



Original Article

Randomized clinical trial on percutaneous minimally invasive osteosynthesis of fractures of the distal extremity of the radius^{☆,☆☆}



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ABSTRACT

Objectives: the purpose of this study was to compare the postoperative radiological and clinical outcomes with minimally invasive percutaneous osteosynthesis using three implants: volar locking plate, intramedullary nail system and nonbridging external fixator for distal radius fractures.

Methods: forty-eight patients (A group, 16; B group 16; C group 16) underwent minimally invasive percutaneous osteosynthesis of reductible and unstable displaced (Type IIB by Rayhack Classification) distal radius fractures. In B group intramedullary nail system was used, in A group the patients were treated with volar locking plate and in C group the patients were treated by nonbridging external fixator from January 2011 to December 2012. The mean follow-up period was 12 months. Radiologic parameters, range of motion, grip strength, and disability of the arm, shoulder, and hand score were evaluated at each examination (3rd and 6th week, and 12th months). The visual analog scale of wrist pain and complications were assessed at the final follow-up.

Results: the groups did not differ significantly in radiological outcomes after 12 months, but the clinical results, VAS scale and dash score in group A (volar locking plate) and B (nail intramedullary) were statistically significantly better than that of C group (nonbridging external fixator). One patient underwent an osteosynthesis with nail intramedullary and another with external fixator (C group) developed persistent pain near the site of the superficial radial nerve because of the distal's screw and pins, respectively.

Conclusion: in clinical parameters, significant differences in outcomes were found between groups A and B after six weeks versus C group.

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Ensaio clínico randomizado de osteossíntese percutânea e minimamente invasiva das fraturas da extremidade distal do rádio

R E S U M O

Palavras-chave:

Fraturas do rádio
Fixação interna de fraturas
Placas ósseas

Objetivos: comparar o resultado clínico funcional dos pacientes com diagnóstico de fratura com desvio, redutível e instável da extremidade distal do rádio submetidos ao tratamento cirúrgico pela técnica de osteossíntese percutânea e minimamente invasiva com o uso de três tipos de implante: placa volar bloqueada, haste intramedular bloqueada e fixador externo. Comparar os resultados quanto à melhoria da qualidade de vida pelo questionário Dash e ao tempo de retorno ao trabalho.

Métodos: divididos em três grupos (A, placa - 16; B, haste - 16; C, fixador externo - 16), 48 pacientes foram submetidos ao tratamento cirúrgico da fratura da extremidade distal do rádio, redutível e instável, classificação Rayhack (Tipo IIB), pelo método minimamente invasivo, com três tipos de implante: haste intramedular bloqueada, placa volar bloqueada e fixador externo radio-radial. Estudo feito de janeiro de 2011 a dezembro de 2012. O tempo de seguimento foi de 12 meses. Parâmetros radiográficos, dor (escala VAS), medida do arco de movimento, força de preensão palmar e o questionário Dash foram avaliados na terceira e sexta semana e no sexto mês de pós-operatório.

Resultados: numa análise vertical dos valores apresentados, observamos uma melhoria estatística significativa em todos os parâmetros clínicos analisados no estudo, nos três grupos. Em relação à análise horizontal, ou seja, na comparação dos grupos entre si, não houve diferenças estatísticas significativas quanto aos parâmetros radiográficos após o 12º mês de seguimento. O grau de força de preensão palmar, a medida do arco de movimento, VAS e Dash apresentaram, na terceira e sexta semana de pós-operatório, valores estatísticos significativos superiores nos grupos A e B. Um paciente do grupo B apresentou dor no punho, por provável proximidade do parafuso com o primeiro túnel extensor, que foi removido; e outro do C apresentou dor no punho, no trajeto do ramo sensitivo do nervo radial, pela presença do pino de Schantz.

Conclusão: a técnica minimamente invasiva é eficaz e segura, com melhoria clínica e funcional em todos os momentos do estudo. Ambos os três implantes são estáveis. Há superioridade estatística significativa dos resultados clínico-funcionais (grau de força e arco de movimento, Dash e VAS) até a sexta semana, para os grupos A (placa) e B (haste). No fim de 12 meses não há diferenças estatísticas significativas entre os grupos.

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Introduction

Fractures that affect the distal radius are among the most frequent fractures of the upper limbs and account for 74.5% of the fractures of the forearm, i.e. an incidence of 1:10,000 people.¹ There is greater incidence in the dominant arm.²

Currently, fractures of the distal extremity of the radius are regarded as complex, with a prognosis depending on the type of fracture and/or the treatment used. In seeking better clinical and functional results, surgical methods are increasingly indicated, and there has been great evolution in the implants developed for the distal extremity of the radius. Nonetheless, there is still space for classical conservative treatment, particularly for fractures without displacement.³

Surgical methods have also evolved, with minimally invasive osteosynthesis techniques and approaches toward soft tissues that are more biological, i.e. less aggressive toward the covering of soft tissues.⁴

The implants that are most often used in our setting for treating these fractures are Kirschner wires, volar locking plates and transarticular external fixators.⁴

Stabilization of fractures of the distal extremity of the radius, using Kirschner wires placed separately or using the transarticular external fixation method, does not allow early rehabilitation of the wrist. Kirschner wires are a method with minimal osteosynthesis and require plaster-cast immobilization throughout the treatment, while external fixation using Schanz pins placed in the second or third metacarpals blocks flexion-extension of the wrist.

However, these and new implants developed for fractures of the distal extremity of the radius, such as intramedullary locking nails⁵ and nonbridging external fixators can be used percutaneously.⁶

The possibility of indirect open reduction of such fractures, i.e. without viewing the focus of the fracture, allows ever-earlier rehabilitation, given that the implants and the surgical approach are also less aggressive and more stable.⁶

Since there are no statistically significant results in the studies so far published with regard to surgical treatment of these fractures, and these systematic reviews and meta-analyses⁷ state that it is necessary to conduct studies with better qualitative evidence, we decided to carry out this study using a minimally invasive technique with three different

implants: intramedullary locking nail, volar locking plate and nonbridging external fixator. All the implants allow the same rehabilitation protocol, with early mobilization recommended immediately after the surgery.

Objectives

To compare the functional clinical results (palm grip strength, wrist range of motion and pain) among patients with a diagnosis of an unstable but reducible displaced extra-articular fracture (type IIB of Rayhack's classification)⁸ of the distal extremity of the radius, who underwent surgical treatment by means of a minimally invasive percutaneous osteosynthesis technique, using three different implants: volar locking plate, intramedullary locking nail and external fixator.

To compare the results with regard to quality-of-life improvement through applying the DASH questionnaire.⁹

Material and methods

Between January 2011 and December 2012, 100 patients who presented at the outpatient clinics of the Hand and Microsurgery Group, ABC School of Medicine, with a diagnosis of fracture of the distal extremity of the radius were evaluated. Forty-eight of these patients were included in the study and underwent physical examination and posteroanterior (PA) and lateral (L) radiographic examinations.

The inclusion criteria were that the patients should be adults aged 18–65 years, of either sex, with a clinical and imaging diagnosis of this fracture (type IIB), and needed to fill out the voluntary free and informed consent statement and the protocol of conflicts of interest, as specified by the Research Ethics Committee (Appendix A).

Patients were excluded according to the following criteria: presentation of associated diseases of the wrist, such as osteometabolic diseases; having undergone any previous surgical procedure; or presentation of conditions that affected the wrists bilaterally.

The functional evaluation was conducted by professionals in the Hand Occupational Therapy Sector of the Mario Covas State Hospital, who did not have access to information on the group to which the patients belonged.

Functional measurements of wrist range of motion were made in degrees using a single specific goniometer. Palm grip strength was measured in kilogram-force (kgf) by means of a hydraulic dynamometer (Jamar®).

The clinical analysis on pain was performed using a visual analog scale (VAS) from zero to ten, for subjective evaluation.

Quality of life was assessed using the DASH questionnaire,⁹ which is the instrument used in the majority of studies published on treatments for fractures of the distal extremity of the radius.

The randomization consisted of making matches in groups of three, by means of a draw, using standardized tickets marked A, B or C (A, volar locking plate; B, intramedullary nail; C, external fixator). The tickets were placed in a bag and mixed, and then the secretary of the sector pulled out a single ticket and placed it on the table. This ticket did not participate further in the draw until the group of three had been completed. This was done in the outpatient clinic, before the surgery.

Thus, the patients were divided into three groups: A, B and C.

The patients underwent percutaneous minimally invasive osteosynthesis using one of the three different implants. The patients in group A received a volar locking plate,^{6,10} those in group B received an intramedullary nail and those in group C received an external fixator.¹¹

Operative technique for osteosynthesis with volar locking plate (group A)

A volar access was used, under the radial flexor tendon of the carpus, 1 cm distally to the fracture, with dissection in layers down to the radius bone (Table 1).

The volar plate was slid in with the aid of radioscapy, through which the ideal positioning could be viewed.

Table 1 – Epidemiological distribution and postoperative follow-up of the patients in group A.

Number	Age (years)	Side affected	Follow-up (months)	Sex	Complications
I	22	Dominant	12	Male	No
II	19	No	12	Male	No
III	42	No	12	Female	No
IV	21	Dominant	12	Female	No
V	38	No	12	Male	No
VI	51	No	12	Female	No
VII	26	Dominant	12	Male	No
VIII	56	Dominant	12	Female	No
IX	55	No	12	Female	No
X	39	No	12	Female	No
XI	23	No	12	Male	No
XII	39	Dominant	12	Female	No
XIII	30	Dominant	12	Female	No
XIV	26	Dominant	12	Male	No
XV	24	No	12	Male	No
XVI	41	No	12	Female	No

Source: medical filing service of the hospitals of the ABC School of Medicine.

Table 2 – Epidemiological distribution and postoperative follow-up of the patients in group B.

Number	Age (years)	Side affected	Follow-up (months)	Sex	Complications
I	33	Dominant	12	Female	No
II	36	Dominant	12	Female	No
III	41	Dominant	12	Male	No
IV	22	Dominant	12	Male	No
V	38	No	12	Male	No
VI	26	No	12	Female	No
VII	26	Dominant	12	Male	No
VIII	51	Dominant	12	Female	No
IX	25	No	12	Female	No
X	28	No	12	Male	No
XI	23	Dominant	12	Male	No
XII	38	No	12	Female	Yes
XIII	26	No	12	Female	No
XIV	46	Dominant	12	Female	No
XV	32	Dominant	12	Male	No
XVI	38	No	12	Male	No

Source: medical filing service of the hospitals of the ABC School of Medicine.

Closed reduction of the fracture was performed, with provisional placement of one Kirschner wire.

A distal volar access was made in the wrist, at the exact location of the first hole of the plate, with dissection in layers down to the bone.

The plate was fixed using a 2.5 mm proximal cortical screw and a 2.5 mm distal locking screw, with viewing of the reduction with the aid of radioscapy.

The remaining screws were then put in: six distal and three proximal screws.¹²

The layers and the skin were then sutured.

Postoperative radioscapy and radiography were performed on the wrist to check on the surgery.

A dressing was then placed around the wrist.

Operative technique for osteosynthesis with intramedullary locking nail (group B)

Closed reduction was performed on the fracture and it was stabilized provisionally using one or two Kirschner wires inserted in the region of the distal ulna, as far as the medial column of the radius, with the aid of radioscapy (Table 2).

The access route was minimal, dorsal and radial, measuring 2 cm, using the first extensor tunnel as the anatomical parameter. A single longitudinal opening was made in the dorsal retinaculum, with exposure of the extensor tendons of the first tunnel, which were pushed away dorsally.

A standard Kirschner wire and guide were then implanted in the region proximal to the radial styloid, which was pegged in the metaphyseal intramedullary region of the radius, just below the first extensor tunnel.

Intramedullary milling was performed using a specific cannulated drill bit, with a guidewire as an essential parameter.

Intramedullary milling tools of the size of the nail (ranging from one to five) were then emplaced manually. For perfect adjustment of the milling tool with the medulla of the bone, the size of the implant to be used was measured.

Finally, the intramedullary nail was emplaced, with the aid of radioscapy.

The fracture was stabilized distally using three 2.7 mm lateral locking screws, which enabled angular stability, using a guide adjacent to the nail.

The system was stabilized proximally using two 2.4 mm dorsal cortical screws, with the aid of a specific guide.

The layers and skin were sutured.

Postoperative radioscapy and radiography were performed on the wrist to check on the surgery.

A dressing was then placed around the wrist.

Operative technique for osteosynthesis with nonbridging external fixator (group C)

Percutaneous accesses measuring 0.5 mm were made in the radial styloid and in the distal region of the medial column of the radius, in order to insert Kirschner wires (Table 3).

Closed reduction was performed on the fracture and two crossed Kirschner wires were emplaced: one entering through the radial styloid and the other through the distal region of the medial column of the bone.

Two 3 mm Schanz pins were placed dorsally and distally to the fracture and two Schanz pins were placed dorsally radially and proximally to the fracture.

The external fixator was assembled on the Schanz pins, which allowed mobility of the wrist and enabled secure stabilization of the fracture.

The skin was sutured.

Postoperative radioscapy and radiography were performed on the wrist to check on the surgery.

A dressing was then placed around the wrist.

Postoperative period for groups A, B and C

The patients were clinically and radiographically assessed before the operation and afterwards, in the third and sixth weeks and sixth month. All of them underwent rehabilitation at the institution's Hand Occupational Therapy Sector, using the same protocol for analgesia, kinesiotherapy and

Table 3 – Epidemiological distribution and postoperative follow-up of the patients in group C.

Number	Age (years)	Side affected	Follow-up (months)	Sex	Complications
I	34	Dominant	6	Male	No
II	45	No	6	Female	No
III	58	Dominant	6	Male	No
IV	42	Dominant	6	Female	No
V	61	Dominant	6	Female	No
VI	29	No	6	Female	No
VII	36	Dominant	6	Female	No
VIII	52	Dominant	6	Female	Yes
IX	23	No	6	Male	No
X	39	No	6	Male	No
XI	34	No	12	Male	No
XII	43	Dominant	12	Male	No
XIII	52	Dominant	12	Female	No
XIV	29	No	12	Female	No
XV	37	No	12	Male	No
XVI	40	Dominant	12	Female	No

Source: medical filing service of the hospitals of the ABC School of Medicine.

functional gain, from the first week after the surgery until discharge.

This study was approved by the Medical Research Ethics Committee of the ABC School of Medicine in July 2007, through CEP/FMABC Protocol Registration No. 160/2007.

All the data were sent for statistical analysis. The statistical level of 5% (0.050) was used for applying statistical tests, i.e. when the calculated significance value (p) was less than 5% (0.050), a difference that was said to be “statistically significant” was observed (marked in red); and when the calculated significance value (p) was greater than or equal to 5% (0.050), a difference that was said to be “statistically non-significant” was observed. The SPSS software (Statistical Package for the Social Sciences), version 13.0, was used to obtain the results.

Results

The results from the patients were presented at three study times: third week (Table 4), sixth week (Table 5) and twelfth month (Table 6).

Table 4 – Clinical and functional results in the third week.

Parameters	Group A – plate	Group B – nail	Group C – fixator
Pain (VAS)	3.8	2.6	3.75
DASH	36.4	23.6	68.13
Strength	53.6	66.67	29.03
ROM	86.1	89.72	71.0
Complications	–	6.25	6.25

Source: medical filing service of the outpatient clinic of the ABC School of Medicine.

ROM, range of motion; DASH, disability of arm, shoulder and hand. % of ROM and strength in relation to the values of the contralateral side.
% complications in relation to the total number of patients.

Table 5 – Clinical and functional results in the sixth week.

Parameters	Group A – plate	Group B – nail	Group C – fixator
Pain (VAS)	1.80	1.00	1.70
DASH	14.7	10.4	29.5
Strength	78.44	88.89	60.00
ROM	94.60	98.01	83.00
Complications	–	6.25	6.25

Source: medical filing service of the outpatient clinic of the ABC School of Medicine.

ROM, range of motion; DASH, Disability of Arm, Shoulder and Hand. % of ROM and strength in relation to the values of the contralateral side.

% complications in relation to the total number of patients.

Statistical study

The three groups studied were described and compared (horizontal statistical analysis) by applying the Kruskal-Wallis test,

Table 6 – Clinical and functional results in the 12th month.

Parameters	Group A – plate	Group B – nail	Group C – fixator
Pain (VAS)	0.0	0.0	0.0
DASH	1.1	1.2	1.50
Strength	97.00	98.90	94.50
ROM	99.95	100	99.4
Complications	–	–	–

Source: medical filing service of the outpatient clinic of the ABC School of Medicine.

ROM, range of motion; DASH, disability of arm, shoulder and hand. % of ROM and strength in relation to the values of the contralateral side.
% complications in relation to the total number of patients.

with the aim of ascertaining possible differences between the three groups studied, when compared concomitantly for the variables of interest.

Since some differences that were said to be statistically different were encountered, the Mann-Whitney test was applied, with adjustment using the Bonferroni correction, in order to attempt to identify which groups differed from each other when compared pair by pair.

The data were described and compared between the observation times, for each study group (vertical statistical analysis).

The Friedman test was applied, with the aim of ascertaining possible differences between the three observation times, for each study group and for the variables of interest.

Since there were statistically significant differences in all of the comparisons made, the Wilcoxon signed-rank test was applied, with adjustment using the Bonferroni correction, in order to attempt to identify which observation times differed from each other when compared pair by pair.

Complications

One patient in group B presented pain in the wrist, probably due to proximity of the distal locking screw to the first extensor tunnel. Just after the sixth month after the operation, this screw was removed and the pain ceased.

Another patient, in group C, presented wrist pain on the path of the sensory branch of the radial nerve, due to proximity of the presence of the Schanz pin. This pain also improved with removal of the pin in the sixth month after the surgery.

Discussion

Evolution of the treatments for fractures of the distal extremity of the radius has taken place along two lines: technologically, through development of implants that enable angular stability, and biologically, also through stabilizing the bone, but preserving the covering of soft tissues and thus enabling earlier functional return for this joint and leaving patients with less economic and social damage.

New designs for volar plates with a minimum thickness of only 2 or 3 mm, and new designs for instruments, with guides coupled to the intramedullary nail, along with the use of radiopaque materials for external fixators, which have become established for treating these fractures over the last ten years, have made it possible to use minimally invasive techniques.

From vertical analysis, i.e. making comparisons between the data obtained within each group, our study showed statistically significant functional clinical results, irrespective of the implant, at all assessment times of the study, which showed that the minimally invasive technique was effective.

From the analysis on the radiographic parameters, all the patients presented the same initial reduction of the fracture, which showed that all the implants used in this study were safe and stable, thus enabling effective bone consolidation at the fracture.

Horizontal comparison of the functional clinical results between the groups (range of motion, palm grip strength, DASH and VAS) showed that there were statistically significant differences between the values for group C and those for groups A and B, in the third and sixth weeks after the surgery. From this, we can affirm that the patients who were treated with an intramedullary nail or a volar plate presented better quality of life and fewer pain symptoms than did those who were treated with an external fixator, up to the sixth week. However, after the sixth week, the clinical-functional parameters became statistically similar between the three groups.

The data obtained in this study were also compared with those from studies in the literature. Our results were similar to those of Schønnemann et al.¹¹ The palm grip strength results were better among patients treated with an intramedullary nail than among patients treated with a nonbridging external fixator,¹²⁻¹⁵ and the results relating to the radiographic parameters analyzed were similar, without any loss of the initial reduction, after consolidation of the fracture. We also used Kirschner wires in association with external fixators, in order to ensure greater fracture stability.¹⁴

Comparing our values with those of Cui et al.,¹⁶ there were similarities in the results, with better evidence among the patients treated with a volar plate than among those treated with an external fixator.

Although the study by Zenke et al.¹⁷ did not show any significant differences between the conventional method and the minimally invasive method using volar plates for treating these fractures, we observed better clinical-functional and DASH results in our study, in relation to the study by Orbay et al.,¹⁰ with palm grip strength of 97% versus 77% and DASH of 1.1 versus 8.28.

Regarding the number of screws for stabilizing the volar plate, better fixation was observed with three screws inserted proximally to the fracture focus (diaphyseal location) and at least six locking screws distally to the fracture focus. This was also observed in the biomechanical study by Mehling et al.¹²

In evaluating complications, the studies by Richard et al.¹⁸ and Rampoldi and Marsico¹⁹ showed better functional results and a lower rate of complications among patients treated with volar plates than among those with external fixation. This was also observed in the present study, with values of 6.25% in group C and 0% in group A.

In a systematic review, Espósito et al.²⁰ found a lower DASH score, better restoration of the length of the radius and lower infection rate in the group of patients with fractures who were treated by means of internal osteosynthesis using a plate than in those treated using an external fixator. These results resemble those of the present study.

Both in our study and in that of Xie et al.²¹ in 2013 (which was a systematic review on surgical treatment of these fractures), there were better functional results (forearm supination, restoration of palmar tilt and radial slope and a lower complication rate) in the group of patients treated with a volar plate than in those treated with an external fixator.

Sando et al.²² conducted a study that showed the existence of publication bias among articles on surgical treatment

of the distal extremity of the radius and found that out of the 215 studies analyzed, 75% presented positive results, 20% neutral results and 5% negative final values. These authors concluded that these articles presented characteristics that would lead to positive results and that these results may have facilitated publication of these studies. They also suggested that a standardized clinical register covering the entire United States should be created for the results to be followed up and assessed. In our study, we attempted to use minimally invasive methods, cases in which the fractures had the same characteristics and recognized assessment and rehabilitation protocols in order to minimize these sources of bias.

Although using intramedullary nails to treat these fractures is not common in our setting, it could be seen in the present study that the results obtained were excellent and that the learning curve was short.

Conclusion

The minimally invasive technique is effective and safe, with clinical and functional improvements at all observation times of the study. The three implants were stable, given that there were no alterations in the radiographic parameters. There were statistically significantly better clinical-functional results (degree of strength, range of motion, DASH and VAS) in group A (plate) and group B (nail), up to the sixth week. However, after the 12th month, there were no statistically significant differences in the clinical-functional parameters analyzed, between the three groups.

Conflicts of interest

The authors declare no conflicts of interest.

Anex 1. Voluntary free and informed consent statement

Study: a randomized comparative study using external fixators, percutaneous volar plates and intramedullary nails to surgically treat fractures of the distal extremity of the radius.

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This study was assessed and approved by the institution's Research Ethics Committee on July 4, 2007 (registration no. 160/2007). This committee is a body that has the aim of protecting your well-being. It is responsible for assessing and following up the ethical issues of all studies involving human beings so that the dignity, rights, safety and well-being of the research subjects are ensured. If you have any doubts and/or questions about your rights as a participant in this study, or if you are dissatisfied with the way in which the study is being

conducted, you can get in touch with the Research Ethics Committee of the ABC School of Medicine at the following address: Avenida Príncipe de Gales, 821, 1st floor, CEPES Building, Santo André, SP, or by telephone: (11)-4993-5453. The hours of attendance are from Monday to Friday from 07:00 to 17:00.

Name of subject or person with legal responsibility:.....

No. of identity document:.....

Sex: M ()/F ()

Date of birth:...../...../.....

Telephone: ().....

Address:.....

I, Mr/Ms

.....; declare for legal purposes that I am being guided in relation to all the risks, discomforts and benefits that result directly or indirectly (causal link) from the procedure(s) that I am undergoing. My participation as a patient, and/or the person responsible, is voluntary and I am aware that I am receiving the best treatment options for the disease or condition that I have, in its current state. I am aware that this participation is for a period of five years. The treatment offered, i.e. surgical treatment with a volar plate for angular stability, a nonbridging external fixator or an intramedullary locking nail, has the aim of achieving adequate stabilization of the fracture of the distal extremity of the radius. It has been discussed and is appropriate and adequate, such that it provides improvement of the present conditions. These surgical procedures will be carried out in patients with a diagnosis of fracturing of the distal radius, comprising the abovementioned surgical treatment. I am aware that complications relating to the disease may occur, with procedures equivalent to the complexity of the general clinical picture, local state and hospital conditions. The surgery will be accompanied by anesthetic procedures and possible complications such as anaphylaxis, drug interactions, cardiorespiratory arrest and various allergies. There are risks of implant loosening and surgical site infection. Additional procedures with medical indications due to severe risks will be performed as described in the literature, if these are essential for my benefit, for treatment in view of emergency situations that might occur, and no non-routine procedures will be performed. If the use of intensive care units, semi-intensive care unit, blood transfusion or special examinations after the procedure(s) becomes necessary, these will be implemented and subsequently properly notified by the persons responsible for the sector. In the event of complications involving bleeding, blood transfusion may be effected, independent of religious convictions or beliefs. I am aware that routine sanitary measures in blood banks ensure the quality of the blood and blood derivatives from this source, but that there are diseases such as AIDS, hepatitis and Chagas disease, among others, that can be transmitted. The routine procedures comprise blood collection by means of peripheral vein puncture, other examinations (when necessary), dressings and the usual postoperative care. In cases of surgical implants, new surgical procedures such as reoperation or removal of implants unrelated to the procedure will be duly excluded and explained. If damage to health were to occur as a result of this investigation, a new surgical procedure with

exchange of the implant(s) will be performed if necessary. Discomfort, pain, loss of strength, diminished range of joint motion, motor incapacity and other risks are inherent to the surgical procedure. Current diseases compatible with the degree of surgical complexity may progress to definitive motor incapacity and death. I will be benefited directly through the opportunity to receive adequate treatment for the disease, in its present state, at the institution that I have voluntarily chosen, from trained and qualified professionals. Regarding alternative procedures that could be advantageous, which I might have chosen, I am rejecting these and placing this treatment as the best option for the present moment of the disease. I have had the opportunity to ask all the questions that I deemed fundamental, important and necessary, and all of these were answered fully and satisfactorily. I am aware of the confidentiality, secrecy and privacy of the study. Nonetheless, at any stage of the treatment, clarifications for possible doubts are assured and I can ask such questions by appointment. I will have the right to be kept up to date with regard to the partial results from the treatment, complications and favorable or unfavorable evolution of the present disease, with support for interurrences from the Hand Surgery Outpatient Clinic of the Padre Anchieta Teaching Hospital. I have the obligation to declare all previous diseases, diabetes, hypertension, contagious diseases, hematological diseases, allergies, drug use, smoking, medications in use, psychiatric treatment, etc.; and to rigorously follow all the guidance, make return visits to the outpatient clinic, take medications in accordance with prescriptions and follow the rules of the hospital and the ABC School of Medicine. There will not be any financial compensation in relation to my participation in the surgery and in the study. I will have the right to the surgical treatments proposed, anesthesia and medical follow-up, in conformity with the fees paid for these procedures, which are expressed in the contract with the Brazilian National Health System (SUS), to which I have a right. If a health problem is detected prior to the start of the study, I would expect to be referred to SUS for treatment. I believe that I have received sufficient explanations regarding the information that I have received and read, relating to the treatment, risks and benefits to which I have a right, and all the obligations. The purposes of the treatment and the study are clear to me; it is also clear that this form does not encompass all the complications. I am aware of making my choice and decision, and I voluntarily agree to submit myself to the treatment proposed. Likewise, I acknowledge that, regardless of the efforts of the doctor and the team, there is no guarantee or absolute assurance that the results will bring a cure for my disease. The guidance regarding anesthesia, the blood bank, the intensive care unit and other factors remains under the responsibility of each hospital sector, and the surgical team does not hold these responsibilities. I declare for legal purposes that I have obtained information relating to voluntary free and informed consent in a clear, assured and appropriate manner. I have had the opportunity to ask all my questions and obtain all the responses. All the information will be confidential; I am free to withdraw from the study at any time without prejudicing my medical care; I may be excluded from the study; and the data will only be used for research.

Place: _____

Signature of patient or legal representative Date ___/___/___

Signature of witness Date ___/___/___

Investigator Date ___/___/___

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