CIRUGIA Y CIRUJANOS (ENG)

ORIGINAL ARTICLE

Parameterizing a tumor humeral prosthesis and development of a set

Parametrización de una prótesis tumoral de húmero y el desarrollo de un set

Benjamín Araujo-Monsalvo[1,2], Janeth Gómez-Procopio[3], Víctor M. Araujo-Monsalvo[4], Luis M. Hernández-Simón[1], Víctor M. Domínguez-Hernández[4,5], Genaro Rico-Martínez[6], Luis M. Linares-González[6], Elisa Martínez-Coria[7] and José L. Nava-Sánchez[8]*

[1]Department of Systems Engineering, Postgraduate Education and Research Section, Higher School of Mechanical and Electrical Engineering, Instituto Politécnico Nacional, Mexico City; [2]Department of Biomedical and Mechatronics Engineering, Universidad del Valle de México, Campus Lomas Verdes, Naucalpan, State of Mexico; [3]Directorate of Academic Evaluation, Universidad Tecnológica de México, Mexico City; [4]Biomechanics Laboratory, Instituto Nacional de Rehabilitación "Luis Guillermo Ibarra Ibarra", Mexico City; [5]School of Engineering and Sciences, Tecnologico de Monterrey, Campus CCM, Mexico City; [6]Department of Bone Tumors, Instituto Nacional de Rehabilitación "Luis Guillermo Ibarra Ibarra", Mexico City; [7]Computed Tomography Department, Instituto Nacional de Rehabilitación "Luis Guillermo Ibarra Ibarra", Mexico City; [8]Tecnológico de Estudios Superiores de Chalco, Chalco, State of Mexico. Mexico

Abstract

Background: *The reconstruction of the proximal humerus is possible from the resection of the tumor and the placement of a prosthesis. In some cases, they do not meet the anthropometric aspects of the patients.* **Objective:** *To determine the parameters to size the components of a humeral prosthesis and the development of a set, using design software.* **Method:** *Forty patients were selected for prostheses, radiographs and CT scans were analyzed and statistical tests were applied to the measurements.* **Results:** *The length of the tumors was 8-20 cm. The minimum length of the humerus was 28 cm and 33 cm the maximum. Correlation was observed between the humerus and the tumor and the height of the patient with p = 0.93088 and p = 0.904564, respectively; humerus diameter, p = 0.2345. The set will include three components, diameter 6-10 mm, and length of 24, 26 and 28 cm. Three modular spacers with lengths of 6, 8.5 and 13 cm. Crowns 6.5 and 8.5 cm long, 1.3 cm in diameter and 5 mm nut.* **Conclusion:** *With the development of the set, poorly calculated resections and adaptation to any humerus size can be resolved.*

Keywords: *Sizing. Humerus. Parameters. Tumor prosthesis. Tumor resection. Set.*

Resumen

Antecedentes: *La reconstrucción del húmero proximal es posible a partir de la resección del tumor y la colocación de una prótesis. En algunos casos, las prótesis no cumplen con los aspectos antropométricos de los pacientes.* **Objetivo:** *Determinar los parámetros para dimensionar los componentes de una prótesis de húmero y el desarrollo de un set, mediante software de diseño*. **Método:** *Se seleccionaron 40 pacientes para prótesis, se analizaron radiografías y tomografías computarizadas, y se aplicaron pruebas estadísticas a las mediciones.* **Resultados:** *La longitud de los tumores fue de 8-20 cm. La longitud mínima del húmero fue de 28 cm y la máxima fue de 33 cm. Se observó correlación entre el húmero y el tumor y la altura del paciente, con p = 0.93088 y p = 0.904564, respectivamente; para el diámetro del húmero, p = 0.2345. El set incluye tres*

***Correspondence:**
Bejamín Araujo-Monsalvo
Calz.Tcomán, 600
Col. San José Ticomán, Del. Gustavo A. Madero
C.P. 07340, Ciudad de México, México
E-mail: araumonb@yahoo.com.mx

Date of reception: 11-11-2019
Date of acceptance: 04-05-2020
DOI: 10.24875/CIRUE.M20000217

Cir Cir (Eng). 2021;89(1):33-38
Contents available at PubMed
www.cirugiaycirujanos.com

componentes, con diámetro de 6-10 mm y longitud de 24, 26 y 28 cm; tres espaciadores modulares con longitudes de 6, 8,5 y 13 cm; coronas de 6,5 y 8,5 cm de largo, 1,3 cm de diámetro y tuerca de 5 mm. **Conclusión:** *Con el desarrollo del set se pueden resolver resecciones mal calculadas y la adaptación a cualquier tamaño de húmero.*

Palabras clave: *Dimensionamiento. Húmero. Parámetros. Prótesis tumoral. Resección tumoral. Set.*

Introduction

The humerus is the third most common site of bone tumors presentation, after the knee and hip. In the classification of musculoskeletal system neoplasms, humerus proximal end ranks third in neoplastic involvement, whether these neoplasms are benign, malignant or metastatic[1,2].

Given that this type of lesions still entail a high risk of complications inherent to the surgical procedure, different techniques have been resorted to, such as arthrodesis, use of endoprostheses, allografts or vascularized grafts of the fibula or clavicle, although none of them has become the standard treatment for this pathology[3,4].

The most important aspect of limb-salvage surgery using an endoprosthesis is to preserve elbow and hand functionality by providing optimal joint function[5].

The endoprostheses that exist in the market cover tumor dimensions of 3-5 cm, with excellent results at the time they are used. Currently, tumors with dimensions of 8-20 cm have been found, which cannot be covered by endoprostheses[6].

For being able to cover these tumor dimensions, Dr. Genaro Rico Martínez designed an endoprosthesis at Luis Guillermo Ibarra Ibarra National Institute of Rehabilitation[7-9].

Currently, patient diagnosis is made by X-ray, and measurement, by the surgeon, followed by prosthesis manufacture by a supplier. Given that there is only one endoprosthetic size available, at the time of surgery (treatment), anatomical differences are observed (endoprosthesis vs. patient), which cause endoprosthesis malpositioning and defective fixation, which leads to surgery rescheduling and manufacture of a new endoprosthesis.

Computed tomography (CT) and its three-dimensional reconstruction provide a more anatomically correct image and both external and internal visualization of the humerus, which allows the staging and evolutionary control of tumors, as well as clarifying X-ray diagnostic doubts and complex fractures[10].

A humeral tumor endoprosthesis, RIMAG[MR] (Osteo Orthopedic Implants, SA de CV, Puebla, Pue., Mexico), was designed at the "Luis Guillermo Ibarra Ibarra" National Institute of Rehabilitation. The endoprosthesis consists of a cylindrical stem with a curved end, an expandable modular spacer and a distal crown to provide stability and better posterior fixation with bone growth through it, at the level of osteotomy[11].

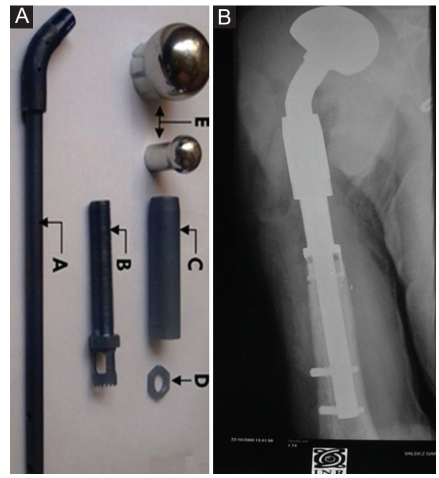

Figure 1. *Components of the non-conventional shoulder tumor endoprosthesis and its placement.* **A:** *Stem.* **B:** *Threaded crown.* **C:** *Sleeve or modular spacer.* **D:** *Nut.* **E:** *Humeral head. Design by Dr. Genaro Rico Martínez, Instituto Nacional de Rehabilitación "Luis Guillermo Ibarra Ibarra".*

The material used in the prosthesis is Ti-6Al-4V, and on the head of the prosthesis, it is combined with high-density polyethylene. Approximate weight of the humeral prosthesis ranges from 350 to 550 g (Fig. 1).

The non-conventional RIMAG[MR] proximal humeral prosthesis system has a 23-26-cm fixed body as the main stem, with holes in the lateral face of the proximal curve for musculotendinous insertion.

The distal portion of the stem has two bolt-locking holes of 3.175 mm (1/8 in) in separation diameter, a modular spacer expandable by adjustment screw (up to 5 cm) with a crown to encircle the bone at the osteotomy site and with windows to provide more stability between the bone-implant binomial, where subsequent bone growth is expected through the window.

The purpose of this article is to determine the parameters of each one of the components of the described prosthesis, with a standard design being

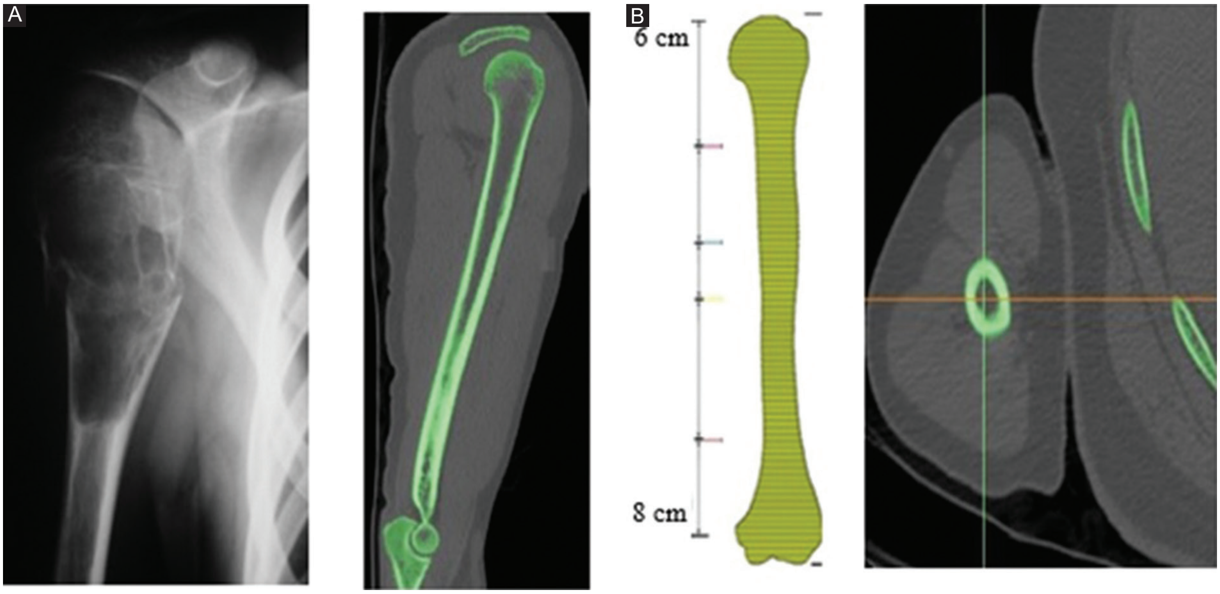

Figure 2. A: *X-ray of humerus with tumor, with existing tumors dimensions being obtained at Instituto Nacional de Rehabilitación "Luis Guillermo Ibarra Ibarra".* **B:** *Tumor-free humerus CT scan of a patient who is candidate for a prosthesis.*

established, and a set will be developed that can be adapted to any humeral size, reconstruct up to humeral distal third and allow miscalculated resections to be resolved.

Method

A study was carried out in which patients of any age and gender, with complete PACS-INR (Luis Guillermo Ibarra Ibarra National Institute of Rehabilitation Picture and Communication System) file and signed informed consent, with aggressive benign tumors, malignant tumors, tumors of medullary origin and metastatic, aggressive benign tumors at Enneking stage 3, intracompartmental (grades IIA and IIB) and metastatic tumors (grade III), were included. From the study, 40 patients who were candidates for prosthesis were selected.

Patients had conventional X-rays of the humerus on anteroposterior and lateral position for the measurement of tumor length and diameter by the doctor, and CT scan for healthy humerus length, as well as medullary canal measurement (Fig. 2A and B).

Malawer surgical classification was used to identify type I intra-articular lesions. Enneking staging system was used and the Musculoskeletal Tumor Society results were applied for endoprosthesis positioning and soft tissue reconstruction after tumor en block resection.

CT scans were performed with a 64-slice GE Light Speed Multislice equipment (GE Light Speed, General Electric Company, Fairfield, CT, USA), blue area with workstation and image viewers.

Images were obtained in DICOM (Digital Imaging and Communication in Medicine) format from CT scans and processed with the Mimics Innovation Suite software, version 17 (Materialise Inc. Leuven, Belgium).

Using the software, measurement of the humerus was carried out for classification (small, medium, large) and to find out its dimensions (length and diameter). In addition, CT scans spinal canal was cleaned for a more accurate measurement of the CT slices diameter.

CT measurement parameters were obtained at 8 cm from the distal area and 6 cm from the proximal area, every 10 slices from them onwards. Polylines were designed and curves were created (Fig. 3A and B).

The CT sections that were obtained were processed on 3-matic (Materialise Inc., Leuven, Belgium) for diameter measurement and data collection. From the images obtained by the software, three measurements of the medullary canal were made: internal (stem diameters), internal (crown diameters) and external (implant diameter), in addition to humeral length (Fig. 4).

Statistical analyses were carried out with Statgraphics Centurion software, version 16.1.11 (Statpoint

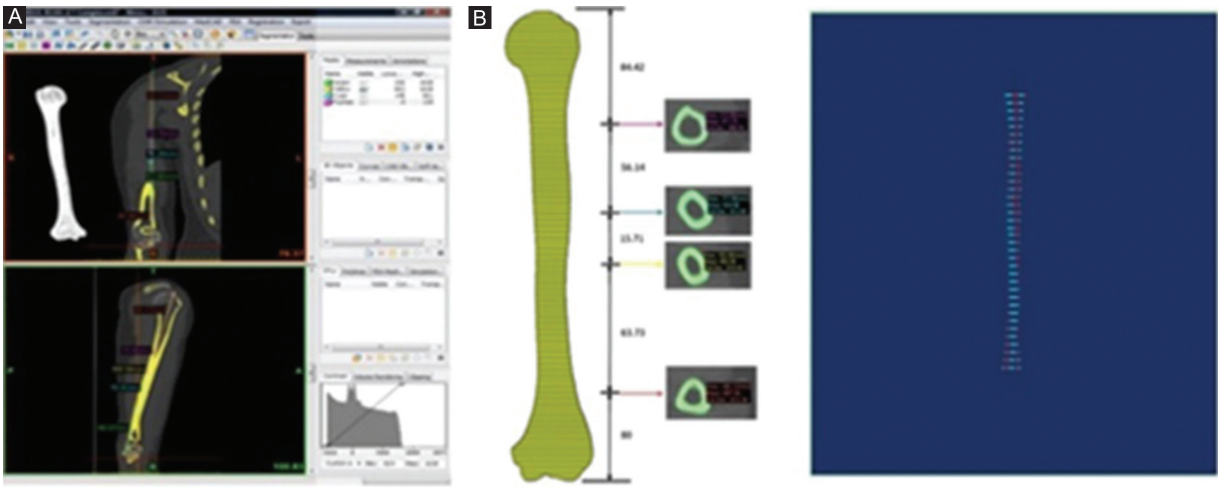

Figure 3. A: *CT sections obtained with the software.* **B:** *Creation of polylines as a guide for CT scans cleaning and measurement. Software: Mimics, 3-matic (Materialise Inc., Leuven, Belgium).*

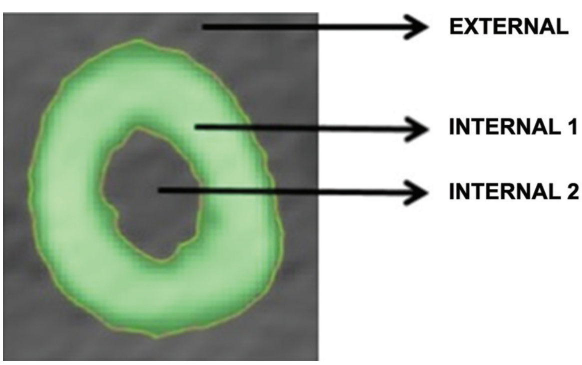

Figure 4. *Humeral CT sections measurement (length and diameter), cleaning of CT medullary canal for its measurement (8 cm distal, 6 cm proximal). Creation of polylines, curves and measurement. Software: Mimics, 3-matic (Materialise Inc., Leuven, Belgium).*

Technologies, Inc., Warrenton, Virginia, USA); Kolmogorov-Smirnov test was applied to determine data distribution.

The correlation between variables was evaluated using a linear regression analysis test and an ANOVA test, as well multiple range analysis (95% Least Significant Difference [LSD]), to obtain the dimensions of each component of the prosthesis and the number of pieces that make up the set. All this with a 95% confidence level and an error of 5%.

Results

Tumor lengths (8-20 cm) were obtained from the radiological studies. According to CT scans, the shortest humerus was 28 cm and the longest was 33 cm. Data distribution was obtained from statistical analysis, as well as the correlation coefficient of data between humeral length, patient height and tumor length (Table 1).

The dimensions of each component (length and diameter), as well as the number of pieces that make up the set, are shown in table 2.

The set will have three stems, with a diameter of 6-10 mm and length of 24 cm for small humeri, 26 cm for medium humeri and 28 cm for large humeri; three modular spacers with lengths of 6 cm for small humeri, 8.5 cm for medium humeri and 13 cm for large humeri; and two crowns, with thread of 6.5 and 8.5 cm in length, and diameter of the crowns of 1.3 cm. A 5-mm nut will also be included. The humeral endoprosthesis set will consist of 14 pieces with different dimensions (Fig. 5). The prosthesis is to be positioned 4 cm past the olecranon fossa at humeral distal portion (elbow).

Discussion

Proximal humerus is a common site for malignant bone tumors. Before the 1970s, malignant bone tumors, particularly osteosarcoma, were systematically treated with humeral disarticulation, which resulted in complete loss of upper extremity functions. With the advances in neoadjuvant chemotherapy, imaging, diagnostic pathology techniques and prosthetic joint technology, tumor resection and shoulder joint prosthetic replacement have become optimal treatments for early and medium primary malignant

Table 1. Data distribution and study variables correlation coefficient

Variable	Normality*	Variables		Results†
		Dependent	Independent	CC
PH	0.9285	HL	PH	0.93088
HL	0.9036	HL	TL	0.904564
SD	0.8472	HL	D	0.23457
ED	0.8591			
SD sh, mh, lh	0.8903, 0.9015, 0.9174			
ED sh, mh, lh	0.9056, 0.9287, 0.9483			

CC: correlation coefficient; D: diameter; ED: external diameter; SD: stem diameter; PH: patient height; sh: small humerus; mh: medium humerus; lh: large humerus; HL: humeral length; TL: tumor length.
*Kolmogorov-Smirnov test.
†Linear regression analysis.

Table 2. Dimensions and number of pieces. Stem, threaded crown, modular spacer

Level (mm)	Number	Average length (cm)	Homogeneous groups	Contrast
6 (1)	2	24, 26	X	6 – (7, 8, 9, 10)
7 (1)	3	24, 26, 28	X	7 – (8, 9, 10)
8 (1)	2	26, 28	X	8 - 9
6.5 (2)	2	1.3	X	6.5 – (8, 9, 11, 13)
8.5 (2)	2	1.3	XX	8.5 – (9, 11, 13)
------ (3)	2	8	X	8 – (9, 11, 13)
------ (3)	3	9	X	9 – (11)
------ (3)	1	7	X	7 – (8, 9, 11, 13)

1: stem; 2: threaded crown; 3: modular spacer.
Test: 95% LSD.

bone tumors, aggressive giant cell tumors and individual metastatic tumors[12].

All reconstruction procedures are debatable, but the development of a prosthesis with an adjustable modular spacer is carried out to answer the need for a system that adapts to the replacement of a particular segment to be created, with bone-implant stability after humeral tumor resection being conferred and limitation by resection with cemented systems being avoided, which, by requiring subsequent examination, may be susceptible to failure in the future due to an imbalance between length and stability of the prosthesis.

The shoulder joint replacement prosthesis (endoprosthesis) includes the proximal humeral prosthesis with different components and various dimensions, which altogether comprises the entire shoulder joint. As for survival of this implant, approximately 70% of patients have had good results or, in other words, the type of resection and reconstruction of soft tissues is probably more important than the type of implant[13,14].

The RIMAG^{MR} non-conventional proximal humeral prosthesis system has a 23-26-cm fixed body as the main stem, with holes on the outer face of the proximal curve for musculotendinous insertion.

The stem distal region has two 3.175-mm (1/8 inch)-diameter locking-bolt holes with 25.4-mm separation, a modular spacer expandable by adjustment screw to up to 5 cm, with a crown to encircle the bone at the osteotomy site with windows to confer more stability to the bone-implant binomial, where subsequent bone growth is expected to occur through the window. In cases in which it is indispensable,

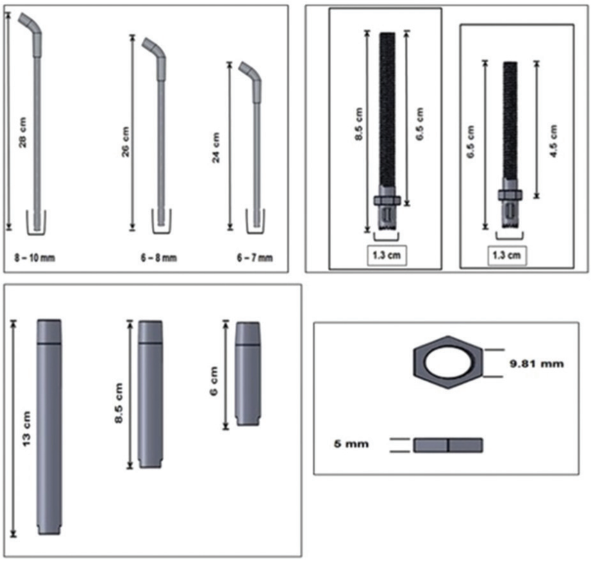

Figure 5. *Prosthesis components dimensions, and composition of the set.*

cement can also be used (so far it has not been used in our series).

The performance of X-rays together with CT scans for non-conventional humeral tumor prosthesis parameterization and sizing of each one of its components for the development of a set emerge as an option for the treatment of tumors in patients admitted to the Luis Guillermo Ibarra Ibarra National Institute of Rehabilitation[15,16].

The statistical tests carried out for the development of the set have the purpose for the specialist to have a range of prostheses with different dimensions for the making of decisions that have a positive impact on patients. This sets the standard for, in future works, a redesign of the prosthesis to be carried out, which should include a conical-shaped stem, in addition to the redesign of the crown with thread.

Acknowledgements

The authors thank the work carried out by technician Martín Luna Méndez, from the computed tomography department at Instituto Nacional de Rehabilitación Luis Guillermo Ibarra Ibarra.

Funding

The authors declare that there were no funding sources.

Conflicts of interest

The authors declare that they have no conflicts of interest relevant to this manuscript.

Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this research.

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors have obtained informed consent from the patients and/or subjects referred to in the article. This document is in the possession of the corresponding author.

References

1. Cortés R, Lezama P, Rubio JA, Domínguez J, Gámiz CA, Pablo Adrián Carrillo PA. Osteosarcoma. Cirugía de preservación de extremidad torácica con prótesis tumoral no convencional RC-8. Reporte de un caso. Arch Inv Mat Inf. 2012;4:43-7.
2. Daigeler A, Lehnhardt M, Dhadra A, Hauser J, Steinstraesser L, Langer S, et al. Proximal major limb amputations — a retrospective analysis of 45 oncological cases. World J Surg Oncol. 2009;7:15.
3. El-Sherbiny M. Reconstruction of the proximal humerus after wide resection of tumors: comparison of three reconstructive options. J Egypt Nat Cancer Inst. 2008;20:369-78.
4. Irlenbusch U, Gebhardt K, Rott O, Werner A. [Reconstruction of the rotational centre of the humeral head depending on the prosthetic design.] Z Orthop Unfall. 2008;146:211-7.
5. Kiliç M, End S, Irlenbusch U. Replication of the rotational center of the humeral head with second-generation stemmed prostheses. Acta Orthop Traumatol Turc. 2011;45:71-8.
6. Kiss J, Sztrinkai G, Antal I, Szendro M. Functional results and quality of life after shoulder girdle resection in musculoskeletal tumors. J Shoulder Elbow Surg. 2007;16:273-9.
7. Kitagawa Y, Thai DM, Choong PFM. Reconstructions of the shoulder following tumour resection. J Orthop Surg. 2007;15:201-6.
8. Linares LM, Rico G, Domínguez VM, Araujo V, Delgado EA, León SR. Tratamiento y reconstrucción en tumores óseos del húmero con prótesis no convencional tipo RIMAG. Acta Ortopédica Mexicana. 2014;28:3-11.
9. Masamed R, Learch TJ, Menendez LR. Bloc shoulder resection with total shoulder prosthetic replacement: indications and imaging findings. AJR. 2008;191:482-9.
10. Pearl ML, Kurutz S, Postachini R. Geometric variables in anatomic replacement of the proximal humerus: how much prosthetic geometry is necessary? J Shoulder Elbow Surg. 2009;18:366-70.
11. Rödl RW, Gosheger G, Gebert C, Lindner N, Ozaki T, Winkelmann W. Reconstruction of the proximal humerus after wide resection of tumours. J Bone Joint Surg Br. 2002;84:1004-8.
12. Scotti C, Camnasio F, Peretti GM, Fontana F, Fraschini G. Modular prostheses in the treatment of proximal humerus metastases: review of 40 cases. J Orthopaed Traumatol. 2008;9:5-10.
13. Shi SF, Dong Y, Zhang CL, Bao K, Ma XJ. Prosthetic replacement of the proximal humerus after the resection of bone tumors. Chin J Cancer. 2010;29:121-4.
14. Teunis T, Nota S, Hornicek FJ, Schwab JH, Lozano S. Outcome after reconstruction of the proximal humerus for tumor resection: a systematic review. Clin Orthop Relat Res. 2014;472:2245-53.
15. Van de Sande MAJ, Sander DPD, Taminiau AHM. Proximal humerus reconstruction after tumour resection: biological versus endoprosthetic reconstruction. Int Orthop (SICOT). 2011;35:1375-80.
16. Zeballos J. Fibrosarcoma proximal de húmero, salvataje de miembro, reconstrucción con endoprótesis no convencional Fabroni. Revista Médic. 2000;11(17).