachialis muscle. Also, retractors for humeral exposure were not used in order to avoid damage to the radial nerve. Reduction was achieved with application of traction in the distal fragment and rotation control was obtained in the medial and lateral condyles, using fluoroscopy. Then a narrow 4.5-mm dynamic compression plate (DCP) was used with 2 screws inserted into each main fragment and, if the surgeon thought that these did not achieve good enough stability, a third screw to guarantee secure plate-to-bone fixation. After osteosynthesis, final radiographs were obtained (Figs. 3-A and 3-B) and the wounds were sutured and bandaged. The upper limb was immobilized with a sling until the first evaluation.

Rehabilitation

The rehabilitation program was similar for the 2 groups. Free movement (active and passive motion) of the elbow and pendulum exercises for the shoulder were allowed as soon as the patient felt comfortable. Internal and external shoulder rotation was permitted 6 weeks after the intervention.

Outcome Assessment

Health-care professionals who were not directly involved in the study performed radiographic and functional evaluations and administered questionnaires. The assessors were blinded to the treatment assignment whenever possible. Before the outcome assessments, the participants were instructed to not reveal the treatment that they had undergone, and an identical opaque gown was used to cover the injured arm in both groups[16].

Study Outcomes

The primary outcome was the mean score on a translated and validated native-language version of the DASH questionnaire (without its 2 optional modules) completed at 6 months to assess upper-limb disability[17,18]. The mean DASH scores were also compared between the groups at 2 weeks; 1, 2, and 6 months; and 1 year.

The secondary outcomes in this study included the Short Form-36 (SF-36) questionnaire[19,20], Constant-Murley shoulder score[21], pain measured on a visual analogue scale (VAS)[22,23], radiographic results, and treatment complications.

TABLE I Baseline Characteristics of the Functional Brace and Bridge Plate Groups

	Functional Brace Group (N = 52)	Bridge Plate Group (N = 58)	P Value
Age* *(yr)*	40.3 ± 17.2	37.3 ± 14.7	0.331
Sex *(no. [%])*			0.158
Male	38 (73%)	35 (60%)	
Female	14 (27%)	23 (40%)	
OTA/AO fracture type† *(no. [%])*			0.320
A	28 (55%)	38 (68%)	
B	17 (33%)	15 (27%)	
C	6 (12%)	3 (5%)	
Fracture location† *(no. [%])*			0.340
Proximal	6 (12%)	6 (11%)	
Middle	38 (75%)	36 (64%)	
Distal	7 (14%)	14 (25%)	
Loss to follow-up after 1 yr *(no. [%])*	8 (15%)	8 (14%)	0.813

*The values are given as the mean and standard deviation. †N = 51 in the functional brace group because 1 patient was lost to follow-up (including radiographic examination) between the intervention and outcome assessments. N = 56 in the bridge plate group because 2 patients were lost to follow-up between the intervention and outcome assessments.

The SF-36 quality-of-life questionnaire assesses 8 health concepts (physical functioning, bodily pain, limitations due to health problems, limitations due to personal or emotional problems, emotional well-being, social functioning, energy/fatigue, and general health perceptions) and 36 items in total. SF-36 data were obtained at 1, 2, and 6 months and at 1 year in the present study.

Functional evaluation of the shoulder was performed using the Constant-Murley score, which includes pain, daily living activities, range of motion, and strength, generating a score from 0 to 100. This score was determined at the same time as the DASH score.

To obtain the VAS pain score, patients were instructed to mark an "X" on a 10-cm line, the left end of which meant "no pain" and the right end of which indicated "pain as bad as it could be." The measured distance between the "X" marked by the patient and the left end of the line was the translation in numbers of the pain reported by the patient. The pain score was also determined at the same time as the DASH score.

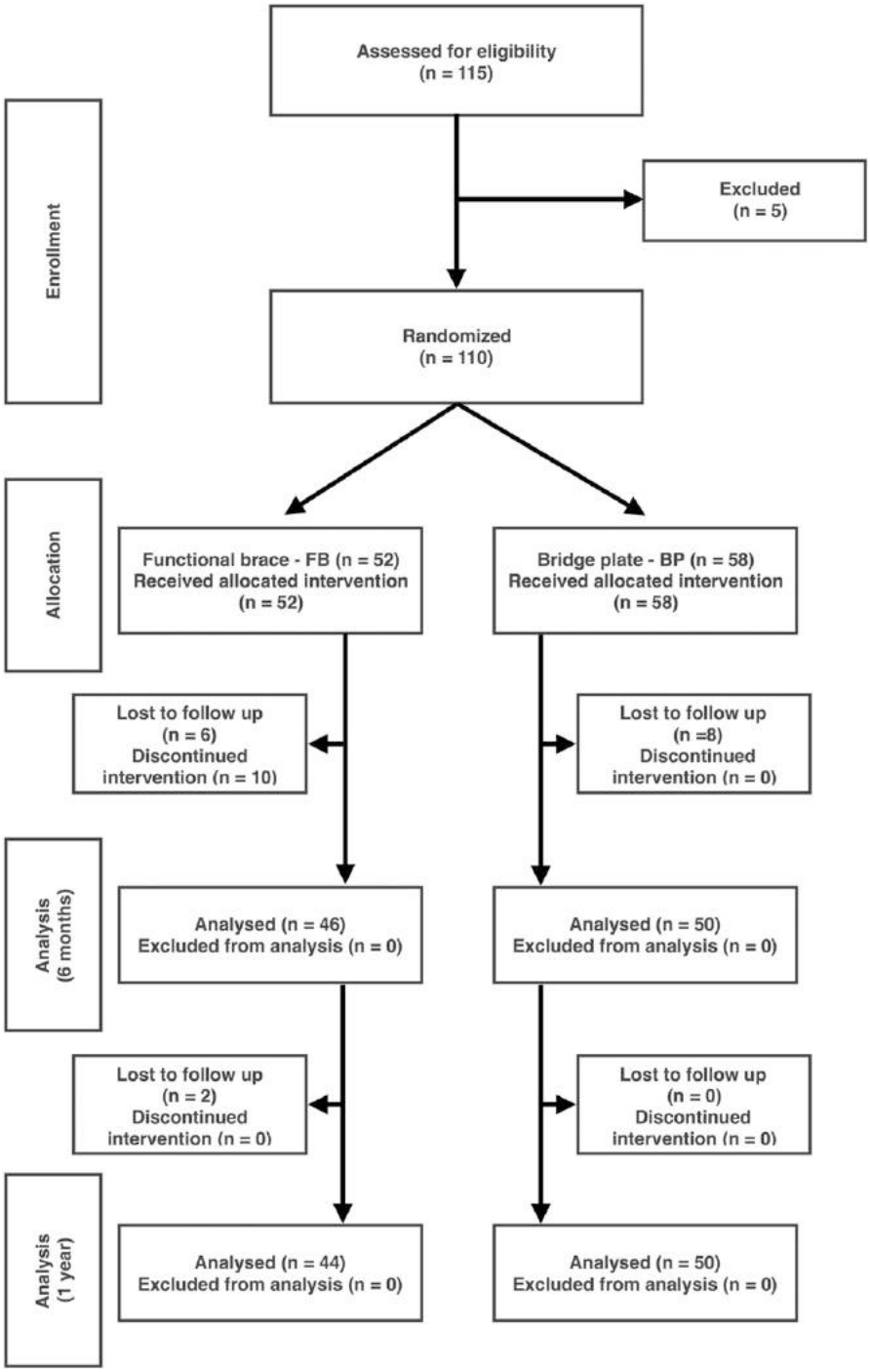

Fig. 4

Flowchart of inclusion of patients with humeral shaft fracture in the study.

Radiographs of the arm in 2 planes (anteroposterior and lateral views) were made to verify the consolidation of, and angles between, the principal fragments of the fracture. Fracture-healing was determined when bone continuity in 3 cortices was detected between the main fragments of the fracture in both planes assessed. The angle between the fragments was measured, in degrees, on both views. These data were obtained at 2 weeks; 1, 2, and 6 months, and 1 year.

Complications due to both interventions were closely monitored and treated as soon as they were detected. They were categorized as severe or minor.

The need to stop, or perform surgical intervention following, functional brace treatment; the need for surgical revision; or clinically important morbidity was considered to be a severe complication and a failure of treatment.

Nonunion was defined as the absence of clinical and radiographic progression of osseous fracture-healing for 3 consecutive months or the absence of healing by 6 months[24].

Complications that represented less interference with the final result of treatment were considered to be minor and represented secondary outcomes. In the functional brace group, these included skin lesions due to prolonged contact with the brace and transient neurological injury (neurapraxia). In the bridge plate group, they included superficial infection that did not require a new surgical procedure, transient neurological injury (neurapraxia), and hypertrophic scarring.

Patients for whom the treatment failed and required additional interventions continued to be monitored, and their results were included in the group to which they had been originally randomized, according to the intention-to-treat principle.

Statistical Methodology

The Student t test was performed to compare the functional brace and bridge plate groups using the mean difference, at all time points at which the outcomes were assessed. The Pearson chi-square test was used to compare categorical variables between the 2 groups.

A significance level of 5% (alpha = 0.05) was used for all statistical tests of the primary outcome (the DASH score at 6 months), so that a p value of <0.05 was considered significant. For secondary outcomes, an alpha value of 0.02 was considered significant, as described in the published protocol[13]. SPSS software version 17, Minitab 16, and Excel Office 2010 were used for the statistical analyses.

Results

Of the 115 patients initially enrolled, 5 were not included in the randomization. Of these 5 patients, 2 presented with a fracture that extended to the proximal end of the humerus, 1 had a fracture that extended to the distal end, 1 had cerebral palsy, and 1 had advanced dementia.

Of the 110 patients included, 52 were allocated to the functional brace group and 58, to the bridge plate group. The average age was 40.3 years in the functional brace group and 37.3 years in the bridge plate group, with no significant difference between the groups. The groups were considered homogeneous, since there was also no statistically significant difference in sex, fracture type (according to the OTA/AO classification)[25], or location of the fracture (proximal, middle or distal third of the shaft). After 12 months, 8 patients (15%) in the functional brace group and 8 (14%) in the bridge plate group were lost to follow-up, with no significant difference between the groups in terms of loss to follow-up (Table I and Fig. 4).

All of the 58 patients allocated to the bridge plate group underwent the surgical procedure with the proposed technique (minimally invasive bridge plate osteosynthesis). The mean time from the injury to the procedure was 12.4 days (range, 8 to 17 days). All 52 patients allocated to the functional brace group were initially treated for approximately 2 weeks with the splint, which was then replaced by the functional brace. The mean

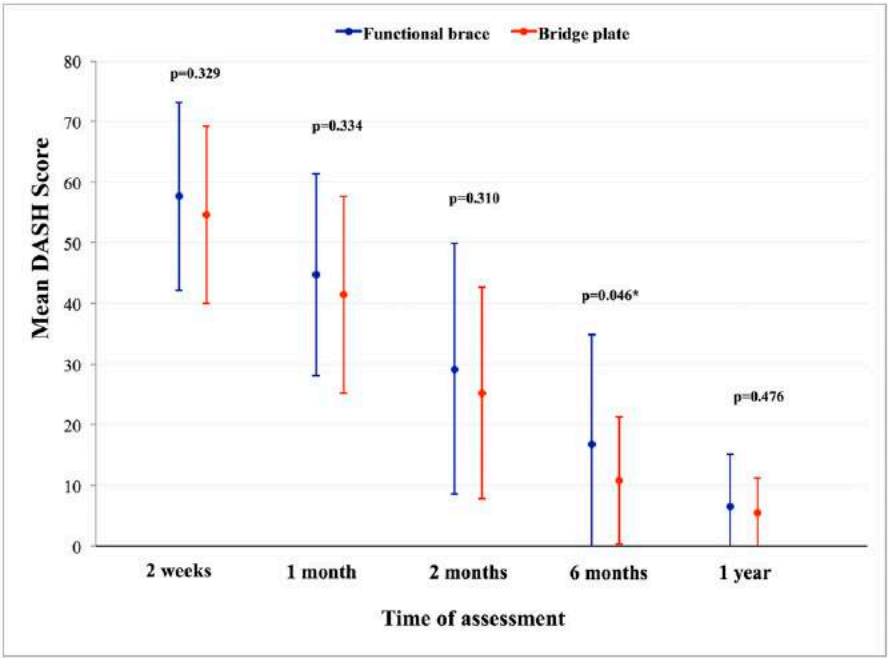

Fig. 5

The mean DASH scores (and SD) were 57.6 ± 15.5, 44.7 ± 16.6, 29.2 ± 20.7, 16.9 ± 18.0, and 6.5 ± 8.6 points at 2 weeks, 1 month, 2 months, 6 months, and 1 year following functional bracing and 54.6 ± 14.6, 41.4 ± 16.3, 25.2 ± 17.4, 10.9 ± 10.5, and 5.5 ± 5.8 points at the respective follow-up periods after treatment with a bridge plate. *Statistically significant.

time from the injury to brace application was 15.2 days (range, 12 to 17 days).

Clinical/Functional Outcomes

The bridge plate group had a significantly more favorable 6-month DASH score (mean, 10.9 compared with 16.9 in the functional brace group; p = 0.046) (Fig. 5).

There was no significant difference between the 2 groups with respect to any of the domains of the SF-36 questionnaire, at any of the measured times. There was a marginal difference in physical functioning at 1 month (mean, 67.6 in the functional brace group and 76.0 in the bridge plate group; p = 0.025) (Table II). There was no difference between the groups with regard to the Constant-Murley score or VAS pain score (Fig. 6).

Severe complications indicating failure of treatment were reported in 10 patients (23%) in the functional brace group and none in the bridge plate group. Of the 10 failures, 7 were due to nonunion, 1 to clinically symptomatic malunion, and 2 to an inability to tolerate the brace. The patients who developed fracture nonunion underwent surgical application of a plate and screws through a posterior approach—with an absolute-stability technique—to promote healing, which was achieved in all cases. The patient who developed fracture malunion had progressive angulation of the fracture fragments resulting in gross deformity of the limb (28° of angular displacement on the last radiographs). Osteotomy was performed, followed by fixation with a plate and screws. The patients who did not tolerate the functional brace underwent surgical treatment with a bridge plate, with good results. No additional surgery was needed in any patient in the bridge plate group (Table III).

Seven patients had a complication that required no additional intervention in the bridge plate group. One patient (2%) had a superficial infection that resolved after treatment with oral antibiotics; 2 patients (4%) had a postoperative transient radial neurapraxia, both of whom had full spontaneous sensory and motor recovery after approximately 5 months; and 4 patients (8%) developed hypertrophic scarring in the wound, with only cosmetic impact. Five patients in the functional brace group developed contact dermatitis from use of the brace, with no functional impact (Table III).

TABLE II SF-36 Scores of Functional Brace and Bridge Plate Groups

	1 Month		2 Months		6 Months		1 Year	
SF-36 Domain	Mean ± SD	P Value	Mean ± SD	P Value	Mean ± SD	P Value	Mean ± SD	P Value
Physical functioning		0.025		0.078		0.122		0.392
Functional brace	67.6 ± 19.1		81.1 ± 14.9		87.8 ± 14.4		94.2 ± 10.5	
Bridge plate	76.0 ± 17.1		86.1 ± 12.6		91.8 ± 10.4		95.7 ± 6.1	
Role limitation (physical)		0.294		0.381		0.259		0.409
Functional brace	3.8 ± 11.7		38.0 ± 31.1		72.3 ± 33.4		90.3 ± 20.3	
Bridge plate	6.5 ± 13.2		43.7 ± 31.8		79.5 ± 28.9		93.5 ± 16.6	
Mental health		0.236		0.143		0.889		0.288
Functional brace	85.6 ± 22.9		95.0 ± 12.0		95.7 ± 13.4		97.2 ± 9.1	
Bridge plate	90.7 ± 19.1		98.0 ± 7.9		96.0 ± 10.9		98.8 ± 5.8	
Energy/fatigue (vitality)		0.723		0.398		0.701		0.362
Functional brace	86.1 ± 9.8		86.8 ± 10.3		89.8 ± 7.5		91.5 ± 7.6	
Bridge plate	85.4 ± 9.2		88.4 ± 7.5		90.4 ± 8.1		92.9 ± 7.4	
Role limitation (emotional)		0.310		0.165		0.261		0.271
Functional brace	85.8 ± 12.5		88.0 ± 11.5		91.0 ± 8.6		94.0 ± 7.8	
Bridge plate	88.3 ± 11.4		91.0 ± 9.9		92.9 ± 7.7		95.7 ± 6.5	
Social functioning		0.107		0.657		0.562		0.111
Functional brace	74.1 ± 20.7		83.3 ± 18.8		91.2 ± 16.7		96.3 ± 9.0	
Bridge plate	80.3 ± 16.5		84.8 ± 13.9		92.8 ± 9.6		93.5 ± 7.4	
Bodily pain		0.754		0.058		0.926		0.644
Functional brace	69.8 ± 17.2		83.9 ± 14.3		86.6 ± 15.3		92.7 ± 11.0	
Bridge plate	70.8 ± 13.7		78.3 ± 14.4		86.3 ± 14.8		91.6 ± 11.5	
General health perception		0.991		0.706		0.230		0.427
Functional brace	85.5 ± 10.0		88.3 ± 9.1		90.2 ± 7.5		91.3 ± 7.6	
Bridge plate	85.5 ± 9.1		87.6 ± 9.0		92.0 ± 6.9		92.4 ± 6.4	

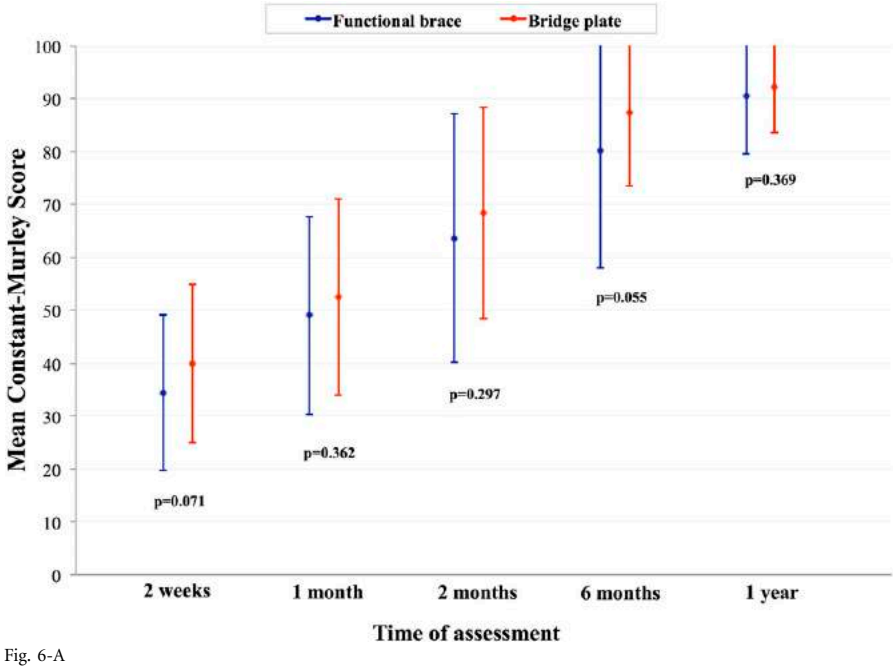

Fig. 6-A

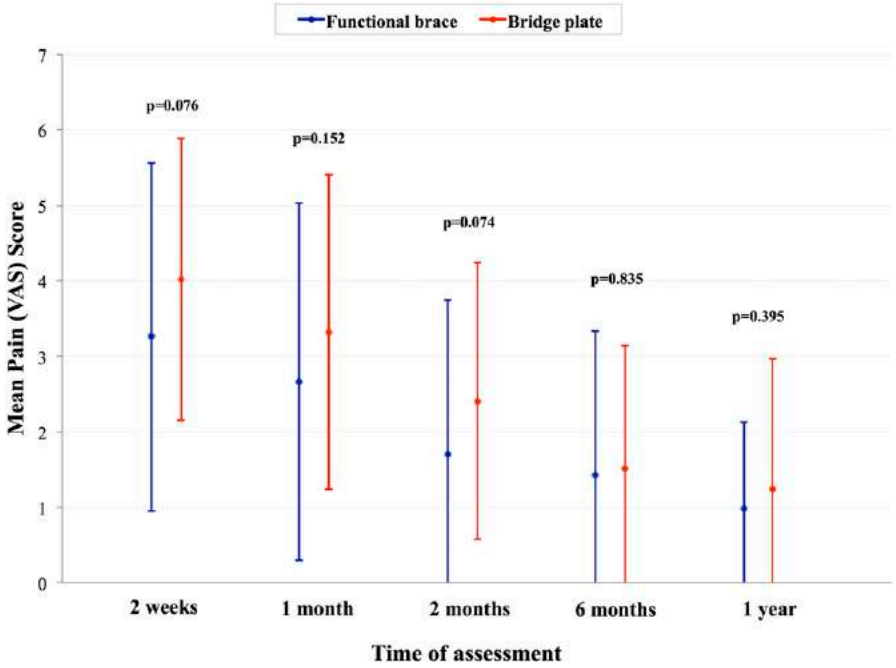

Fig. 6-B

Fig. 6-A The mean Constant-Murley scores (and SD) were 34.4 ± 14.6, 49.0 ± 18.7, 63.7 ± 23.4, 80.0 ± 22.1, and 90.4 ± 10.8 points at 2 weeks, 1 month, 2 months, 6 months, and 1 year following functional bracing and 39.9 ± 14.9, 52.5 ± 18.5, 68.3 ± 20.0, 87.3 ± 13.8, and 92.2 ± 8.6 points at the respective follow-up periods after treatment with a bridge plate. **Fig. 6-B** The mean VAS pain scores were 3.3 ± 2.3, 2.7 ± 2.4, 1.7 ± 2.0, 1.4 ± 1.9, and 1.0 ± 1.2 points at 2 weeks, 1 month, 2 months, 6 months, and 1 year following functional bracing and 4.0 ± 1.9, 3.3 ± 2.1, 2.4 ± 1.8, 1.5 ± 1.6, and 1.2 ± 1.7 points at the respective follow-up periods after treatment with a bridge plate.

Radiographic Analysis

The functional brace group had significantly greater final angular displacement of the main fracture fragments on the anteroposterior radiographs (10.5°) compared with the bridge plate group (2.0°). There was no significant difference between the groups with regard to the final angular displacement on the lateral views (Table III).

TABLE III Complications and Radiographic Outcomes of Functional Brace and Bridge Plate Groups

	Functional Brace Group (N = 46*)	Bridge Plate Group (N = 50)	P Value
Severe complications *(no. [%])*			
Nonunion	7 (15%)	0 (0%)	0.004†
Symptomatic malunion	1 (2%)	0 (0%)	0.295
Intolerance of treatment	2 (4%)	0 (0%)	0.136
Minor complications *(no. [%])*			
Superficial infection	0 (0%)	1 (2%)	0.335
Transient radial neurapraxia	0 (0%)	2 (4%)	0.170
Hypertrophic scar	0 (0%)	4 (8%)	0.050
Contact dermatitis	5 (11%)	0 (0%)	0.017†
Radiographic outcome (angular displacement)‡ *(°)*			
Anteroposterior view	10.5 ± 8.9	2.0 ± 4.7	<0.001†
Lateral view	1.4 ± 9.1	0.2 ± 0.7	0.350

*These data were collected at 6 months, when 46 patients were available for follow-up. Two other patients were lost to follow-up at 1 year. †A significant difference. ‡The values are given as the mean and standard deviation.

TABLE IV Comparison of No-Failure and Failure Subgroups in Functional Brace Group (N = 46*)

	No Failure	Failure	P Value
Age† *(yr)*	38.5 ± 17.7	41.8 ± 12.7	0.582
Sex *(no. [%])*			0.089
Female	10 (28%)	0 (0%)	
Male	26 (72%)	10 (100%)	
OTA/AO fracture type *(no. [%])*			0.760
A	19 (53%)	6 (60%)	
B	12 (33%)	4 (40%)	
C	5 (14%)	0 (0%)	
Fracture site *(no. [%])*			0.097
Proximal	7 (19%)	0	
Middle	23 (64%)	10 (100%)	
Distal	6 (17%)	0	

*These data were collected at 6 months, when 46 patients were available for follow-up. No more failures of treatment were reported after 6 months. †The values are given as the mean and standard deviation.

Analysis of Subgroups

The 10 patients in the functional brace group who had treatment failure did not differ, with regard to sex, age, fracture site, or OTA/AO classification, from the patients without failure in that group (Table IV).

Discussion

Previous randomized controlled trials comparing 2 surgical methods—intramedullary nailing and use of a compression plate—for humeral shaft fractures showed good results with both techniques[26,27]. The present study provides Level-I evidence concerning treatment of humeral shaft fractures and is the first comparing surgical treatment with nonoperative management for these fractures. A previous, thorough plan was executed in order to minimize bias. Non-pharmacological randomized controlled trials present difficulties in blinding assessors and participants[28]. In this trial, blinded assessment of the self-reported questionnaires (DASH, SF-36, and pain VAS) was possible whereas blinded radiographic evaluation was not. Blinded assessment of complications and the Constant-Murley score was attempted by instructing participants not to reveal their allocation to the assessor and to wear an opaque gown covering their affected arm.

Functional clinical outcomes measured with the DASH and quality of life measured with the SF-36 have increasingly been used in the literature on various orthopaedic conditions—as primary outcomes in most of these studies[29].

The bridge plate group in this trial had a statistically more favorable mean DASH score at 6 months. However, the difference in the mean scores between the groups was 6.0 points, which was less than the minimal clinically important difference of 10 points reported in previous studies[14,30].

Only 4.2% of clinical trials assess quality of life as an outcome, and fewer include interpretation of SF-36 scores[31,32]. Because these outcomes were previously defined as secondary for our study, a p value of <0.02 was considered significant. A p value of 0.025 was found for the difference, favoring the bridge plate group, in the physical functioning domain at 1 month, which can be interpreted as only a trend.

Other studies have shown fracture consolidation rates of 77% to 100% with functional bracing[33-35], and the rate of 85% (7 nonunions) in the functional brace group in our randomized controlled trial is similar. We found a higher rate of complications

related to nonoperative brace treatment than after surgical treatment with the bridge plate.

The nonunions in this study may have influenced other outcomes. It was possible to explore this issue as the intention-to-treat principle was applied to our randomized controlled trial. Less favorable DASH scores at 6 months in the functional brace group can be related to limb impairment of patients who developed nonunion and were still recovering from corrective surgery for this complication.

There was no association between clinical failure and the age or sex of the patient or the type (OTA/AO classification) or location of the fracture. Interestingly, none of the 7 patients who developed nonunion and neither of the 2 who did not tolerate the use of the brace were obese or had larger breasts.

The strengths of this study include the fact that it was a randomized controlled trial, with adequate methods of randomization and allocation; absence of industry conflicts of interest as it received governmental funding; previous publication of the protocol[13]; <20% loss to follow-up; and blinded assessment with self-administered outcomes tools. Limitations of this study include its lower external validity, since it was conducted in a single center; however, 2 ongoing registered randomized clinical trials comparing surgical and nonsurgical treatment of humeral shaft fractures are in progress[36,37]. We hope that publication of these trials will make it possible to synthesize data from all of the studies, providing more robust evidence regarding the treatment of humeral shaft fractures.

The present study demonstrated a statistically significant advantage of surgical treatment over functional bracing in terms of the self-reported DASH outcome at 6 months as well as a lower nonunion rate and less residual deformity in the coronal plane seen on radiographs after the surgery. Only the nonunion rate is likely of clinical relevance. ■

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A commentary by Brian K. Lee, MD, and John M. Itamura, MD, is linked to the online version of this article at jbjs.org.

Treatment of Displaced Midshaft Clavicle Fractures: Figure-of-Eight Harness Versus Anterior Plate Osteosynthesis

A Randomized Controlled Trial

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Background: Most midshaft clavicle fractures affect the economically active population, which is negatively impacted by transient limb impairment during the treatment. There is still debate about the advantages and disadvantages of surgical treatment for these fractures.

Methods: In this prospective randomized controlled trial, 117 patients were allocated to 1 of 2 groups: nonsurgical treatment with a figure-of-eight harness or surgical treatment with anteroinferior plate osteosynthesis. The primary outcome was upper-limb limitation measured with the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire at 6 months. Other outcomes included pain, radiographic findings, satisfaction with the cosmetic result, complications, and time to return to previous work and activities. Participants were assessed at 6 weeks, 6 months, and 1 year after the intervention.

Results: No difference between the 2 groups was detected in the DASH score at any time point ($p = 0.398$, 0.403, and 0.877 at 6 weeks, 6 months, and 1 year, respectively), pain levels measured with a visual analogue scale (VAS), time to return to previous activities, or dissatisfaction with the cosmetic result. Seven patients (14.9%) developed nonunion after nonsurgical treatment, a nonunion rate that was significantly higher than that in the surgical group, in which all fractures had healed ($p = 0.004$). The patients in the nonsurgical group had radiographic evidence of greater clavicle shortening ($p < 0.001$) and more of the patients in that group answered "yes" when asked if their clavicle felt short ($p < 0.001$) and if they felt bone prominence ($p < 0.001$). More patients answered "yes" when asked if they felt paresthesia in the surgical group (7; 13.7%) than in the nonsurgical group (1; 2.1%) ($p = 0.036$).

Conclusions: This study did not demonstrate a difference in limb function between patients who underwent surgical treatment and those nonsurgically treated for a dislocated midshaft clavicle fracture. Meanwhile, surgical treatment decreased the likelihood of nonunion.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

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Most midshaft clavicle fractures occur in the economically active population (people in their twenties, thirties, and forties), and these fractures may have a substantial negative functional impact[1-4].

Both surgical and nonsurgical treatment can have unfavorable outcomes such as transient or permanent limb impairment, the need for immobilization, the need for a secondary procedure for implant removal, or symptomatic nonunion or malunion[5-9]. These

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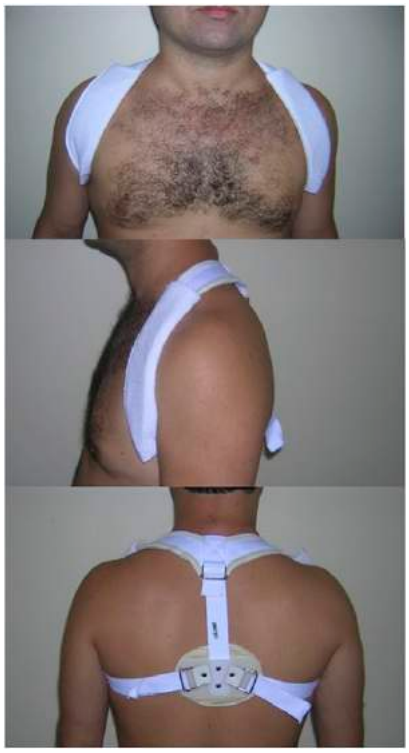

Fig. 1
Figure-of-eight harness for nonsurgical treatment.

outcomes have been assessed in a growing number of clinical trials and systematic reviews comparing different methods of treatment with the aim of providing better evidence to support shared decision-making with patients about how best to treat this injury[9-17].

The present study was designed to compare the effectiveness of 2 specific nonoperative and operative methods for treatment of displaced midshaft clavicle fractures. The figure-of-eight harness was chosen as the nonoperative method because it provides high rates of fracture-healing and, in contrast to a sling, encourages use of the limb during treatment[18-20]. Anterior plate osteosynthesis was selected as the surgical option as there may be less of a need for implant removal because of its theoretically more comfortable positioning[21]. Our hypothesis was that patients who undergo surgical treatment with open reduction and internal fixation would have superior upper-limb functional results with similar complication rates compared with those who undergo nonsurgical treatment with a figure-of-eight harness.

Materials and Methods

This multicenter randomized controlled trial (RCT) was developed in an upper limb surgery center of the Department of Orthopedics and Traumatology at Universidade Federal de São Paulo in São Paulo, Brazil, and at the Vila Velha Evangelico Hospital in Espirito Santo, Brazil, both of which are regional referral centers for trauma and pathological conditions of the shoulder. The protocol was registered in Current Controlled Trials (International Standard Randomized Controlled Trial Number [ISRCTN] 66495030).

We recruited adult patients with a midshaft clavicle fracture who had signed the informed consent form. Inclusion criteria were (1) <15 days between the fracture and trial enrollment and (2) a displaced fracture with total translation and no contact between the main fragments seen on at least 1 radiograph. Exclusion criteria were (1) pathological fracture, (2) open fracture, (3) associated ipsilateral limb injury, (4) associated neurological or vascular injury, (5) bilateral fracture, and (6) multiple injuries.

Interventions were performed by 6 orthopaedic surgeons (3 from each center), all of whom had at least 2 years of experience in treating shoulder conditions and were familiar with both treatment methods.

Allocation and Randomization

Patients who met the inclusion and exclusion criteria were informed about the study and its objectives. Then, after reading and signing the written consent form and undergoing the pre-anesthesia evaluation, a participant was assigned a number in sequential order. The researcher then attached to this patient's medical record an opaque sealed envelope from a set numbered sequentially from 1 to 120 that contained the treatment assignment (surgical or nonsurgical). The sequence of interventions contained in these envelopes had been generated randomly with a computer program by an individual not directly related to the study. After verifying the inclusion and exclusion criteria, the person performing the intervention contacted the randomization and allocation center at the Hand and Upper Limb Surgery Clinic at Universidade Federal de São Paulo and then opened the envelope to reveal the method to be performed.

Intervention

In both centers, initial evaluation consisted of clinical examination as well as anteroposterior and oblique clavicle radiographs with 30° of cephalic inclination (Zanca views)[22] and bilateral anteroposterior clavicle radiographs.

Nonsurgical treatment was performed using a figure-of-eight harness (Salvapé) (Fig. 1). Patients allocated to this group were educated about managing the tension of the brace and skin care and were instructed to use the ipsilateral arm for normal activities as much as possible.

The intervention in the surgical group took place at both institutions' surgical centers and was done with general anesthesia with an ipsilateral interscalene nerve block. The patient was placed in the beach-chair position and, after administration of prophylactic antibiotics, skin preparation, and draping, an oblique incision of approximately 10 cm was made over the clavicle, followed by dissection by planes and identification, isolation, and protection of supraclavicular nerves. The fracture was reduced, and the clavicle was fixed with a 3.5-mm reconstruction plate placed on the anteroinferior surface of the bone. For proper stabilization, the fixation involved at least 6 cortices in the medial fragment and another 6 in the lateral fragment (Fig. 2). Immobilization with a sling was maintained for 7 to 10 days, until the skin sutures were removed. Active range-of-motion exercises were then initiated.

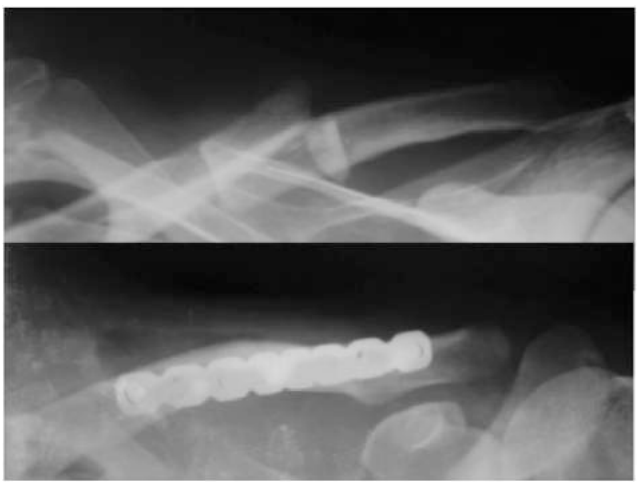

Fig. 2
Postoperative radiographs.

To ensure that the procedures and outcome evaluations were similar in the 2 centers, all orthopaedic surgeons reviewed and agreed to each step of the procedure (surgery and treatment with the harness) before patient recruitment. All staff from both centers who would administer the questionnaires and obtain the scores were trained how to carry out these measurements.

Patients scheduled weekly appointments until the sixth week after the procedure in order to be followed closely for possible complications. Radiographs were also obtained in the second week. Functional outcomes were measured and radiographs were made at 6 weeks, 6 months, and 1 year. An extra time-point for pain measurement was added at 3 months. If the fracture had not healed by the sixth week, radiographs were obtained every 15 days until consolidation was achieved or nonunion was diagnosed.

Outcomes

The primary outcome was upper-limb function at 6 months, measured with the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire translated into Brazilian Portuguese[23], which has been validated.

Secondary outcomes included functional and radiographic findings as well as complications. The functional secondary outcomes were pain assessed with a visual analogue scale (VAS)[24], time to return to work or previous activities, and patient satisfaction with the cosmetic result (yes or no). The radiographic findings were consolidation of the fracture, which was considered to be obliteration of 3 cortices at the fracture site, and bone shortening after consolidation. Bone shortening was determined on an anteroposterior chest radiograph by outlining the sternal and acromial edges of each of the 2 clavicles, drawing a line connecting the centers of these 2 structures, and calculating the

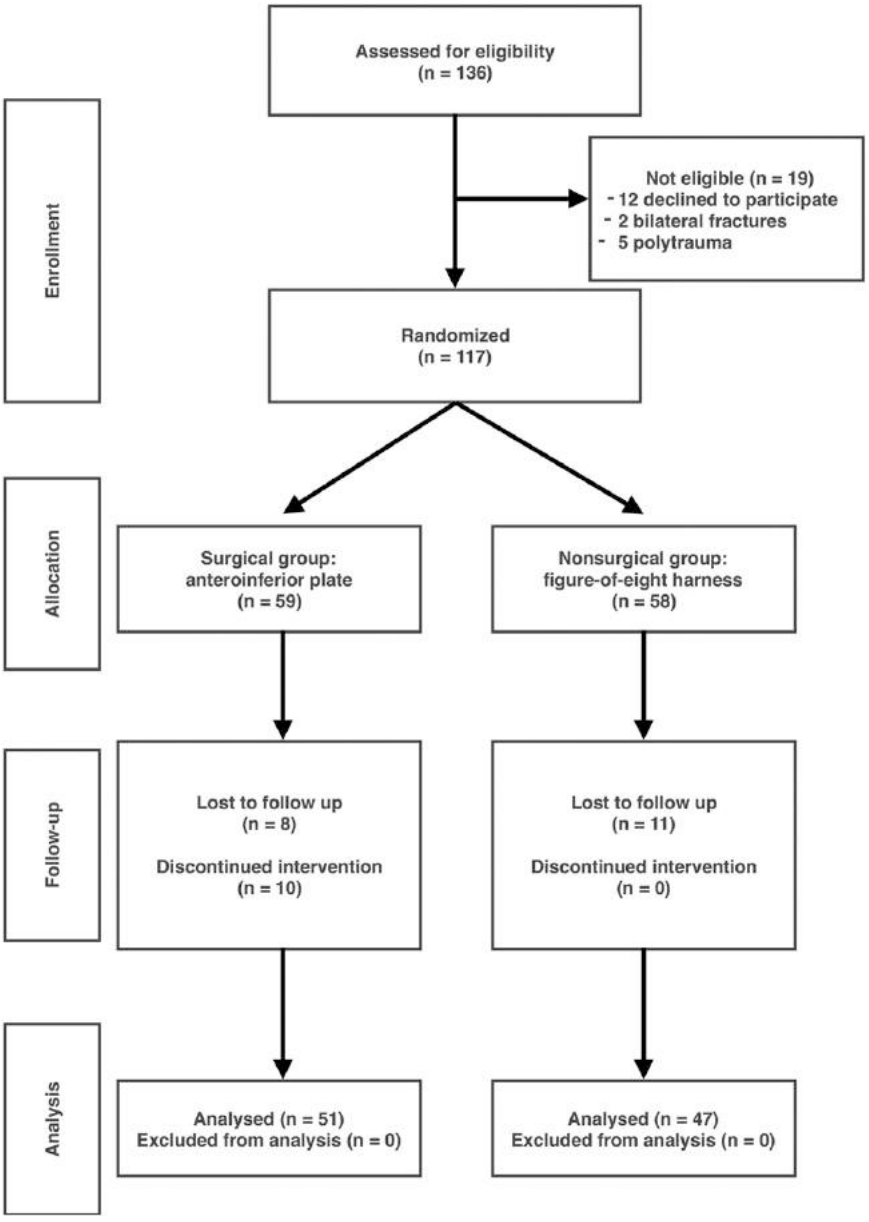

Fig. 3

Flowchart of inclusion in study of midshaft clavicle fractures.

difference in length between the normal and affected sides[6]. Complications, assessed as a dichotomous variable (yes or no), were recorded with their date of occurrence and method of treatment. Initial complications, considered until the sixth week, included infection, skin lesions, and neurological symptoms (paresthesia). The long-term complications were fracture nonunion, defined as a lack of radiographic healing after 6 months of treatment (surgical or nonsurgical); shoulder droop; shoulder malpositioning; and bone prominence. A change in the initially assigned treatment due to complications or fracture nonunion after 6 months was categorized as a severe complication. Patients who developed such complications were clinically followed and the results were included in their originally allocated group, according to the intention-to-treat principle.

Sample Size

Sample size was calculated prior to study enrollment on the basis of a 95% confidence interval (CI), a power of 90%, a standard deviation (SD) of 15% for the DASH score, and an absolute difference of 10 points in the DASH score between the surgical and nonsurgical groups. This revealed that 47 patients were needed for each group and, to account for participants being lost to follow-up, a total of 120 patients with a displaced midshaft fracture had to be recruited.

Blinding and Similarity of Rehabilitation

The outcome assessors were not directly involved in the study. To blind these assessors, all patients wore a figure-of-eight harness and a bandage on the ipsilateral clavicle and were instructed not to reveal the treatment that they had undergone. The rehabilitation program, which was strictly the same for the 2 groups, consisted of active motion of the elbows, wrists, and hands on the first day, passive motion of the shoulder after the seventh day, and then active motion of the shoulder as the patients felt comfortable and experienced less pain.

Statistical Analysis

When we compared epidemiological data, we used the chi-square test for all dichotomous variables except for the affected side, for which the Fisher exact test was used. Analysis of variance (ANOVA) was used to compare results that were continuous variables, and a test of equality of 2 proportions was applied for qualitative results. In all analyses, a p value of <0.05 was considered significant.

Results

In the period of the study, 136 patients with a clavicle fracture were evaluated, and 19 were considered ineligible (Fig. 3). Of the 117 eligible patients, 58 were allocated to the nonsurgical group and 59, to the surgical group. Nineteen patients (11 in the nonsurgical group and 8 in the surgical group) were lost to follow-up—2 because they died from other causes and 17 because they did not return for evaluations. Thus, 47 patients in the nonsurgical group and 51 in the surgical group were included in the final analysis.

The nonsurgical group had a higher mean age than the surgical group (34.6 and 30.5 years, respectively; p = 0.046). There were no differences between the groups with regard to sex, affected side, mechanism of trauma, hand dominance, fracture configuration (OTA/AO classification)[25], or time from trauma to treatment. A motorcycle accident was the most common cause of the injuries (Table I).

TABLE I Baseline Characteristics of Surgical and Nonsurgical Groups

	Surgical Group (N = 59)	Nonsurgical Group (N = 58)	P Value
Mean age ± SD *(yr)*	30.5 ± 9.6	34.6 ± 12.6	0.046*
Sex *(no. [%])*			0.177
Female	6 (10.2)	11 (19.0)	
Male	53 (89.8)	47 (81.0)	
Mean time to evaluation ± SD *(days)*	6.2 ± 3.3	6.7 ± 3.7	0.443
Side affected *(no. [%])*			0.649
Right	25 (42.4)	27 (46.6)	
Left	34 (57.6)	31 (53.4)	
Dominant hand *(no. [%])*			0.662
Right	56 (94.9)	56 (96.6)	
Left	3 (5.1)	2 (3.4)	
Mechanism of trauma *(no. [%])*			
Motorcycle accident	35 (59.3)	32 (55.2)	0.650
Bicycle accident	6 (10.2)	7 (12.1)	0.774
Fall from standing height	8 (13.6)	9 (15.5)	0.764
Other	10 (16.9)	10 (17.2)	0.967
OTA/AO fracture type *(no. [%])*			
B1	21 (35.6)	20 (34.5)	0.900
B2	31 (52.5)	34 (58.6)	0.508
B3	7 (11.9)	4 (6.9)	0.357

*A significant difference.

TABLE II DASH and VAS Pain Scores for Surgical and Nonsurgical Groups

	Mean ± SD		
	Surgical Group	Nonsurgical Group	P Value
DASH			
6 weeks	22.7 ± 22.4	26.3 ± 22.4	0.398
6 months	5.0 ± 11.5	7.0 ± 11.6	0.403
1 year	3.3 ± 10.4	3.0 ± 9.4	0.877
VAS			
6 weeks	2.23 ± 1.99	2.69 ± 2.53	0.289
3 months	1.53 ± 2.01	1.71 ± 2.16	0.656
6 months	0.78 ± 1.45	0.92 ± 1.51	0.633
1 year	0.46 ± 1.18	0.38 ± 1.04	0.711

No difference in the primary outcome—upper-limb function measured with the DASH score—or in pain measured with the VAS was detected between the groups at any of the assessment time points (Table II).

When radiographs were analyzed, we found the mean amount of bone shortening due to malunion to be greater in the nonsurgical group (0.93 cm) than in the surgical group (0.48 cm) ($p < 0.001$). The mean time to return to work or previous activities was 112 days in the surgical group and 127 days in the nonsurgical group, which was not a significant difference ($p = 0.385$) (Table III).

All of the fractures healed in the surgical group, whereas 7 patients developed fracture nonunion after nonsurgical treatment ($p = 0.004$). Two of these patients underwent surgical treatment of the fracture nonunion, whereas 5 allowed the fracture to remain united as they were asymptomatic. Paresthesia was found in 7 patients in the surgical group and in 1 in the nonsurgical group ($p = 0.036$). No difference was found between the groups with regard to dissatisfaction with the cosmetic result (11 patients in the surgical group and 7 in the nonsurgical group; $p = 0.390$) or shoulder droop (14 versus 17; $p = 0.373$). More patients in the nonsurgical group than in the surgical group answered "yes" when asked if they had shoulder malpositioning, shortening, and bone prominence ($p = 0.020$, $p < 0.001$, and $p < 0.001$, respectively) (Table IV).

No restriction in the range of shoulder movement was found in either group at the final assessment.

Two cases of superficial infection were found in the surgical group; both were treated with oral antibiotic therapy and fully resolved. Another patient in the surgical group developed deformity with bending of the reconstruction plate, but fracture-healing was still achieved.

TABLE III Radiographic Clavicle Shortening and Time to Return to Work/Activities for Surgical and Nonsurgical Groups

	Mean ± SD		
	Surgical Group	Nonsurgical Group	P Value
Shortening *(cm)*	0.48 ± 0.45	0.93 ± 0.66	<0.001*
Time to return to work/activities *(days)*	111.7 ± 62.9	126.6 ± 104.4	0.385

*A significant difference.

TABLE IV Complications for Surgical and Nonsurgical Groups

	No. (%)		
Complications	Surgical Group (N = 51)	Nonsurgical Group (N = 47)	P Value
Nonunion	0 (0.0)	7 (14.9)	0.004*
Paresthesia	7 (13.7)	1 (2.1)	0.036*
Dissatisfaction with cosmetic result	11 (21.6)	7 (14.9)	0.390
Shoulder droop	14 (27.5)	17 (36.2)	0.373
Shortening	8 (15.7)	27 (57.4)	<0.001*
Shoulder malpositioning	1 (2.0)	7 (14.9)	0.020*
Bone prominence	3 (5.9)	33 (70.2)	<0.001*

*A significant difference.

Discussion

Recently, there has been an increased tendency to treat clavicle fractures with surgery[26]. We believe that this is the first study in which surgery with an anteroinferior plate was compared with a figure-of-eight harness in an RCT. The choice of a plate in this position was based on previous reports that high percentages of superiorly positioned plates are removed because of discomfort due to prominence of the implant[8,9,27,28].

In contrast to our initial hypothesis, we could not identify a difference between the groups with regard to upper-limb function measured with the DASH questionnaire, even at the initial assessments. Furthermore, we did not detect a minimum clinically relevant difference or minimal detectable change (10.2 and 10.5, respectively[29]) in the mean DASH scores. Some studies have demonstrated differences in DASH scores in favor of surgical treatment[9,12]. However, our findings are in agreement with another RCT[13], which did not detect a clinical difference between the results of surgical and nonsurgical treatments. The variations in results among the studies may be due to differences in the populations and treatment approaches. Pain and range of motion were similar in the 2 groups in our trial.

Nonsurgical treatment resulted in more residual clavicle shortening than surgery, which was expected as surgical procedures are directed at achieving the most anatomical reduction possible. Nevertheless, no difference in functional result was found between the groups. The relationship between shortening and functional results has been controversial, with 1 study denoting no functional deficit with shortening[30] and another even suggesting that initial shortening is an indication for surgical treatment[5]. The time to return to work or previous activities was greater in our nonsurgical group but not significantly so.

The surgical group had a lower total complication rate than the nonsurgical group. This finding should be analyzed with caution because the same patient may present with >1 complication, leading to an overestimation of the results. For example, a patient with bone shortening due to malunion may have a higher chance of being dissatisfied with the cosmetic result and of having bone prominence and shoulder asymmetry.

Two nonunions in the nonsurgical group were treated with surgical fixation after 6 months, with 1 of them requiring iliac crest graft. Five other patients with nonunion in this group chose not to undergo surgery as they were asymptomatic. The nonunion rate in the nonoperative group was 14.9%, which is similar to the rate in another study[5].

Three patients (5.9%) in the surgical group had the plate and screws removed after 1 year. This rate is lower than that in a study with a superior plate positioning (18%)[9] and in 1 in which nails were used (89%)[12]. Of the 3 cases of plate removal, 2 were due to prominence of the plate and dissatisfaction with the cosmetic result and 1 was due to bending of the plate with normal fracture-healing.

Paresthesia was found in both groups and was more prevalent in the surgical group, despite the attempt to isolate supraclavicular nerve branches. Similar rates were found in other studies[9]. No additional procedures were needed to deal with this complication. In the nonsurgical group, the paresthesia was transient, occurring only while the patient wore the harness, which has been reported in other studies[31]. It is worth pointing out that this device was applied to provide comfort for the patient, not to regain bone length. Usually, exaggerated tension must be applied to obtain the full length of the clavicle, creating discomfort and increasing the risk of paresthesia.

The surgical group had a higher prevalence of dissatisfaction with the cosmetic result, which was always related to the appearance of the surgical incision. Dissatisfaction following nonsurgical treatment was due to bone prominence or shortening caused by malunion. The high rates of dissatisfaction in this study may be related to the geographic location of this RCT, where a tropical climate leads most people to wear clothes that leave the shoulders uncovered.

This RCT has limitations, including the assessment of only 1 functional outcome. Also, we believe that the results may deteriorate with longer follow-up, especially in cases with shortening and nonunion. In addition, we did not perform stratification or block randomization for fracture types with a higher risk of worse results. Finally, there was no cost-effectiveness analysis in our trial.

Future clinical trials might include different surgical fixation methods and different nonsurgical treatments, longer follow-up, cost-effectiveness analysis, and subgroup analysis to seek characteristics that can lead to better or worse results after treatment of displaced clavicle fractures.

In conclusion, this study did not demonstrate a difference in shoulder function between surgical and nonsurgical treatment of dislocated midshaft clavicle fractures. However, surgery did decrease the likelihood of nonunion, which should be taken into account when conducting shared decision-making with patients who sustain a midshaft clavicle fracture. ■

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BMC Musculoskeletal Disorders

RESEARCH ARTICLE Open Access

Correlation of the degree of clavicle shortening after non-surgical treatment of midshaft fractures with upper limb function

Gustavo Santiago de Lima Figueiredo*, Marcel Jun Sugawara Tamaoki, Bruno Dragone, Artur Yudi Utino, Nicola Archetti Netto, Marcelo Hide Matsumoto and Fábio Teruo Matsunaga

Abstract

Background: Despite the use of non-surgical methods to treat for the majority of midshaft fractures of the clavicle, it is remains controversial whether shortening of this bone following non-surgical treatment of a middle third fracture affects upper limb function.

Methods: We conducted a cohort study by sequentially recruiting 59 patients with a fracture of the middle third of the clavicle. All patients were treated nonsurgically with a figure-of-eight bandage until clinical and radiological findings indicated healing of the fracture. Functional outcome was assessed using the Disability of Arm, Hand and Shoulder (DASH) score revalidated for the Portuguese language, other outcomes assessed included: pain measured by visual analogue scale (VAS); radiographies to measure the degree of shortening, fracture consolidation and fracture malunion. Information were also collected regarding the mechanism of injury, patient's daily activities level and epidemiological features of the patient cohort. The results of our findings are expressed as the comparison of the functional outcome with the degree of shortening.

Results: Patients were assessed six weeks and one year after injury. In the first evaluation, the mean DASH score was 28.84 and pain measured by VAS was 2.57. In the second evaluation (one year after injury) the mean DASH score was 8.18 and pain was 0.84. The mean clavicle shortening was 0.92 cm, ranging from 0 to 3 cm (SD = 0.64). There were no correlation between the degree of shortening and DASH score after six weeks and one year ($p = 0.073$ and 0.706, respectively). When only patients with of shortening greater than 2 cm were assessed for correlation, the result did not change.

Conclusion: We conclude that clavicle shortening after nonsurgical treatment with a figure-of-eight bandage does not affect limb function, even when shortening exceeds 2 cm.

Trial registration: ISRCTN85206617. Registered 12 May 2014

Keywords: Fracture, Clavicle, Shortening, Conservative treatment, DASH

Background

Fractures of the clavicle are very common, representing approximately 2.6 % of all skeletal fractures[1], where fracture of the middle third of the clavicle represents for 80 % to 85 % of clavicle fractures. Anatomically, the middle third of the clavicle is the narrowest portion of the bone and is less coated with soft tissues, making this portion of the bone more susceptible to fractures [1–6]. Very often this type of fracture is associated with displacement caused by muscle insertions: the sternocleidomastoid muscle pulls the medial fragment upward and posteriorly, and the pectoralis major muscle, the deltoid muscle, and gravity pull the lateral fragment downward and anteriorly [7].

Nonsurgical treatment of clavicle fractures with a figure-of-eight bandage or sling have been used for decades with excellent results and low complication rates [8–10]. However, some recent studies have questioned

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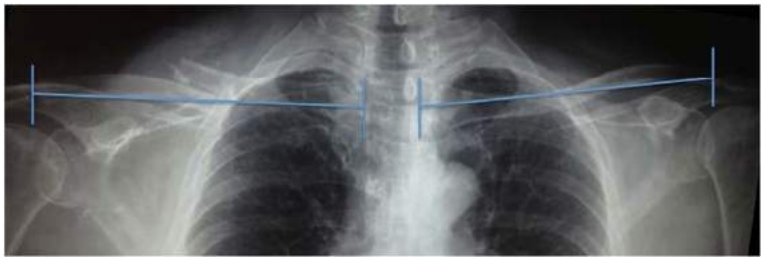

Fig. 1 Measurement of shortening

these results, especially in cases of displacement and clavicular shortening [11, 12].

The clavicle is the only bone that connects the shoulder to the axial skeleton. Shortening of the clavicle, according to anatomical studies, is associated to decreased strength and range of motion [13]. Other studies have also demonstrated a relationship between shortening and worse functional outcomes, recommending surgical treatment in case where shortening is greater than 2 cm [14].

In contrast, retrospective studies report good functional outcome and low complication rates in patients that have undergone conservative treatment even when the clavicle is shortened [10, 15]. Similarly, the congenital absence of the clavicle (e.g., Cleidocranial dysostosis) or its removal as part of surgical procedures (e.g., Mumford surgery, vascular surgery) has little influence on upper limb function in these patients [16].

Thus, it is still controversial whether clavicle shortening affects upper limb function. In view of this controversy, we developed this study to assess the relationship between shortening of the clavicle after conservative treatment with figure-of-eight bandage and upper limb function. Our null hypothesis is that there is no relationship between shortening and functional impairment.

Methods

This cohort study included 59 sequentially recruited patients with midshaft clavicle fractures. They were treated and assessed in the Discipline of Hand and Upper Limb Surgery at Universidade Federal de Sao Paulo (UNIFESP) from January 2010 to June 2012.

We included patients aged 18 and older with a fracture of the middle third of the clavicle by clinical examination and radiographies. Exclusion criteria included neurological and vascular associated injuries, open fractures, associated fracture in the upper limb, bilateral fractures, clavicle fractures with bone contact (assessed by anteroposterior and Zanca radiographic views), "fractures with 14 or more days old since fracture, previous surgery, in the affected limb or previous disease that could change outcomes.

All patients were informed about the objectives of the protocol and agreed and signed the Consent Form to participate in the study. This project was approved by the National Ethics Committee on Research under the number 11376613.2.0000.5505.

All patients were treated with a figure-of-eight bandage, for a minimum of six weeks until clinical and

Table 1 Description of epidemiologic results

Variable	Frequency	%
Gender		
Male	48	81.4
Female	11	18.6
Ethnicity		
Caucasian	52	88.1
Other	7	11.9
Dominant limb		
Right	57	96.6
Left	2	3.4
Affected limb		
Right	25	42.4
Left	34	57.6
Mechanism of injury		
High energy	42	71.2
Low energy	17	28.8
Occupation		
High demand	24	40.7
Low demand	35	59.3
Total	59	100

Table 2 Description of DASH, VAS, shortening and age result

Variable	Mean	SD	Median	Minimum	Maximum	N
Age (years)	34	12.73	30.37	17.91	64.21	59
DASH 6 weeks	28.84	23.62	28.33	0.83	85.83	55
DASH 1 year	3.38	9.21	0.00	0.00	58.00	54
VAS 6 weeks	2.57	2.52	1.80	0.00	9.50	54
VAS 1 year	0.34	0.98	0.00	0.00	5.00	54
Shortening (cm)	0.92	0.64	0.80	0.00	3.00	54

Table 3 Corralation of DASH and VAS with shortening

Shortening correlation			
Variable	Correlation	N	p
DASH 6 weeks	−0.246	54	0.073
DASH 1 year	−0.017	54	0.904
VAS 6 weeks	−0.078	54	0.577
VAS 1 year	0.002	54	0.991

radiological healing of the fracture were observed. In the first evaluation, the length of both clavicles was measured on a single anteroposterior radiograph with the patient seated [22]. Both clavicles of each patient were measured from the centre of the sternoclavicular joint to the centre of the acromioclavicular joint; the degree of shortening was calculated as the difference between the lengths of the two clavicles (Fig. 1).

During treatment, patients were allowed to use the affected limb as tolerated. Each patient underwent rehabilitation from the sixth week onward, with exercises to increase range of motion and passive, active, and progressive strengthening.

The main outcome measured was using the Disability of Arm, Hand and Shoulder (DASH) score revalidated for the Portuguese language [24], consisting of 30 questions concerning the level of difficulty in completing everyday tasks, and pain was assessed using the visual analogue scale (VAS). Both outcomes were assessed at consultations six weeks and one year after injury. Assessment at 6 weeks aimed to evaluate the early outcome, especially in relation to pain. The evaluation after 1 year aimed to evaluate the late outcome, especially in relation to function. We also evaluated demographics and epidemiological characteristics of the cohort.

Statistical analysis were performed by comparing the results of the DASH questionnaire and pain level of patients with the degree of clavicle shortening on the affected side using the Spearman correlation. Patient functional outcomes were also compared with patient epidemiological characteristics using the Mann Whitney test.

The main outcomes assessed for correlation with clavicle shortening were pain levels and limb function. Second, we examined the association of the objective variables age, sex, and affected limb with the dichotomous, subjective variables of occupation, cause of trauma, aesthetic satisfaction, and occurrence of complications.

Results

Seventy patients were seen during the study period. After the initial evaluation 11 patients were within the exclusion criteria: two open fractures, one ipsilateral humeral fracture, five fractures with bone contact, two fractures met with more than 14 days of the initial trauma and one patient with contralateral cuff injury, totaling 59 patients included.

Of the fifty nine patients included in the protocol, 48 were males (81.4 %) and 11 females (18.6 %). The mean age was 34 years, ranging from 17 to 64 years (SD = 12.73). The dominant limb was affected in 27 of patients (45.76 %) and the left side accounted for 34 (57.6 %) of the fractures (Table 1).

The inclusion of patients in the protocol was performed 1 to 14 days after the injury, with a mean of 6.56 days (SD = 3.77 days). All patients were followed for at least one year, with a loss of follow up of 5 patients (8.47 %) (5 patients) (Table 2).

The functional outcome assessed by the DASH questionnaire at six weeks and one year averaged 28.84 and 8.18, respectively. Pain level assessed by VAS at six weeks and one year averaged 2.57 and 0.84 respectively.

The degree of shortening averaged 0.92 cm, ranging from 0 to 3 cm (SD = 0.64 cm). There was no correlation between the shortening of the limb and the DASH score of function at six weeks or one year (p = 0.073 and 0.706 respectively). Setting a minimum threshold of 2 cm shortening did not improve the correlation (Tables 3 and 4) (Fig. 2).

Seven patients with shortening greater than 2 cm scored lower on the VAS than patients whose shortening

Table 4 Correlation of DASH and VAS with shortening when set a threshold of 2 cm

Variable	Shortening	Mean	CI	Minimum	Maximum	N	p
DASH 6 weeks	<2 cm	29.27	23.56	0.83	85.83	47	0.705
	≥2 cm	25.66	27.42	0.83	83	7	
DASH 1 year	<2 cm	3.38	9.56	0	58	47	0.528
	≥2 cm	3.33	7.02	0	19	7	
VAS 6 weeks	<2 cm	2.62	2.61	0	9.5	47	>0.999
	≥2 cm	2.24	1.96	0.1	4.8	7	
VAS 1 year	<2 cm	0.37	1.04	0	5	47	0.782
	≥2 cm	0.16	0.42	0	1	7	

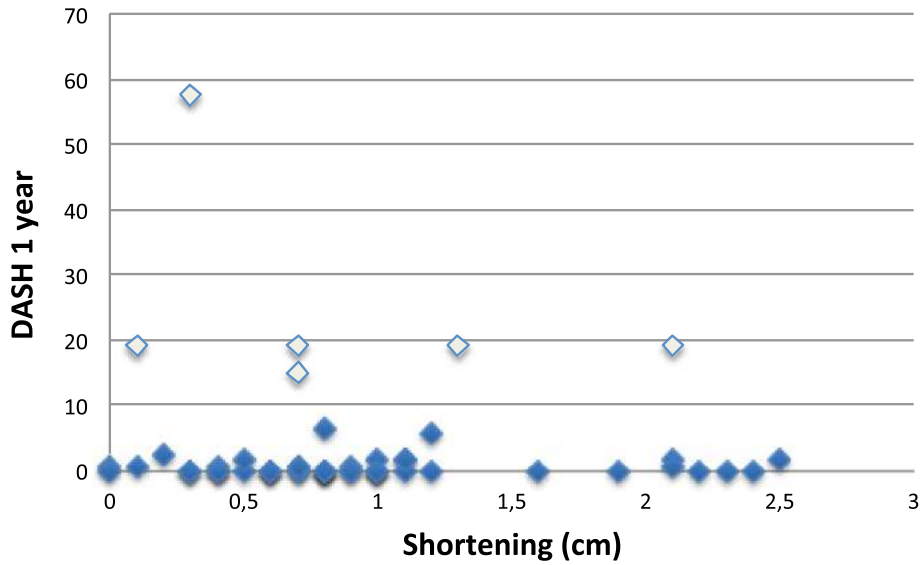

Fig. 2 Correlation of DASH results in 1 year and shortening (cm)

was less than 2 cm (47 patients) (0.16 compared to 0.37). This suggests that patients with a greater degree of shortening tended to experience less pain, although this difference was not significant (p = 0.782).

The mechanisms of injury were divided in either high or low energy trauma, and the patient occupations were classified as high or low demand. High-energy trauma accounted for 42 (71.2 %) of all fractures. Of these high-energy trauma injuries, 34 (80.95 %) resulted from motorcycle accidents, which caused more injuries than any other trauma [17].

The DASH score in cases of high-energy trauma averaged 3.50 with a SD of 10.26, while the score in cases of low-energy trauma averaged 3.05 with a SD = 5.95. However, this difference was not significant (p = 0.629).

After one year of follow-up and return to their occupation, patients with high-demand occupations such as mason or woodworker had the best average DASH score: 2.91 (SD = 5.93). However, the mean score was not significantly different from the score of patients with low-demand occupation such as teacher or salesman, 3.75 (SD = 11.26).

Ten patients (16.6 %) presented a complication. Six patients (11.1 %) developed non-union after nine months of treatment, [19] all of them had less than 1cm of shortening. One patient(1.85 %) presented transient paraesthesia around the fracture. And three patients (5.55 %) demonstrated aesthetic dissatisfaction with osseous deformity.

For all patients who developed non-union, surgical treatment was indicated, but they all, but they chose not to undergo surgery because they were satisfied with the function of the limb.

Discussion

Classically, most mid-third diaphyseal fractures of the clavicle are treated using a non-surgical figure-of-eight bandage or a simple sling. However, some authors have recently questioned this type of treatment in certain types of fracture, particularly those with large deviations due to non-union rates higher than those described in literature [8, 9] and functional deficit in the affected limb [14].

The consequences of malunion of the clavicle are still controversial. According to some authors [11, 14, 18], shortening greater than 1,5 – 2,0 cm is associated with worse functional outcome. In contrast, others have demonstrated no direct relationship between the degree of shortening and function [10, 15]; this result is also

Table 5 Correlation of DASH with mechanism of injury

Variable	Mechanism of injury	Mean	CS	Median	Minimum	Maximum	N	p
DASH 6 weeks	High energy	28.41	22.71	29.165	0.83	85.83	40	0.940
	Low energy	30.00	26.70	17.5	0.83	85.83	15	
DASH 1 year	High energy	3.50	10.26	0	0	58	39	0.629
	Low energy	3.05	5.95	0	0	19	15	

demonstrated in our study, in which we observed seven patients with clavicular shortening greater than 20 mm. All seven exhibited clinical outcomes at one year classified as excellent. Their mean DASH score of 3.33 was similar to the mean DASH score of 3.38 for patients with less shortening.

Studies that demonstrate a direct relationship between the shortening and loss of function in the limb are generally retrospective, whereas prospective studies such as present study do not show this result. The differences in findings may result from factors such as selection bias; patients with longer follow-up periods tend to be those with the worst outcome.

In our study of 54 patients evaluated after one year, 53 had excellent clinical results as assessed by the DASH questionnaire and 1 patient exhibited a poor clinical outcome, similar to other studies using this questionnaire [15].

According to the literature, the failure rate of conservative treatment ranges from 4.4 % to 31 % [20–23]. The most common complications are pain. aesthetic complaints, numbness, and loss of strength and function. The rate of 16.6 % complications in this study agrees with the values mentioned above.

Moreover, as there are major differences between the studies discussed, when considering patient characteristics such as those used in our research it can assist in choosing treatment and predicting the prognosis of this type of injury. Nevertheless, factors such as energy of the trauma and functional demands at work did not affect the results here.

Limitations of this study include the small number of patients with shortening greater than 20 mm and the use of subjective questionnaires rather than objective measurements such as strength and range of motion. Another limitation is the follow-up time of only one year. A longer follow-up period might expose deteriorating function, especially in patients with high-energy demand occupations. Other limitation is that anteroposterior ragiographs to measure clavicle length may cause some errors due to rotation failure.

Conclusions

We conclude that the shortening of the clavicle that results from conservative treatment with a figure-of-eight bandage, even when more than 2 cm, does not affect subjective limb function.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

GSLF made important contributions in the preparation and design of the present study, participated in the patients follow-up, reviewed the bibliography for references and performed the statistical analysis; MJST participated collecting information on patient follow-up, measured the radiographs, designed and prepared the study and made statistical analysis; BD participated collecting information, made statistical analysis and reviewed the bibliography; NAN participated in pacients follow-up, radiographics analysis and discussed the results; MHM participated in pacients follow-up, radiographics analysis, made statistical analysis; FTM participated in the translation of study, statistical analysis and designing the study; AYU participated in the study design and preparation and statistical analysis and reviewed the bibliography. All authors read and approved the final manuscript.

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TRIALS

STUDY PROTOCOL Open Access

Treatment of the humeral shaft fractures - minimally invasive osteosynthesis with bridge plate versus conservative treatment with functional brace: study protocol for a randomised controlled trial

Fabio T Matsunaga, Marcel J S Tamaoki, Marcelo H Matsumoto, João B G dos Santos, Flavio Faloppa and João C Belloti*

Abstract

Background: Humeral shaft fractures account for 1 to 3% of all fractures in adults and for 20% of all humeral fractures. Non-operative treatment is still the standard treatment of isolated humeral shaft fractures, although this method can present unsatisfactory results. Surgical treatment is reserved for specific conditions. Modern concepts of internal fixation of long bone shaft fractures advocate relative stabilisation techniques with no harm to fracture zone. Recently described, minimally invasive bridge plate osteosynthesis has been shown to be a secure technique with good results for treating humeral shaft fractures. There is no good quality evidence advocating which method is more effective. This randomised controlled trial will be performed to investigate the effectiveness of surgical treatment of humeral shaft fractures with bridge plating in comparison with conservative treatment with functional brace.

Methods/Design: This randomised clinical trial aims to include 110 patients with humeral shaft fractures who will be allocated after randomisation to one of the two groups: bridge plate or functional brace. Surgical treatment will be performed according to technique described by Livani and Belangero using a narrow DCP plate. Non-operative management will consist of a functional brace for 6 weeks or until fracture consolidation. All patients will be included in the same rehabilitation program and will be followed up for 1 year after intervention. The primary outcome will be the DASH score after 6 months of intervention. As secondary outcomes, we will assess SF-36 questionnaire, treatment complications, Constant score, pain (Visual Analogue Scale) and radiographs.

Discussion: According to current evidence shown in a recent systematic review, this study is one of the first randomised controlled trials designed to compare two methods to treat humeral shaft fractures (functional brace and bridge plate surgery).

Trial registration: Current Controlled Trials: ISRCTN24835397

Keywords: Humeral fractures, Immobilisation, Fracture fixation, Internal, Orthopaedic fixation devices

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Background

Humeral shaft fractures account for 1 to 3% of all fractures in adults [1,2] and for 20% of all humeral fractures [3]. These fractures have an annual incidence from 13 to 14.5 per 100,000 people [4,5]. Non-operative treatment is still the standard treatment for isolated humeral shaft fractures [6,7], although this method can present unsatisfactory results, such as, nonunion and shoulder impairment [8,9]. Fourteen percent of patients treated with this method have restricted range of motion and 12.6% have consolidation, with more than 10° of displacement [10].

Surgical treatment is recommended for patients with neurovascular injuries, medullar or brachial plexus injuries, and open fractures, for patients with multiple injuries, and for floating elbow and unsatisfactory reductions [11-13]. Humeral shaft fractures can also be treated surgically for the following indications: *Arbeitsgemeinschaft für Osteosynthesefragen* (AO)-Orthopaedic Trauma Association (OTA) type A fractures, proximal third oblique fractures and distal third shaft fractures [14-16]. Surgical options for treatment of humeral shaft fractures include open reduction and internal fixation with a compression plate, intramedullary nail osteosysthesis and minimally invasive bridge plate fixation. Open reduction and rigid internal fixation with absolute stability using dynamic compression plates [17-19] is today's standard and is the more common surgical option for treatment of these fractures.

Modern concepts of internal fixation of shaft fractures of the long bones advocate relative stabilisation techniques with no harm to the fracture zone. These have largely been used for fractures of the leg and thigh for which they have become the gold standard treatment. In humeral shaft fractures, these concepts are also being applied with the use of the intramedullary nail [20-22]. In a systematic review, when compared to compression plate osteosynthesis, the use of the intramedullary nail presented a higher risk of shoulder impingement, shoulder pain, and restriction of movements [23]. Recently described by Livani and Belangero [24], minimally invasive bridge plate osteosynthesis with anterior access has been shown to be a secure technique with good results for the majority of humeral shaft fractures [25-27].

Good quality evidence, including trials comparing surgical and nonsurgical interventions for treating these fractures, is lacking [28]. This study will, therefore, be performed to investigate the effectiveness of surgical treatment of humeral shaft fractures with bridge plating in comparison with conservative treatment with a functional brace, considering patients' superior limb function, their quality of life and treatment complications.

Methods

This randomised controlled trial will follow the Consolidated Standards of Reporting Trials (CONSORT) Statement [29]; it will be performed in the Hand and Upper Limb Surgery Institute of the Orthopaedics and Traumatology Department of Universidade Federal de Sao Paulo and was approved by the ethical committee (CEP UNIFESP 1595/09). The project is registered in the Current Controlled Trials database (ISRCTN 24835397 http://www.controlled-trials.com/ISRCTN24835397), and was cited by a Cochrane Systematic Review [28]. This study has its funding approved under the process number 2011/21611-2 by a government-based noncommercial agency: Fundação de Amparo à Pesquisa do Estado de São Paulo (FAPESP).

Inclusion criteria

All patients eighteen years of age or older, with completely deviated humeral shaft fractures (between 4 cm distal to the surgical neck of the humerus and 4 cm proximal to the superior border of the olecranon fossa), who agree to participate and give written informed consent, will be included in the study.

Exclusion criteria

Patients with pathological or open fracture, previous disease in the limb that could influence the results, an immature skeleton, those whose fracture occurred more than 21 days previously or those with neurovascular-associated injury will be excluded. If patients do not wish to participate or are unable to understand or sign the informed consent form (due to conditions such as cognitive impairment, or mental illness), if poor compliance is expected, or if there any conditions that contraindicate any of the methods for randomized, will also be considered exclusion criteria. Patients who have high risk of anaesthesiology-associated problems will also be excluded.

Sample size

The sample size was calculated for a significance level of 0.05, statistical power of 90% and SD of 15% in Disability of the Arm, Shoulder and Hand (DASH) scores and an absolute difference between the groups of 10 points in the DASH scores. It was calculated that 50 patients were needed in each group [30,31]. Allowing for a 10% loss to follow up at 24 weeks, we aim to recruit a total of 110 patients.

Randomisation and allocation

The randomisation sequence will be generated by computer software (http://www.randomizer.org), creating a list from 1 to 110, each number being related to one of the two proposed methods of treatment. We will perform simple (unrestricted) randomisation, making the intervention assignment unpredictable, including the

last 10 participants. According to this list, inside each of the 110 opaque sealed envelopes numbered from 1 to 110, will be a piece of paper containing the words 'functional brace' or 'bridge plate.

Participant allocation will be performed after explaining the protocol and describing both of the procedures to be randomised, and after participants have agreed to take part and signed the informed consent form (Additional file 1 and Additional file 2). They will also be clinically evaluated to determine whether they are suitable candidates for surgery. After this, an independent person will open the envelope before proceeding to the intervention (Figure 1).

Intervention methods

Nonsurgical treatment (functional brace)

Patients randomised to nonsurgical treatment will undergo closed reduction and initial immobilisation with a coaptation U-splint [32] (Figure 2) from the axilla to the elbow, ending in the deltoid. After 14 days, the immobilisation will be replaced by a functional brace [6] (Figure 3) allowing the patients to move their shoulder and elbow freely to exercises and rehabilitation. This brace will be kept until fracture consolidation, determined on radiography by two previously-assigned assessors. Any disagreements will be resolved by discussion with a third assessor.

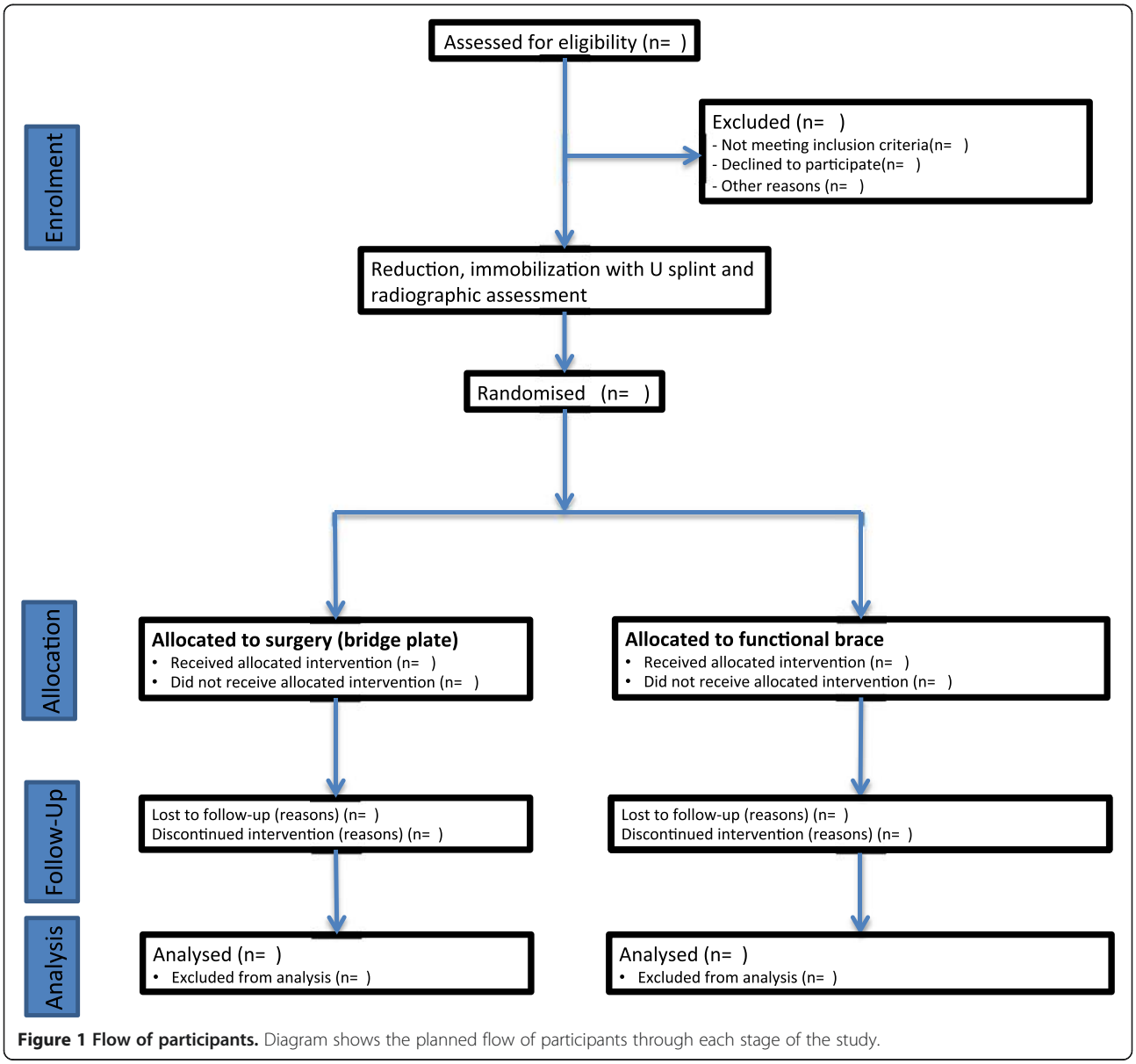

Figure 1 Flow of participants. Diagram shows the planned flow of participants through each stage of the study.

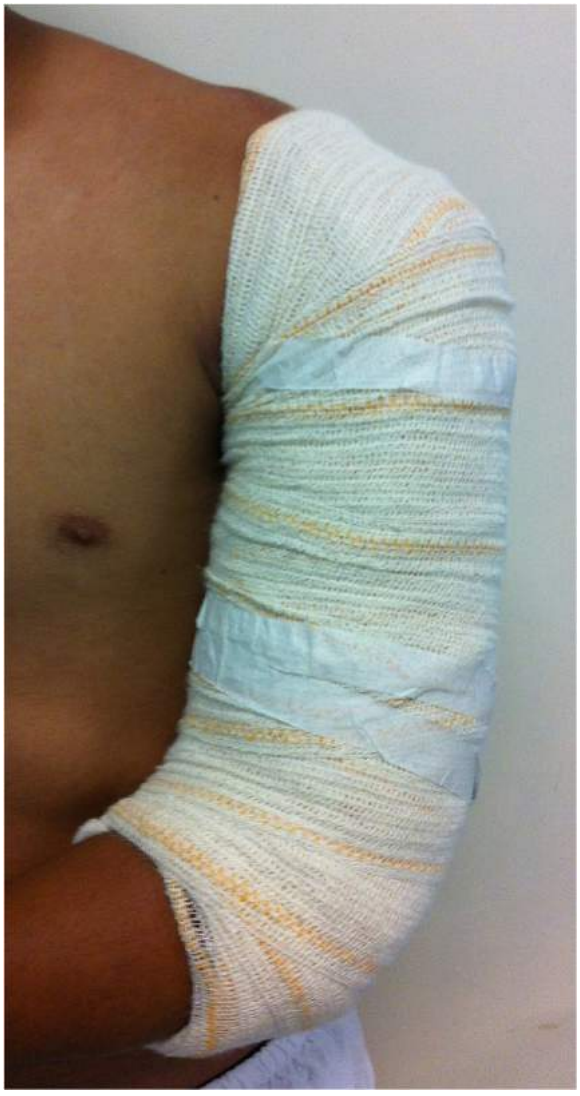

Figure 2 Initial immobilisation with the splint.

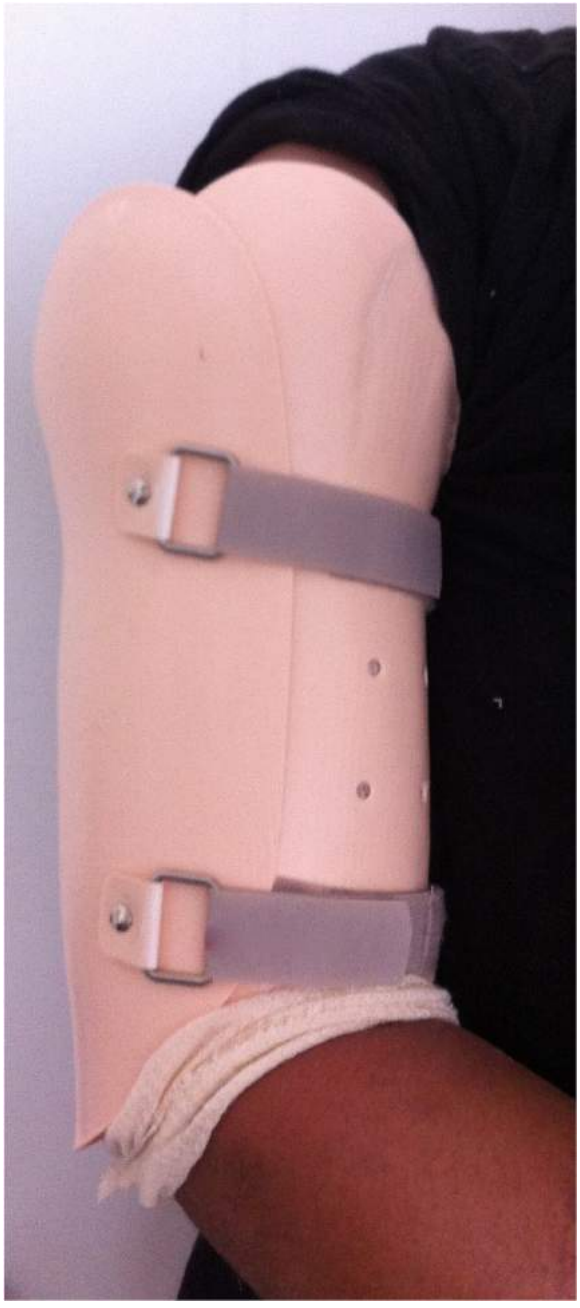

Figure 3 Functional brace.

Surgical treatment (bridge plate osteosynthesis)

Patients randomised to surgical treatment will undergo preoperative evaluation of age, clinical condition (acute infection) and co-morbidities. The intervention will take place in the surgical centre of the institution, where four previously-specified surgeons, who are experienced with the surgical technique described by Livani and Belangero [24], will perform the surgical procedures. After the anaesthetic procedure, the patient will be kept in the horizontal dorsal decubitus position and two incisions will be made. The 3 to 5 cm proximal incision will access the proximal fragment between the biceps *brachii* muscle medially and the deltoid muscle laterally. The 3 to 5 cm distal incision will expose the anterior humeral cortex of the distal fragment, after dissection of the lateral cutaneous nerve of the forearm, and after the brachialis muscle is split longitudinally (Figure 4). In distal-third fractures, the lateral column of the distal humerus will be accessed with subperiosteal dissection of the lateral supracondylar crest and reflection of the *brachioradialis* and extensor *carpi radialis longus* muscles and the radial nerve. After indirect reduction under fluoroscopy, a narrow 4.5-mm dynamic compression plate (DCP) will be used and will be introduced in a proximal to distal direction (Figure 5). In fractures of the distal third of the humeral shaft, the plate will be introduced in a distal to proximal direction. Two to three screws will be inserted in each bone fragment. After osteosynthesis, final

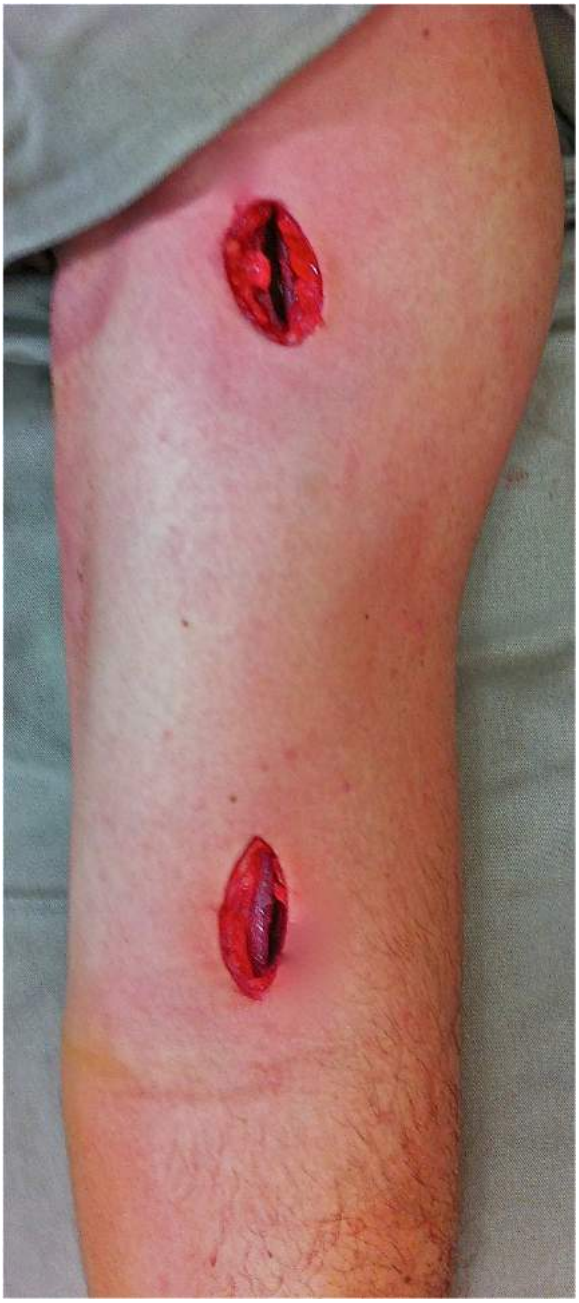

Figure 4 Surgical incisions for minimally invasive bridge plate osteosynthesis.

radiographs will be obtained, and the wound will be sutured and bandaged The patient will be kept immobilised with a sling until ambulatory evaluation.

Treatment after the intervention

Patients from both of the randomised groups will be included in the same rehabilitation programme. Free-elbow passive and active motion and pendulum exercises for the shoulder will be allowed as soon as the patient can tolerate them. Internal and external shoulder rotations will be introduced 6 weeks after the intervention.

Outcome assessment

All study participants will be evaluated at 2 and 4 weeks; 2, 6 and 12 months after the intervention. Radiographic evaluations, pain measurements using the visual analogue scale (VAS) [33], and application of the DASH [30,34] (Additional file 3 and Additional file 4), Short Form (SF)-36 and Constant shoulder score questionnaires will be performed by professional orthopaedists and physiotherapists who will not be directly associated with the study. Assessors will be blinded to the treatment assignment. Prior to outcome functional assessments, patients will be instructed not to reveal their treatment and will have their fractured arm covered with an opaque gown, identical in both groups [35].

Primary outcome

Our primary outcome will be the DASH [30,34] scores 6 months after the procedure (either surgical or nonsurgical) for treatment of humeral shaft fractures. The final score will be calculated using the specified formula:

$$\text{DASH score} = (\text{Raw score} - 30)/1.2.$$

The two optional modules of the DASH questionnaire will not be applied in this study.

Secondary outcomes

Secondary outcome measures include: (i) the SF-36 questionnaire [36,37], (ii) procedure complications, (iii) pain, measured by the VAS [33], (iv) Constant questionnaire functional score [38]; (v) radiographic characteristics in terms of (a) consolidation of the fracture and (b) displacement and angulation of the fracture fragments.

The SF-36 is a questionnaire containing 36 items. This survey assesses eight health concepts: physical functioning, bodily pain, limitations due to health problems, limitations due to personal or emotional problems, emotional well-being, social functioning, energy/fatigue and general health perceptions. The VAS consists of a 10-cm line anchored by two extremes: 'no pain' and 'pain as bad it could be'. Patients are asked to make a mark on the line, which represents the intensity level of their perceived pain, and the scale is scored by measuring the distance from 'no pain' to the patient's mark.

Consolidation will be considered as a dichotomous variable: fracture healing or no healing. Displacement and angulation of bone fragments will be measured on radiographs.

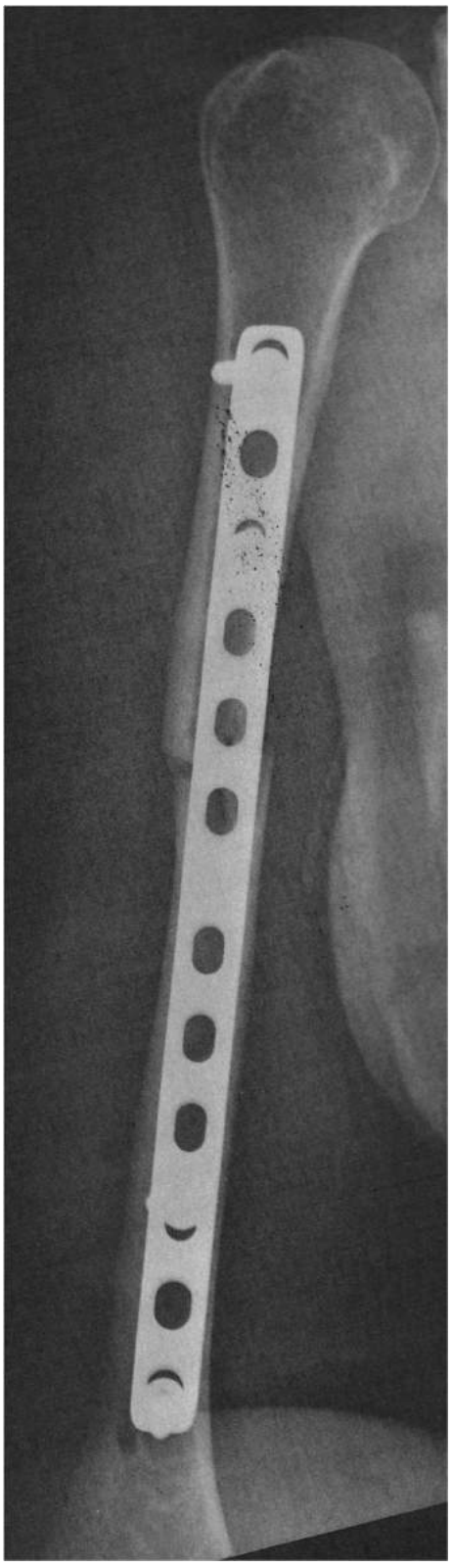

Figure 5 Postoperative radiography.

Data analysis

Patients, who for any reason demonstrate that their treatment may require additional interventions, will be followed up, and their results will be included in the group into which these patients had initially been randomised, according to the intention-to-treat principle. The Pearson chi-squared test will be used to analyse the results from the two groups in relation to the categorical variables, and Student's *t*-test will be used to compare the groups in relation to the numerical variables. Student's *t*-test (parametric) will be used to compare the clinical evolution of each group 2, 4, 8, 24 and 48 weeks after the intervention. For the primary outcome, a significance level of 5% (alpha = 0.05) will be used for all statistical tests, such that tests presenting a *P*-value less than 0.05 will be considered statistically significant. For the secondary outcomes we will consider an alpha value of 0.02.

Safety

Rates of complications are part of secondary outcome analysis and will be closely monitored. Expected complications in both intervention groups include skin abrasion, skin pressure ulcers, forearm and hand swelling, sensomotor deficit, wound healing problems, hardware displacement and failure, superficial and deep infection, malunion, nonunion, and shoulder and elbow impairment. Complications will be categorized as minor or major according to their severity. Causes of complications will be studied and they will be treated as soon as detected. Complications that may lead to surgical intervention, surgical revision, or clinically important morbidity are classified as severe adverse events. This protocol does not include a data safety monitoring committee.

Discussion

According to current evidence from a systematic review [28], this study is one of the first randomised controlled trials designed to compare surgical to nonsurgical management of humeral shaft fractures, to evaluate outcomes of quality of life, safety and effectiveness.

Despite the risk of a surgical intervention, the minimally invasive plate osteosynthesis technique seems to be reproducible and applicable in almost all types of humeral shaft fractures. It had the advantage of minimal soft tissue dissection and lower rates of iatrogenic nerve injury when compared to the conventional plate technique. Intramedullary nail osteosynthesis has resulted in higher rates of reoperations and shoulder impairment compared to the compression plate technique [23,25,27]. Functional bracing is a traditional method of treatment but can have some complications, such as, nonunion in proximal-third fractures, residual angulation of more than 10° and skin abrasion [16,39].

Fractures too proximal or too distal in the humeral shaft cannot be surgically treated with this minimally invasive technique, which is a limitation of this trial. Another limitation is the fact that this study will take place in only one centre. This not only impacts recruitment, but also may limit the generalisability of the results to other settings. However, the use of broad inclusion criteria is the strength of the trial.

This study aims to provide conclusive, good quality evidence for orthopaedic practice and will contribute to the evidence base of methods used to treat humeral shaft fractures.

Trial status

This trial started recruiting patients on 6 May 2012.

Additional files

Additional file 1: Consent for participation in a research (Portuguese).

Additional file 2: Consent for participation in a research (English).

Additional file 3: DASH questionnaire in Portuguese.

Additional file 4: DASH questionnaire in English.

Abbreviations

AO: Association for the study of internal fixation; CONSORT: Consolidated standards of reporting trials; DASH: Disability of the arm, shoulder and hand; DCP: Dynamic compression plate; OTA: Orthopaedic trauma association; SF-36: Short form-36; VSA: Visual analogue scale.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

FTM contributed to trial design, developed the protocol and is the principal investigator of the trial. MJST participated in the conception and design of the trial, drafted the manuscript and acts as coordinating investigator of the trial. MHM participated in development of the trial protocol and coordinates trial monitoring. JBGS and FF participated in the design of the trial and revised the trial manuscript. JCB conceived the trial and acts as coordinating investigator of the trial. All authors contributed to the manuscript and approved the final manuscript.

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