

# BMJ Open Protocol of BRICS: Brazilian multicentric pragmatic randomised trial of surgical interventions for displaced diaphyseal clavicle fracture study: MIPO versus ORIF for the treatment of displaced midshaft clavicle fractures

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## ABSTRACT

**Introduction** Fractures of the diaphysis of the clavicle are common; however, treatment guidelines for this condition are lacking. Surgery is associated with a lower risk of non-union and better functional outcomes but a higher risk of complications. Open reduction and internal fixation with plates and screws are the most commonly performed techniques, but they are associated with paraesthesia in the areas of incisions, extensive surgical exposure and high rates of implant removal. Minimally invasive techniques for treating these fractures have a lower rate of complications. The aim of this study is to evaluate which surgical treatment option (minimally invasive osteosynthesis or open reduction and internal fixation) has better prognosis in terms of complications and reoperations.

**Methods and analysis** The study proposed is a multicentric, pragmatic, randomised, open-label, superiority clinical trial between minimally invasive osteosynthesis and open reduction and internal fixation for surgical treatment of patients with displaced fractures of the clavicle shaft. In the proposed study, 190 individuals with displaced midshaft clavicle fractures, who require surgery as treatment, will be randomised. The assessment will occur at 2, 6, 12, 24 and 48 weeks, respectively. The primary outcome of the study will be the number of complications and reoperations. For sample size calculation, a moderate effective size between the techniques was considered in a two-tailed test, with 95%

## Strengths and limitations of this study

- This randomised controlled trial is the first to assess, as the primary outcome, which surgical option is superior considering complications and reoperations ratio for treatment of diaphyseal clavicle fracture.
- The pragmatic design of this study is ideal for practical recommendations to orthopaedic surgeons.
- Minimally invasive techniques do not require adjuvant methods to reduce fractures.
- A previous sample size calculation was performed.
- Previous protocol publication, minimising publication bias.
- Risks of losing track of participants in pragmatic multicentric design.

confidence and 90% power. Complications include cases of infection, hypertrophic scarring, non-union, refracture, implant failure, hypoesthesia, skin irritation and shoulder pain. Reoperations are defined as the number of surgeries for pseudoarthrosis, implant failure, infection and elective removal of the implant.

**Ethics and dissemination** Study approved by the institutional ethics committee (number 34249120.9.0000.5505—V.3). The results will be disseminated by publications in peer-reviewed journals and presentations in medical meetings.

## INTRODUCTION

Clavicle fractures are among the most common fractures in medical care, accounting for 5% of all fractures in adults.<sup>1</sup> It frequently occurs in the diaphyseal region.<sup>2</sup> The best choice of treatment for displaced and multi-fragmented diaphyseal clavicle fracture (DCF) is under debate due to the heterogeneity in the results of studies comparing surgical and non-surgical choices.<sup>3,4</sup> Despite that, the surgical approach results in fewer non-unions,<sup>5-8</sup> lower incidence of symptomatic malunion,<sup>6</sup> delayed union,<sup>7</sup> better shoulder functional scores in short-term and long-term follow-up,<sup>7</sup> and a greater likelihood of union at 1-year follow-up.<sup>9</sup> Therefore, surgery is associated with a lower risk of non-union and better functional outcomes, but a higher risk of complications.<sup>3</sup>

For surgical treatment, open reduction and internal fixation with plate and screws (ORIF) is the most commonly performed technique among orthopaedic surgeons.<sup>10,11</sup> It is associated with numbness in the incision areas<sup>11</sup> and increased risk of infection due to extensive surgical exposure.<sup>12</sup> Patients who undergo ORIF frequently complain of irritation related to the surgical implants leading to subsequent surgery for hardware removal.<sup>13</sup> Data indicate that the need for this additional surgical procedure varies from 3% to 53%.<sup>4,10,14,15</sup>

An alternative to ORIF is minimally invasive osteosynthesis with plate (MIPO), which is based on biological osteosynthesis principles<sup>12</sup> with indirect reduction, ligamentotaxis and fixation of the plate in a bridge-way disposal.<sup>16</sup> This technique is performed through small incisions that are distant from the traumatised area.<sup>17</sup> MIPO is associated with high rates of consolidation<sup>11</sup> and a low rate of complications such as non-union or paraesthesia.<sup>18</sup>

Few studies have compared the effectiveness of MIPO and ORIF for treating DCF. Although both techniques have similar rates of bone healing and function in 12 months,<sup>19,20</sup> MIPO is associated with better outcomes, fewer complications,<sup>11</sup> lesser paraesthesia at incision site<sup>21,22</sup> and higher patient satisfaction than ORIF.<sup>21</sup>

This study presents a protocol of an interventional study in patients with surgical indication for displaced or multifragmented DCF and reveals the treatment option (MIPO or ORIF) with fewer complications/reoperations. Further, it evaluated the differences between these treatments according to the results of upper-limb and shoulder function, pain and quality of life (QL).

## MATERIALS AND METHODS

### Study design and settings

This manuscript was written according to the Standard Protocol Items: Recommendations for Interventional Trials guidelines (online supplemental appendix 1) for the protocols of randomised clinical trials. The proposal

is a multicentric, pragmatic, open-label randomised clinical trial of surgical interventions, analyses of the superiority of MIPO<sup>20</sup> or ORIF.<sup>8</sup>

### Recruitment

Health institutions in Brazil, Hospital São Paulo—UNIFESP (São Paulo-SP), Hospital Universitário—UFJF (Juiz de Fora-MG), Hospital de Base—FAMERP (São José Rio Preto-SP), Hospital Santa Teresa—Faculdade de Medicina de Petrópolis (Petrópolis-RJ), Hospital Estadual Sumaré—UNICAMP (Campinas-SP), Hospital Maternidade Therezinha de Jesus (Juiz de Fora-MG), Hospital Monte Sinai (Juiz de Fora-MG), Hospital Universitário Ciências Médicas (Belo Horizonte-MG), Hospital Belo Horizonte (Belo Horizonte-MG), Hospital Lifecenter (Belo Horizonte-MG), Hospital Maradei (Belém-PA), Hospital Santa Marcelina (São Paulo-SP) e Hospital Servidor Publico Estadual de São Paulo (São Paulo-SP), with secondary or tertiary level for general or orthopaedic trauma care, or institutions that manage patients with fractures of the clavicle shaft that are referred from other community institutions, will be used as recruitment centre. In these institutions, after identifying eligible participants, they will be informed verbally about the study and its objectives (figure 1). A booklet (online supplemental appendix 2) with information about the study, pictures demonstrating the techniques and their differences, was prepared for visual assistance to the researchers and participants. Those who will consent to participate by signing the written consent form (online supplemental appendix 3) after reading the booklet carefully will be assigned a registration number.

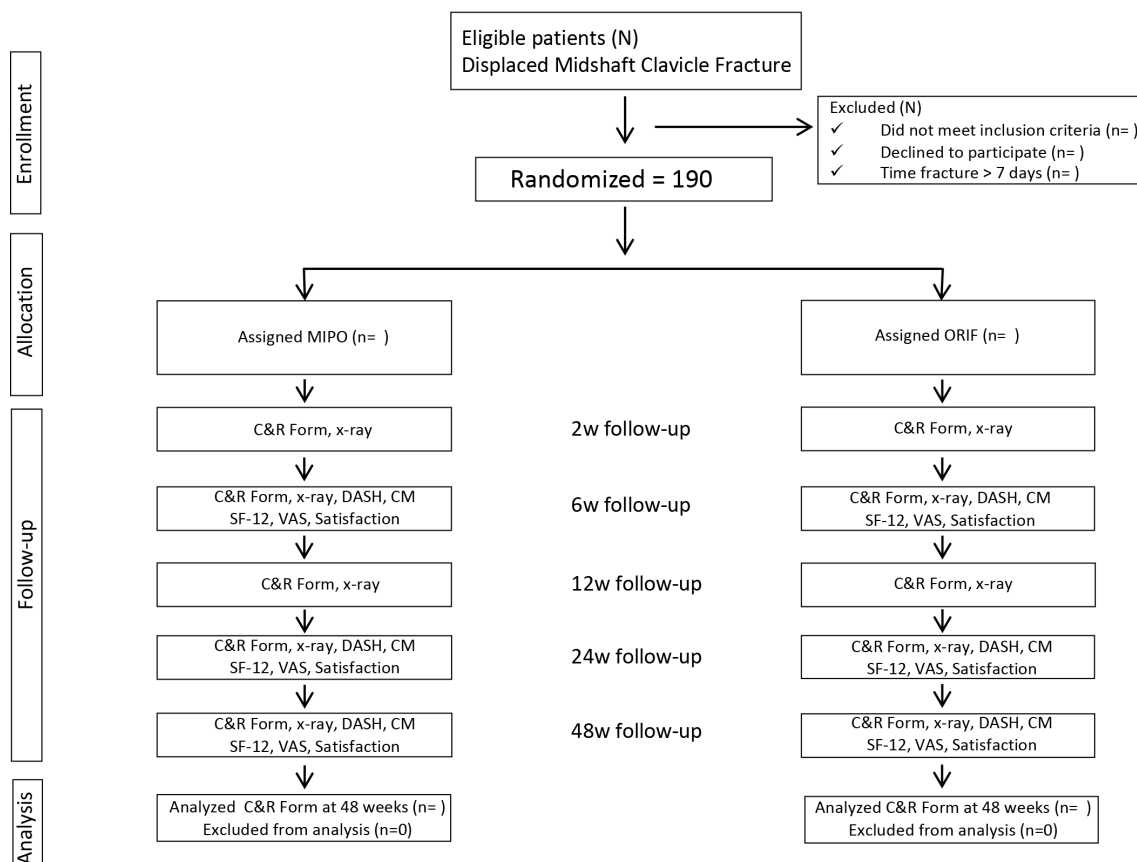
### Inclusion and exclusion criteria

Inclusion criteria include age  $\geq 18$  years, diagnosis of clavicle fractures with  $>100\%$  displacement or translation classified as type 2B1 or 2B2 according to Robinson's classification,<sup>23</sup> and evolution of up to 21 days. We will exclude patients with open clavicle fractures or associated vascular and nerve injuries, DCFs with extension to the acromioclavicular (AC) and sternoclavicular joints, fractures and/or dislocations concomitant with trauma to the scapular girdle, associated fractures of other segments of the same upper limb (arm, forearm, wrist and hand), history of fractures or dislocation of the clavicle or AC joint, pathological fractures and metabolic and/or congenital diseases.

### Withdrawal from the study

Participants who wish to withdraw after operation as instructed in the preparticipation recommendations will still be able to continue with the usual treatment instituted at the participating institutions. In case of withdrawal at any point during the evaluation, the data will be considered missing and the data imputation technique will be evaluated. Data of participants who will discontinue from the study will be available in Research Electronic Data Capture (REDCap) during revision and will be presented

## Methods – Flowchart - CONSORT



**Figure 1** Flowchart of study protocol. CM, Constant-Murley; CONSORT, Consolidated Standards of Reporting Trials; C&R, Complications and Re-operations; DASH, Disability of Arm, Shoulder and Hand; MIPO, minimally invasive osteosynthesis with plate; ORIF, open reduction and internal fixation; SF-12, Short Form-12; VAS, Visual Analogue Scale.

in the results, Consolidated Standards of Reporting Trials (CONSORT) flow chart and tables.

### Randomisation

Each participant will be assigned a number in a sequential order. The randomisation sequence will be generated using a computer software (randomizer.org). The participating centres will be divided into three groups for the distribution of randomisation blocks. The criteria for this division will be geographical and according to the evaluation of the research group. Randomisation will be performed in four blocks before recruitment begins. The first sequence of 30 participants will be used for the internal pilot to evaluate the communication between the assisting teams for the recruitment and the follow-up team for the protocol. The subsequent three sequences of equal numbers will depend on the calculated sample size. The lists will be created by an individual not belonging to the research group chosen by the secretariat of the Upper Limb Discipline of the Department of Orthopedics and Traumatology, Federal University of São Paulo. This individual will prepare a sequence of opaque envelopes identified with the participant's registration number and containing only one intervention to be performed according to the computer-generated sequence. In the

allocation request of the participating researcher, this independent individual will access the envelope and disclose its contents.

### Blinding

As it is a clinical trial on surgical treatment techniques, this study has an open design. However, to minimise observer bias during functional evaluations, the examiner will be an independent evaluator, not an orthopaedic surgeon, and the participant will use an opaque shirt to cover the surgical scar, to prevent the identification of the method performed.

### Interventions

Since the clinical trial involves surgical techniques, before the beginning of the study, representatives of the participating centres will join in virtual meetings in which they will be instructed on the techniques to be randomised (MIPO<sup>20</sup> or ORIF<sup>8</sup>). There will be a standardisation of the techniques with pictures and video presentation. During the alignment meetings, the main authors will discuss all doubts about the procedures, especially MIPO,<sup>20</sup> their specificities and the equipment to be used. All the participating researchers are orthopaedists and shoulder surgeons with experience in trauma surgery and clavicle

fracture, and when joining the study, they declared familiarity with both techniques. Furthermore, the coparticipating surgeons will be informed that the surgeon might use adjunctive devices such as reduction screw, Kirchner wire or reduction tip in focus to adequately reduce fractures and that the MIPO<sup>20</sup> technique might be converted intraoperative to ORIF<sup>8</sup> if necessary. In cases of ORIF<sup>8</sup> the surgeon might consider using lag screw, cerclage wire, non-absorbable suture or another device to provide more stability to the fixation. These choices will be described in the data collection protocol and analysed in the study result. Both procedures will use the same implant and non-locking 3.5 mm reconstruction plate. The size will depend on the patient's profile, technique applied and fracture pattern. Both procedures will be performed under general anaesthesia with ipsilateral interscalene nerve block, in the beach chair position and with the aid of radioscopy.

**MIPO:**<sup>20</sup> Initially, the frontal and craniocaudal radiographic views of the clavicle will be provided to aid the surgical procedure. The fracture reduction manoeuvre will be performed by holding the injured limb by the arm and moving it backward and superiorly, observing the length and shape of the clavicle with the aid of radioscopy to choose the size of the 3.5 mm reconstruction plate. Palpation of the medial and lateral ends of the clavicle to locate the anatomical landmarks (sternal border and acromial border, respectively), a transverse incision 1 cm lateral to the sternal border of approximately 2 cm and dissection of deep planes to the bone bed (superior surface of the clavicle) will be performed. On the lateral region 1 cm medially from the acromial border, a second incision will be made approximately 2 cm transversely with dissection of the deep planes up to the superior surface of the clavicle. With instruments for blunt dissection, the upper region of the clavicle will be prepared from medial to lateral for the implant to slide into an upper position. Intraoperative plate modelling with medial anterior convexity and lateral posterior convexity, both at the level of the third most lateral and medial holes in the plate, respectively, will be performed according to the verification of the clavicular S shape on radioscopy. The plate in the supraclavicular face, from medial to lateral, will be inserted, followed by a reduction manoeuvre and provisional fixation with 2.5 mm K-wires inserted in one of the holes of the plate. The plate will be fixed with three cortical screws on each side, starting with the medial side. The final positioning of the plate and screws will be verified. The wounds will be vigorously irrigated with saline solution 0.9%, and the deep planes will be closed with 3.0 mononylon and 2.0 intradermal sutures.

**ORIF:**<sup>8</sup> An oblique incision of approximately 10 cm over the clavicle followed by plane dissection and identification, isolation and protection of the supraclavicular nerves will be performed. The fracture will be reduced, and the clavicle fixed with a 3.5 mm reconstruction plate placed on the anteroinferior surface of the bone. For proper stabilisation, fixation of at least six cortices in the

medial and lateral fragments will be performed. Reduction and final positioning of the plate and screws will be performed. The wounds will be vigorously irrigated with short form (SF) 0.9%. The deep planes will be closed with 3.0 mononylon and 2.0 intradermal sutures.

### Postoperative care

For both groups, the operated limb will be immobilised in a sling for 4 weeks, after which the participants will be instructed to begin immediate elbow flexion and extension exercises, full wrist and hand movements, and active 'hand to mouth' manoeuvres. Shoulder elevation, rotations and abduction above 30° will be discouraged to avoid early implant fatigue. After 4 weeks, full active movements of the shoulder will be allowed without load execution. Sports and activities with load on the limb will be allowed after signs of fracture healing are observed on control radiographs.

### Follow-up

Enrolled patients will undergo assessments within 2, 6, 12, 24 and 48 weeks, respectively (figure 1). These reports will be submitted for clinical and digital radiographic evaluation (online supplemental appendix 4). In addition, in the 6-week, 24-week and 48-week follow-up consultations, they will be subjected to additional functional evaluation using Disability of Arm, Shoulder and Hand (DASH),<sup>24</sup> Constant-Murley (CM),<sup>25</sup> Visual Analogue Scale (VAS) for pain,<sup>26</sup> SF-12 V.2<sup>27</sup> and satisfaction scale.<sup>14</sup> To improve adherence to the intervention protocol, the participants will be reminded of the recommendations and dates of return through phone calls, email or text messages.

### Primary outcome

The total number of complications and reoperations per patient at 1-year follow-up will be considered the primary outcome. It is a numerical discrete variable obtained by adding the number of complications and hospitalisations observed per participant at 1 year (48 weeks) of follow-up. Complications<sup>11</sup> such as infection (superficial or deep), hypertrophic scarring, pseudoarthrosis, refracture, implant failure, hypoesthesia, skin irritation and shoulder pain (except hypoesthesia) will be considered. Infections will be diagnosed clinically by the surgical team during postoperative follow-up in the presence of inflammatory signs around the surgical wound, with or without secretions. Superficial infection will be defined as infection that does not require surgical debridement according to the researcher's judgement and treated with oral antibiotics and ambulatory dressings. Deep infection will be considered infection requiring surgical debridement. Culture of soft tissue and/or bone fragments and laboratory testing (full blood count, creatinine, polymerisation chain reaction and erythrocyte sedimentation rate) for diagnosis and treatment will be performed. Pseudoarthrosis<sup>28</sup>: non-consolidation of fractures after 24 weeks of surgical treatment will be diagnosed clinically and radiographically. Bone union will be considered when there will be signs of

bone callus in at least three cortices on the AP and caudal cephalograms. Hypoesthesia will be defined as decreased sensitivity to light touch in the region around the surgical scar<sup>29</sup> and over the anterior wall of the thorax. Skin irritation will be defined as discomfort related to the presence of the implant.<sup>13</sup> Reoperations will be defined as the number of surgical procedures performed for the treatment of pseudoarthrosis, implant failure, debridement of deep infection and programmed removal of the implant.

### Secondary outcomes

For functional evaluation, DASH<sup>24</sup> and CM<sup>25</sup> will be used. DASH is a self-report score developed to assess single or multiple disorders of the upper limb and can be applied to assess any region of the upper limb.<sup>24</sup> It is a questionnaire that produces a value of patient function that represents the combined skills of both upper extremities.<sup>24</sup> The CM score is used to assess the shoulder specifically and is an oriented applied score. It assesses the daily activities, strength, pain and physical data such as range of motion and shoulder pain.<sup>25</sup> Due to the COVID-19 pandemic, the CM score will be used only when possible and practicable.

Other aspects of health will be measured: pain using the VAS<sup>26</sup> and QL using the SF-12 V.2.<sup>27</sup> The VAS provides a simple and efficient measure of pain intensity and is used when a fast pain index that can be assigned a numerical value is needed.<sup>26</sup> QL is the individual's perception of his position in life, in the context of the culture and value systems in which he lives and in relation to his goals, expectations, standards and concerns.<sup>27</sup> SF-12 is an instrument for measuring QL composed of 12 items that assess eight different dimensions of influence on QL considering the individual's perception of aspects of his health in the last 4 weeks.<sup>27</sup>

The questionnaires will be administered by an examiner blinded to the surgical procedure, with the participant wearing clothing (T-shirt), which will cover the incision and allow evaluation of the shoulder movements. Satisfaction assessment will be done using a three-degree Likert scale in dissatisfied/partially to satisfied/satisfied.<sup>14</sup> Clinical evaluation will comprise the measurement of shoulder range of motion, and the measurement of strength in the elevation plane with the aid of a Science Supply Solutions manual dynamometer # U40812 (Science Supply Solutions, Bensenville, Illinois, USA), (graduation 1 kg/10 N). Due to the COVID-19 pandemic, strength measurement will only be performed if possible and practicable. Preoperative radiographic AP and caudal cephalic views to assess the classification of the fracture according to Robinson,<sup>23</sup> presence of an intermediate vertical fragment, and a chest radiograph for digital measurement of the length of the clavicles will be performed.<sup>30</sup> Postoperative follow-up radiographic evaluation will be performed in the AP and caudal cephalic views to assess bone healing and implant integrity. Bone union will be considered when there are signs of bone callus in at least three cortices on the AP and caudal cephalograms. The length of the clavicles will be measured according to the Smeakal *et al*<sup>30</sup> criteria and

in clinical evaluation with a tape by measuring from one end of the clavicle to the other (both palpable) during the 24 and 48 weeks follow-up visit.

### Data collection and management

Participant data will be collected using the study forms (online supplemental appendix 4) and stored in the REDCap platform, which will be used as the study repository. The main researcher will supervise the completion of the electronic spreadsheet and will be responsible for its safety and correct completion. Incorrect or missing data will be assessed by the principal investigator and corrected when necessary. Data of the participants who will discontinue from the study will be available in REDCap for the revisors and will be presented in the results, CONSORT flow chart and tables. During the study, data monitoring will be done by a committee composed of the main researcher, two coresearchers, the cosupervisor and the main supervisor. The data will be stored for a period of 5 years after the end of the study.

### Confidentiality

Each participant will receive a number on inclusion in the study, which will be used for their identification in the trial. All data will be stored in the REDCap repository, and only the main researchers will have access to it. The set of data for statistical analysis will not use personalised identifications, thereby protecting the patient's individuality. All the data of the participants will be protected in the dissemination of the results, both in publication and in academic conferences. All information collected will be used only for this research and will not be exchanged with other institutions.

### Data access and dissemination

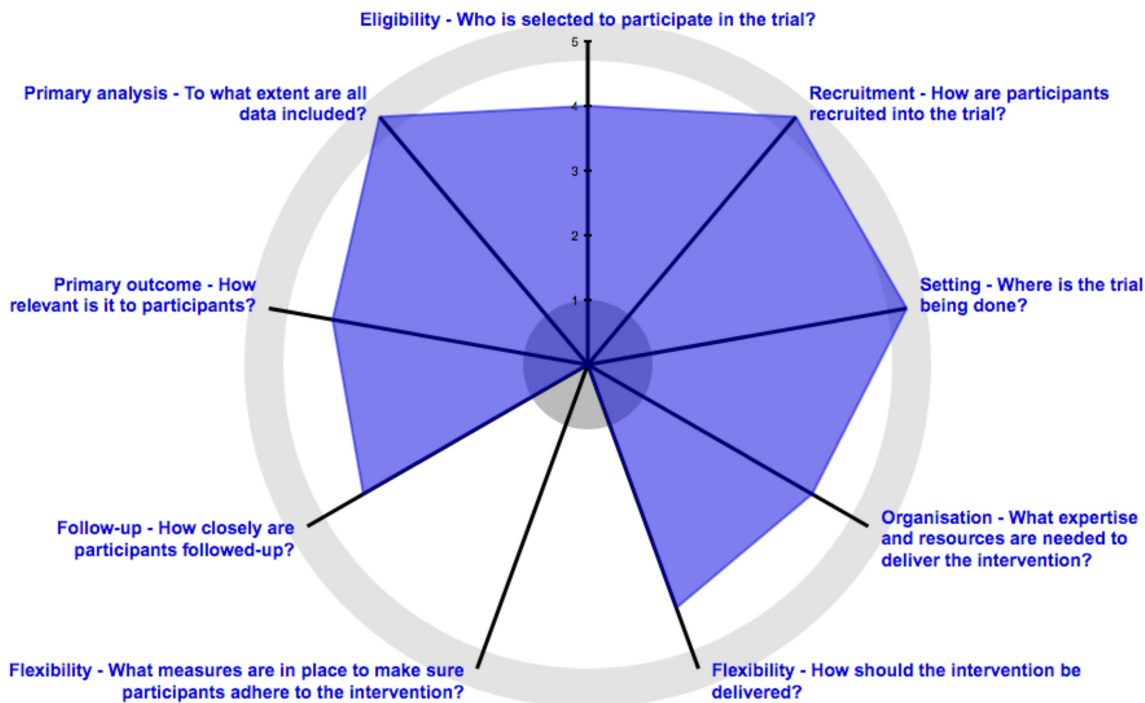
The study protocol will be available on request. The study data will be collected for academic and non-commercial use, and all participants will have access to their data on request. The researchers involved in the study will have access to the end of the summary data of the research, and will be allowed to publish the study and present it at a scientific event.

### Patient and public involvement

As part of the development of this protocol, the study outcomes (primary and secondary) were presented to a sample of patients with DCF who were eligible for the trial. The sample analysed the primary and secondary outcomes chosen by the authors and considered them relevant. The results of the study will be made available to patients on request.

### Level of pragmatism

This study aims to evaluate both interventions under the usual conditions. The degree of differentiation between explanatory or pragmatic clinical trials was assessed according to the PRagmatic Explanatory Continuum Indicator Summary - 2 (PRECIS-2),<sup>31</sup> which has nine domains (eligibility, recruitment, configuration, organisation,



**Figure 2** PRECIS-2 (PRagmatic Explanatory Continuum Indicator Summary-2), wheel of pragmatism of the study.

flexibility, adherence, monitoring, primary outcome and secondary outcome).<sup>31</sup> The score in each domain ranges from 1 (very explanatory) to 5 (very pragmatic). The analysis of the main researcher showed values compatible with the pragmatic characteristics of the study<sup>32</sup> (figure 2).

### Sample size

The sample size was calculated using the G-Power V.3.1 software<sup>33</sup> in order to compare the two surgical techniques in relation to the proportion of complications and reoperations in patients with deviated fracture in the clavicle, considering a two-tailed test, 95% confidence and 90% confidence. power. To determine the effect size, data from the study by Zhao *et al*<sup>11</sup> were used. The authors found that the odds ratio (OR, 0.33) (95% CI 0.16 to 0.71) of the MIPO was greater than that of ORIF for complications and reoperations. Considering this CI, it appears that the risk of complication is 1.40–6.25 times greater for the conventional technique. In view of the above and considering the feasibility of this study, a proportion of 30% of complications and reoperations for the conventional technique was estimated as 10% for the minimally invasive technique, that is, a moderate effect size ( $h=0.50$ ),<sup>34</sup> requiring 82 patients in each group. Considering a loss rate of up to 15%, 95 participants in each group will be needed, resulting in a total of 190 individuals.

### Statistical analysis

The collected data will be analysed with the intention of treatment in all participants with at least one evaluation return after the surgical procedure. The primary point of analysis will be in 12 months. The Mixed-Model for Repeated Measures method will be used to impute

missing data for participants who will discontinue from the study. Results will be presented descriptively with continuous data expressed as means, SD and medians, while categorical data will be presented as means or percentages. For inferential analysis, the normality of the variables will be assessed. The dichotomous variables will be analysed using Fisher's exact test and  $\chi^2$  test; the continuous variables will be analysed using the t-test. In the case of non-normal distribution, non-parametric tests appropriate to the nature of the variable will be used. The primary outcomes: complications and reoperations will be analysed at the end of the 48-week period. Paired and subgroup analyses are foreseen between periods of 6, 24 and 48 weeks for the described outcomes. The results will be analysed using 95% CI. All statistical tests will be bilateral, with a value of  $p=0.05$ . The data will be analysed using the statistical analysis software R, V.3.1.0, and with the program IBM SPSS (Statistical Package for the Social Sciences), V.22.0.

### DISCUSSION

Displaced fractures of the clavicle diaphysis (DCF) are a common occurrence in orthopaedic care, and the understanding of the ideal treatment, whether clinical or interventional, depends mainly on the evaluation of the outcome chosen for analysis. Recent data have demonstrated that no superiority was found either in operative or non-operative treatment according to the functional analysis, but the risk of non-union was higher in the non-operative group,<sup>35</sup> which is in line with other publications describing benefits of surgical treatment such as significantly lower rates of pseudoarthrosis,<sup>5–8</sup> less incidence of

symptomatic malunion<sup>6</sup> and greater likelihood of union after 1 year of treatment.<sup>9</sup>

Therefore, the most appropriate surgical treatment option is the technique that combines the best benefits of the intervention with the lowest rate of complications and reoperations, including elective removal of implants. Literature reports that the most frequently used method among orthopaedic surgeons is the ORIF with plates and screws.<sup>10 11</sup> The use of flexible or locking intramedullary nails was compared with the use of plates, and all nails needed to be removed in subsequent procedures,<sup>10 15</sup> which did not occur with the plates. However, the need to remove the plates varies from 3% to 53%.<sup>4 10 14 15</sup>

The minimally invasive technique has been described for the treatment of DCFs but is not widely performed. Studies have shown that it maintains the advantages of ORIF fixation, such as high consolidation and function. However, MIPO uses principles of biological osteosynthesis, where the approach is made with distant access to the fracture site, with indirect reduction and ‘bridge’ fixation. One of the advantages of ORIF is less paraesthesia in the surgical incisions and greater patient satisfaction. Zhao *et al*<sup>11</sup> compared the results of MIPO vs ORIF in relation to complications and reoperations and reported that the average complication rate was 8.2% when performing MIPO vs 20.2% with the conventional surgical technique. The authors of this protocol believe that it is necessary to evaluate, among surgical techniques, the one with the best rate of consolidation and function, lower rate of complications, and minimal need for reoperation. As a strength of this trial, literature reports that the primary outcome was only analysed as secondary values.<sup>8 10 14</sup> To our knowledge, this is the first randomised, pragmatic, and controlled trial on DCF osteosynthesis techniques that proposes the number of complications and reoperations as the primary outcome for analysing superiority. To date, this is the largest registered randomised controlled trial for the surgical treatment of patients with DCF, with a sample size of 190 individuals.

The researchers participating in this study are familiar with the surgical treatment of DCF. Tamaoki *et al* state that all patients treated with ORIF presented with consolidation of the fractures, but 13.7% reported paraesthesia and 21.6% were dissatisfied with the treatment’s comedic result.<sup>8</sup> Mendes *et al* reported that 93.7% of patients treated with MIPO presented with consolidation without complaining of paraesthesia in the surgical incisions.<sup>18</sup> Literature reports that the 3.5 mm reconstruction plate is an implant that is used successfully in the surgical treatment of DCF, mainly for its adaptation to the morphology of the clavicle.<sup>36</sup> Although it has a lower resistance than other implants,<sup>37</sup> it is accessible to all researchers participating in the study, and given the pragmatic design of this trial, it was considered as the ideal for the BRICS trial. It is expected from this study that the MIPO technique for the treatment of displaced DCF should have a lower rate of complications, reoperations and a higher participants’ satisfaction than ORIF.

## ETHICS AND DISSEMINATION

This study was approved by the institutional ethics committee (number 34249120.9.0000.5505—V.3). For proper dissemination of the evidence synthesis, we plan to publish this trial in a peer-reviewed journal, as well as share the findings at medical conferences, both on trauma care (eg, Brazilian Orthopaedic Trauma Society, Orthopaedic Trauma Society Meeting) and shoulder surgery (International Congress of Shoulder and Elbow Surgeons, Brazilian Congress of Shoulder and Elbow Surgeons).

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**Contributors** AFM was the main researcher involved in the study concept and design, data collection, and drafting of the manuscript. OLC, P.J.L, GGM, AU, BDST, RFL, ACG and CAMM: study design, implementation, and data collection. RFC, JMD, JDMN, ARP, G.J.L, MPDAG, DRZ, RMB, OCP, FMH, RWS, PCG, FDOF, GGG, JMAF, BGSeS, VMDO, LFDS, CCP and JAF took part in the implementation and data collection. FTM took part in coorientation, study concept, writing and data collection. JCB participated in coorientation and study design. MJST took part in the main orientation, literature revision, study design, writing and paper submissions. All authors contributed to the refinement of this study protocol and approved the final manuscript.

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#### REFERENCES

- McKee RC, Whelan DB, Schemitsch EH, et al. Operative versus nonoperative care of displaced midshaft clavicular fractures: a meta-analysis of randomized clinical trials. *J Bone Joint Surg Am* 2012;94:675–84.
- Stanley D, Trowbridge EA, Norris SH. The mechanism of clavicular fracture. A clinical and biomechanical analysis. *J Bone Joint Surg Br* 1988;70:461–4.
- Reito A, Launonen A, Paloneva J. Factors explaining heterogeneity in studies comparing surgical and nonsurgical treatment of midshaft clavicle fractures: a meta-regression analysis of randomized controlled trials and high-quality observational studies. *J Shoulder Elbow Surg* 2020;29:1726–34.
- Lenza M, Buchbinder R, Johnston RV, et al. Surgical versus conservative interventions for treating fractures of the middle third of the clavicle. *Cochrane Database Syst Rev* 2013;CD009363.
- Smeeing DPJ, van der Ven DJC, Hietbrink F, et al. Surgical versus nonoperative treatment for midshaft clavicle fractures in patients aged 16 years and older: a systematic review, meta-analysis, and comparison of randomized controlled trials and observational studies. *Am J Sports Med* 2017;45:1937–45.
- Amer K, Smith B, Thomson JE, et al. Operative versus nonoperative outcomes of middle-third clavicle fractures: a systematic review and meta-analysis. *J Orthop Trauma* 2020;34:e6–13.
- Guerra E, Previtali D, Tamborini S, et al. Midshaft clavicle fractures: surgery provides better results as compared with nonoperative treatment: a meta-analysis. *Am J Sports Med* 2019;47:3541–51.
- Tamaoki MJS, Matsunaga FT, Costa ARFda, et al. Treatment of displaced midshaft clavicle fractures: figure-of-eight harness versus anterior plate osteosynthesis: a randomized controlled trial. *J Bone Joint Surg Am* 2017;99:1159–65.
- Axelrod DE, Ekhtiari S, Bozzo A, et al. What is the best evidence for management of displaced midshaft clavicle fractures? A systematic review and network meta-analysis of 22 randomized controlled trials. *Clin Orthop Relat Res* 2020;478:392–402.
- Andrade-Silva FB, Kojima KE, Joeris A, et al. Single, superiorly placed reconstruction plate compared with flexible intramedullary nailing for midshaft clavicular fractures: a prospective, randomized controlled trial. *J Bone Joint Surg Am* 2015;97:620–6.
- Zhao E, Zhang R, Wu D, et al. Comparison between minimally invasive plate osteosynthesis and conventional open plating for midshaft clavicle fractures: a systematic review and meta-analysis. *Biomed Res Int* 2019;2019:1–9.
- Perren SM. Evolution of the internal fixation of long bone fractures. The scientific basis of biological internal fixation: choosing a new balance between stability and biology. *J Bone Joint Surg Br* 2002;84:1093–110.
- Hulsmans MHJ, van Heijl M, Houwert RM, et al. High irritation and removal rates after plate or nail fixation in patients with displaced midshaft clavicle fractures. *Clin Orthop Relat Res* 2017;475:532–9.
- Woltz S, Stegeman SA, Krijnen P, et al. Plate fixation compared with nonoperative treatment for displaced midshaft clavicular fractures: a multicenter randomized controlled trial. *J Bone Joint Surg Am* 2017;99:106–12.
- Ferran NA, Hodgson P, Vannet N, et al. Locked intramedullary fixation vs plating for displaced and shortened mid-shaft clavicle fractures: a randomized clinical trial. *J Shoulder Elbow Surg* 2010;19:783–9.
- Baumgaertel F, Buhl M, Rahn BA. Fracture healing in biological plate osteosynthesis. *Injury* 1998;29 Suppl 3:3–6.
- Toogood P, Huang A, Siebuhner K, et al. Minimally invasive plate osteosynthesis versus conventional open insertion techniques for osteosynthesis. *Injury* 2018;49 Suppl 1:S19–23.
- Mendes Junior AF, Mota Neto Jda, Oppe IG, et al. Surgical treatment of comminuted midshaft clavicle fracture by minimally invasive technique: description and preliminary results. *Rev Bras Ortop* 2021;56:490–6.
- Sohn H-S, Kim WJ, Shon MS. Comparison between open plating versus minimally invasive plate osteosynthesis for acute displaced clavicular shaft fractures. *Injury* 2015;46:1577–84.
- Kim JY, Yoo BC, Yoon JP, et al. A comparison of clinical and radiological outcomes of minimally invasive and conventional plate osteosynthesis for midshaft clavicle fractures. *Orthopedics* 2018;41:e649–54.
- Jiang H, Qu W. Operative treatment of clavicle midshaft fractures using a locking compression plate: comparison between mini-invasive plate osteosynthesis (MIPPO) technique and conventional open reduction. *Orthop Traumatol Surg Res* 2012;98:666–71.
- You J-M, Wu Y-S, Wang Y. Comparison of post-operative numbness and patient satisfaction using minimally invasive plate osteosynthesis or open plating for acute displaced clavicular shaft fractures. *Int J Surg* 2018;56:21–5.
- Robinson CM, Goudie EB, Murray IR, et al. Open reduction and plate fixation versus nonoperative treatment for displaced midshaft clavicular fractures: a multicenter, randomized, controlled trial. *J Bone Joint Surg Am* 2013;95:1576–84.
- Orfale AG, Araújo PMP, Ferraz MB, et al. Translation into Brazilian Portuguese, cultural adaptation and evaluation of the reliability of the disabilities of the arm, shoulder and hand questionnaire. *Braz J Med Biol Res* 2005;38:293–302.
- Barreto RPG, Barbosa MLL, Balbinotti MAA, et al. Versão brasileira do Constant-Murley score (CMS-BR): validade convergente e de constructo, consistência interna e unidimensionalidade. *Rev Bras Ortop* 2016;51:515–20.
- Sehn F, Chachamovich E, Vidor LP, et al. Cross-Cultural adaptation and validation of the Brazilian Portuguese version of the pain catastrophizing scale. *Pain Med* 2012;13:1425–35.
- Damásio BF, Andrade TF, Koller SH. Psychometric properties of the Brazilian 12-Item short-form health survey version 2 (SF-12v2). *Paidéia* 2015;25:29–37.
- Reis FB, Hungria Neto JS. Pires Res. Pseudoartrose. *Rev Bras Ortop* 2005;40:79–88.
- Beirer M, Postl L, Crönlein M, et al. Does a minimal invasive approach reduce anterior chest wall numbness and postoperative pain in plate fixation of clavicle fractures? *BMC Musculoskelet Disord* 2015;16:128.
- Smekal V, Deml C, Irenberger A, et al. Length determination in midshaft clavicle fractures: validation of measurement. *J Orthop Trauma* 2008;22:458–62.
- Loudon K, Treweek S, Sullivan F, et al. The PRECIS-2 tool: designing trials that are fit for purpose. *BMJ* 2015;350:h2147.
- PRECIS-2 wheel. Available: <https://www.precis-2.org/Trials/Details/637>
- Faul F, Erdfelder E, Lang A-G, et al. G\*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behav Res Methods* 2007;39:175–91.
- Cohen J. A power primer. *Psychol Bull* 1992;112:155–9.
- Ban I, Kristensen MT, Barfod KW, et al. Neither operative nor nonoperative approach is superior for treating displaced midshaft clavicle fractures: a partially blinded randomized controlled clinical trial. *Bone Joint J* 2021;103-B:762–8.
- Vancelef S, Herteleer M, Carette Y, et al. Why off-the-shelf clavicle plates rarely fit: anatomic analysis of the clavicle through statistical shape modeling. *J Shoulder Elbow Surg* 2019;28:631–8.
- Robertson C, Celestre P, Mahar A, et al. Reconstruction plates for stabilization of mid-shaft clavicle fractures: differences between nonlocked and locked plates in two different positions. *J Shoulder Elbow Surg* 2009;18:204–9.