Functional Outcome Following Reconstruction with the Thai Modular Proximal Humeral Endoprosthesis

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Background: *Proximal humeral replacement with endoprosthesis is a well-accepted procedure for treatment of malignant or aggressive bone tumors. In Thailand, the Thai modular proximal humeral (TMPH) endoprosthesis has been manufactured and little is known about the results following its implantation.*

Objective: *To report the short-term functional and oncologic outcomes following implantation of the TMPH endoprosthesis system and its complications.*

Material and Method: *We prospectively reviewed 10 consecutive patients treated with wide proximal humeral resection and implantation with the TMPH endoprosthesis in our three centers: six patients from Lerdsin General Hospital, three patients from Maharaj Nakorn Chiang Mai Hospital, and one patient from King Chulalongkorn Memorial Hospital. The mean age was 52 years old, range (17 to 78). The mean resection length was 13 cm, range (9 to 17). The mean follow-up time was 9.7 months, range (0.6 to 19.5); the mean follow-up time for surviving patients was 14.5 months, range (8.7 to 19.5). The musculoskeletal tumor society (MSTS) score, radiographs, and complications were recorded.*

Results: *Three patients died of disease at 2.6 months, range (2.1 to 4.1) and one patient died of his underlying disease at 0.6 months after the surgery. There were no infection, proximal migration, recurrence, or implant-related complication. The mean MSTS score was 21, range (18 to 25). The mean active shoulder abduction was 42°, range (20° to 80°) and flexion was 45°, range (25° to 85°). The mean passive shoulder abduction was 104°, range (45° to 170°) and flexion was 102°, range (45° to 170.5°).*

Conclusion: *Although longer follow-up is required, our satisfactory result showed that reconstruction using the TMPH endoprosthesis is a practicable option with good functional result and low complication rate.*

Keywords: *Proximal humerus, Endoprosthesis, Outcome, Complications*

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Primary and metastatic bone tumors involving the proximal humerus are common[1,2]. Although many options of treatment have been described, it is accepted that wide resection of the proximal humerus is required for bone sarcomas as well as metastatic disease and aggressive benign bone tumors with marked bony destruction[1,3]. Many options for reconstruct the bone defect after resection included endoprosthesis[4-13], allograft or allograft prosthesis composite[9,12,13], recycling autograft or recycling autograft-prosthetic composite[6,8], and claviculo pro humeri[12]. Endoprosthetic reconstruction has advantages regarding relative shorter operative time, ease of the procedure, wide spread availability, and low complication rate. Good results from studies using different types of implants have been reported[1,4,5,7,9,12]. In Thailand, we manufactured the Thai Modular Proximal Humeral (TMPH) endoprosthesis but little is known about the results following its implantation. The objective of the present study is to report the short-term functional and oncologic outcomes following implantation of the TMPH endoprosthesis system and its complications.

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Material and Method

Between March 2015 and March 2016, 10 patients underwent proximal humeral replacement using TMPH endoprosthesis in three institutions where the study were approved by their independent ethics committee; six patients were treated at Lerdsin General Hospital, three patients were treated at Maharaj Nakorn

Chiang Mai Hospital, and one patient was treated at King Chulalongkorn Memorial Hospital. Inclusion criteria were tumor with destruction of the proximal humerus and treatment using a TMPH endoprosthesis.

Seven men and three women, with a mean age of 52 years (range 17 to 78) were included in this study. The histological diagnosis was bone metastasis in six (two from carcinoma of lung and one each patient from sarcomatoid carcinoma of the kidney, renal cell carcinoma, prostate carcinoma, and carcinoma of unknown origin), primary bone sarcoma in three (two osteosarcomas and one Ewing sarcoma), and benign giant cell tumor in one patient. Most patients had metastatic disease prior to treatment (n = 8). All patients were treated with wide resection of the proximal humerus and/or appropriate chemotherapy and/or radiation therapy according to specific type of tumor and the corresponding protocol. Preoperative radiographs in two planes (antero-posterior and lateral) and magnetic resonance imaging (MRI) were obtained in all patients.

We prospectively collected data including patient characteristics, age at diagnosis, diagnosis, duration of follow-up, methods of shoulder capsule reconstruction, humeral resection length measured from the most superior part of the humerus, post-operative complications, and oncologic outcome including patient status, local recurrence, and metastasis. Functional outcome was assessed at the time of final follow-up using the Musculoskeletal Tumor Society (MSTS) score for the upper extremity[14]. The MSTS score is divided into six subgroups: pain, emotional acceptance, function, hand position, manual dexterity, and lifting ability. For each subgroup, a minimum of 0 points and a maximum of 5 points can be reached. A score of 24 or more represents an excellent outcome, a score between 18 and 24 represents a good outcome, and a score less than 18 represents poor outcome. The active and passive range of shoulder motion in degrees was recorded for shoulder abduction, forward flexion, external rotation, and internal rotation. Radiographs in two planes were reviewed at every follow-up for evidence of proximal migration, subluxation or dislocation, aseptic loosening, and hardware failure. Proximal migration was defined as an acromio-humeral interval of less than 5 mm measured on antero-posterior shoulder radiograph.

Operative techniques and implant details

An anterior deltopectoral approach was utilized for all cases. Intraarticular resection was used in nine patients and extraarticular resection at the glenoid neck was performed in one patient due to tumor extension. Rotator cuffs tendons were released from the humeral head and were able to circumferentially suture to the prosthetic holes in five patients by using 5 mm Mersilene tape (Ethicon, Inc., Somerville, NJ). For the remaining five patients whom part of the rotator cuffs were resected with the tumor, vascular graft was used to reconstruct. The axillary nerve was identified in all patients, but had to be transected because of tumor involvement in one patient. The humeral osteotomy was performed by oscillating saw according to the intramedullary extension of the tumor on MRIs. The mean humeral resection length was 13 cm (range 9 to 17). The components of the TMPH endoprosthesis were chosen depending on the resection length. All humeral heads were unipolar. The fixation was achieved by an intramedullary stem with cemented technique in all cases.

The TMPH endoprosthesis was designed and made by the collaboration of the Orthopedic Oncology Lerdsin Hospital (OOLH), National Metal and Material Technology (MTEC), and the Thai Musculoskeletal Tumor Society (TMSTS). The size and diameter of the prosthesis were designed based on parameter measured from 76 Thai cadaveric humeri[15]. The TMPH endoprosthesis consists of head, neck, body, and stem connected together using taper method. The head is made of CoCrMo alloy and 40 mm in diameter with holes to allow suturing of rotator cuffs or muscles and rough surface at the lateral part of the head to allow soft-tissue ongrowth. The neck and the body are made of titanium alloy (TiAl6V4). The stem is made of CoCrMo alloy with rough surface at its body using sand-blasted method to allow soft-tissue ongrowth.

All patients used the same postoperative functional protocol. The patients were kept in arm sling and were allowed for pendulum exercise for the first two weeks. After that, progressive passive ranges of motion to achieved full motion and active ranges of motion of the shoulder as tolerated were encouraged. Descriptive statistics of patients are presented in Table 1.

Results

Three patients died of disease at 2.6 months, range (2.1 to 4.1) and one patient died of his underlying disease of chronic renal failure at 0.6 months after the surgery. The mean follow-up was 9.7 months (range 0.6 to 19.5) for all patients and 14.5 months (range 8.7 to 19.5) for seven surviving patients. Functional outcome was analyzed according to the functional

rating system of the MSTS score for the upper extremity[14] and the mean MSTS score was 21 points (range 18 to 25), which were equal to 70% in percentage scale. The mean MSTS pain score was 4.4/5 points. The details of each category for MSTS rating system were summarized (Table 2). Excellent MSTS results were obtained in three patients who had relatively lower mean age of 31 years old (range 17 to 46) when compared to six patients with good MSTS score with mean age of 62 years (range 31 to 78).

Range of motion of the shoulder was recorded in all patients except for one patient who died at early postoperative period. The mean active range of shoulder motions on abduction, forward flexion and internal rotation were largely limited at 42° (range 20° to 80°, SD 21°), 45° (range 25° to 85°, SD 20°), and 19° (range 0° to 40°, SD 11°), respectively (Table 3). The mean passive range of shoulder motion on abduction, forward flexion, and internal rotation were 104° (range 45° to 170°, SD 44°), 102° (range 45° to

Table 1. Demographic data of patients

Patient No.	Sex/age	Diagnosis	Resection length (cm)	MSTS score	Follow-up time (months)	Patient status
1	M/63	Metastasis (prostate)	14	NA	0.6	Died of chronic renal failure
2	M/53	Osteosarcoma	12	22	2.1	DOD
3	M/68	Metastasis (lung)	13	21	3.1	DOD
4	M/31	Metastasis (lung)	13	19	4.1	DOD
5	F/78	Metastasis (sarcomatoid carcinoma of kidney)	17	18	8.7	AWD
6	M/71	Metastasis (unknown origin)	9	18	11.1	AWD
7	M/68	Metastasis (renal cell)	15	21	15.4	AWD
8	F/46	Giant cell tumor	9	24	15.8	CDF
9	F/28	Ewing sarcoma	13	24	16.7	CDF
10	M/17	Osteosaroma	17	25	19.5	NED

F = female; M = male; MSTS = musculoskeletal tumor society; NA = not applicable; AWD = alive with disease; CDF = continuous disease free; DOD = died of disease; NED = no evidence of disease

Table 2. Number of patients classified by categories according to the functional rating system of the musculoskeletal tumor society (MSTS) for the upper extremity

Rating	Pain	Emotional acceptance	Function	Positioning of the hand	Manual dexterity	Lifting ability
5	None (4)	Enthused (2)	No restriction	Unlimited	No limitation (3)	Normal load
4	Intermediate (5)	Intermediate (4)	Intermediate	Intermediate (4)	Intermediate (4)	Intermediate
3	Modest	Satisfied (3)	Recreational restrictions (6)	Not above shoulder (5)	Loss of fine movements (2)	Limited (7)
2	Intermediate	Intermediate	Intermediate (3)	Intermediate	Intermediate	Intermediate (2)
1	Moderate	Accepts	Partial occupational restriction	Not above waist	Cannot pinch	Helping only
0	Severe	Dislike	Total occupational restriction	Flail	Cannot grasp	Cannot help

Table 3. Active and passive range of shoulder motion in patients following endoprosthesis reconstruction

Patient No.	Resection type	Shoulder reconstruction type	Range of shoulder motion (degree)							
			Active abduction	Passive abduction	Active flexion	Passive flexion	Active external rotation	Passive external rotation	Active internal rotation	Passive internal rotation
1.	Intraarticular	Vascular graft	NA	NA	NA	NA	NA	NA	NA	NA
2.	Intraarticular	Vascular graft	30	45	35	50	25	35	85	85
3.	Intraarticular	Vascular graft	20	45	25	45	10	30	80	80
4.	Intraarticular	Suture to rotator cuff	40	100	40	100	10	40	80	80
5.	Intraarticular	Suture to rotator cuff	30	90	35	90	20	35	80	80
6.	Intraarticular	Vascular graft	20	90	25	90	10	35	80	80
7.	Intraarticular	Suture to rotator cuff	30	85	30	60	20	35	80	85
8.	Intraarticular	Suture to rotator cuff	65	170	70	170	25	50	85	85
9.	Extraarticular	Suture to rotator cuff	65	140	60	140	20	40	85	85
10.	Intraarticular	Vascular graft	80	170	85	170	40	50	85	85

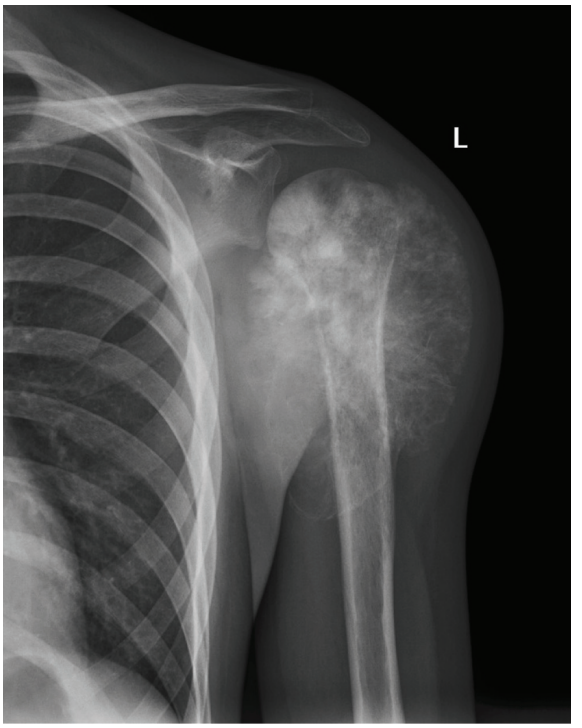

Fig. 1 Antero-posterior view of plain radiograph showed osteosarcoma involving the left proximal humerus.

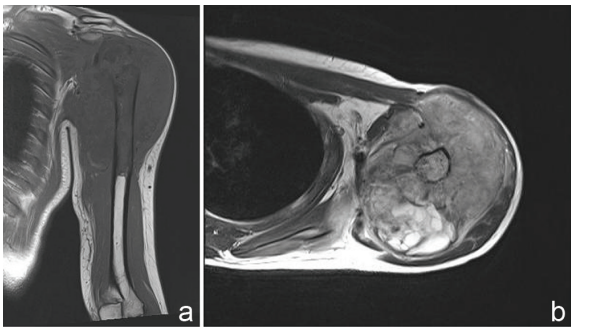

Fig. 2 Coronal T1 (a) and axial T2 (b) weighted magnetic resonance images showed soft-tissue extension around the proximal humerus of the same patient.

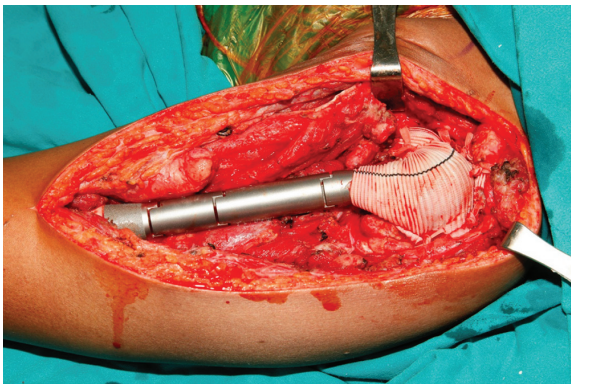

Fig. 3 The TMPH endoprosthesis after cementation to the humerus and shoulder capsule reconstruction by using vascular graft and Mersilene tape.

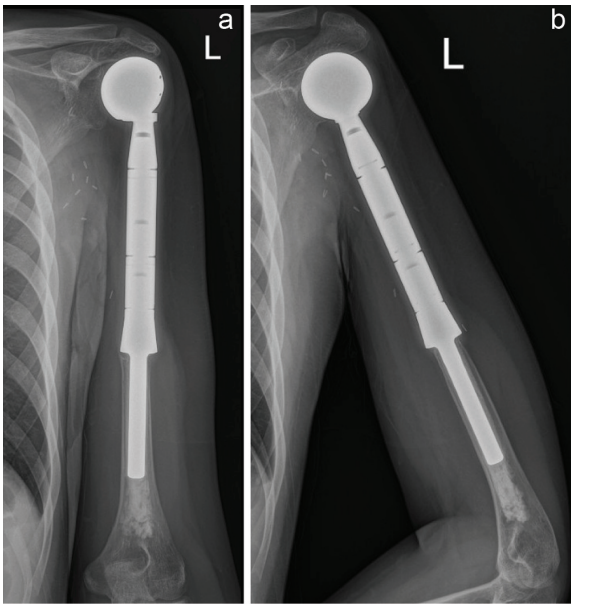

Fig. 4 Plain radiographs in antero-posterior (a) and lateral (b) view of the patient at 1.5 years after the surgery.

170°, SD 46°), and 39° (range 35° to 50°, SD 7°), respectively. The mean active and passive internal rotation were 82° (range 80° to 85°, SD 3°) and 83° (range 80° to 85°, SD 3°), respectively.

Immediately after the surgery, one patient developed neurapraxia of the radial and the median nerve, which was not recovered at 15 months after the surgery. There were no deep or superficial infection, proximal migration, subluxation, dislocation, or tumor recurrence found in the present series. No case of aseptic loosening found, nor did any implant fracture or other implant-related complication. Fig. 1 to 5 shows an example of patient with osteosarcoma underwent TMPH proximal humeral endoprosthesis.

Discussion

Proximal humeral resection and reconstruction is generally required when tumors destroy and create large bone defects of the proximal humerus. Many methods of reconstruction have been described such as biologic reconstructions that included osteoarticular allograft, allograft-prosthetic composite, recycling autograft, fibula autograft, and non-biologic reconstructions, which include endoprosthesis reconstruction[1,4-13]. No matter what type of reconstructions, the shoulder

Fig. 5 Clinical picture of patient at 1.5 years after proximal humeral replacement using TMPH endoprosthesis showed good passive abduction.

function after hemiarthroplasty-type reconstructions can be expected to be suboptimal with limited active range of motion[1]. However, endoprosthesis is one of the most durable reconstruction and provides stable platform for elbow and hand functions with low-reoperation rate and high patient satisfaction[1,4,5,7,9,12]. With the collaboration of the OOLH, the MTEC, and the TMSTS, we designed and made the TMPH endoprosthesis. Later, ten TMPH endoprostheses were implanted in patients at the three institutions.

The mean MSTS score of patients in our series, of 70% were comparable to 61% to 79% that was obtained from many previous studies after endoprosthesis reconstruction[4,12,13,16]. Due to various differences in tumor extension, abductor resection, remaining nerve function, and method of reconstruction of the shoulder capsule, the score could vary and be difficult to compare between series. According to the MSTS rating system, our results showed higher rating for relief of pain, emotional acceptance, and manual dexterity, and poorer results for function and lifting ability with the score of 70%. Our data were comparable to other series[1,4]. It is difficult to improve the shoulder function and lifting ability after the surgery using hemiarthroplasy type of proximal humeral replacement since many part of the shoulder muscles had to be resected or detached from their origins or insertions and the reattachment methods is still not effective enough for the patient to regain fully shoulder function. As far as we know, there is still no consensus on how to reconstruct the shoulder capsule to get more active abduction and flexion, which were approximately 35° to 45° in most series. Only the use of reversed shoulder prosthesis could predict a better functional result and active range of motion when the deltoid and the axillary nerve are kept intact[17,18].

The most common complication reported was proximal migration of the prosthesis, which was up to 42% from van de Sande et al[13]. Although it is generally well-tolerated, the real cause is still in controversy. Although, at least one study found association between failed re-fixation of muscles or rotator cuffs and proximal migration[1], others did not[11,13]. The reason that our results showed no proximal migration should be due to short follow-up time. The functional outcome details and complications for endoprosthetic reconstruction of the proximal humerus are summarized on Table 4.

Dislocation of the shoulder was found between 2% to 31% in previous studies[9,11-13] and it was caused by failed capsule reconstruction of the shoulder. Many methods have been described to prevent dislocation such as the use of vascular graft, mesh, Dacron tape, Mersilene tape (Ethicon, Inc., Somerville, NJ), Trevira tube (Implantcast GmbH, Buxtehude, Germany), Ethibond (Ethicon, Inc., Somerville, NJ), or secure fixation of the remaining rotator cuff to the holes at the prosthesis[1,7,9-11]. We used 5 mm Mersilene tape to secure the rotator cuffs and the remaining capsule to holes at the endoprosthesis, unless the cuffs or capsules were not enough or available. In those cases, we then augmented this gap with vascular graft. Full passive abduction, flexion, internal, and external rotation should be tested before closing the wound. If the suture was torn after testing, re-secured with non-absorbable suture should be added. In our series, we did not have any dislocation or subluxation.

Limitation

We acknowledge our small number of patients, multi-center treatment, and short follow-up time with no control group. These could explain why we did not experience other possible complications such as recurrence, proximal migration, and aseptic loosening of the stem, and removal of implants, which have been reported in literatures. However, it was our intention to preliminary reports our satisfactory short-term results using the TMPH prosthesis.

Table 4. Functional outcome details and complications for endoprosthetic reconstruction of the proximal humerus

Study/year	Proximal humeral endoprosthesis (n)	Cemented/ cementless (n)	Reconstruction length (cm)	Follow-up time (months)	Mean MSTS score (%)	Dislocation/ subluxation (n)	Infection (n)	Aseptic loosening (n)	Cranial migration (n)	Local recurrence (n)	Implant removal (n)	Limb survival
Fuhrmann, et al[4]/2000	22	0/22	NA	3.9 years (2.1 to 7.4)	60 (33 to 80)	0	1/22	0	11/22	0	NA	NA
Rödl, et al[12]/2002	19	NA	16 (8 to 28)	>2 years	79	NA	0	0	NA	2/19	2/19	NA
Kumar, et al[5]/2003	100	100/0	17 (6.8 to 26.8)	108 (24 to 242)	79 (24 to 30)	2/100	1/100	6/100	NA	15/100	15/100	93% at 10-year
Mayilvahanan, et al[7]/2006	57	57/0	10.8 (5 to 21)	5.5 years (2 to 14.5)	87	1/57	2/57	2/57	6/57	4/57	5/57	83% at 10-year
Cannon, et al[1]/2009	83	NA	14 (6 to 24)	30 (1 to 199)	63 (40 to 83)	5/83	2/83	0	22/83	0	2/83	NA
Potter, et al[9]/2009	16	16/0	13.8 (6 to 24)	113 (24 to 214)	69	5/16	0	0	NA	NA	0	100%
Raiss, et al[11]/2010	39	33/6	13 (7 to 19)	38 (3 to 138)	63 (23 to 90)	4/39	2/39	1/39	14/39	2/39	2/39	90% at 11.5-year
van de Sande, et al[13]/2011	14	4/10	9.6 (6.5 to 14)	10 years (1 to 25)	77	1/14	0	NA	6/14	3/14	0	100%
Liu, et al[6]/2014	25	NA	10.98±1.51	55.0±26.7	63.6±5.7	NA	0	9/25	NA	3/25	9/25	80.6% at 5-year
The present study	10	10/0	13 (9 to 17)	13 (7 to 18)	70 (60 to 83)	0	0	0	0	0	0	NA

Conclusion

In conclusion, reconstruction of the proximal humerus using the TMPH endoprosthesis seems to be a practicable option following resection. The complications are comparable to other series. Although more patients and longer follow-up time are needed, our results showed that with proper technique of resection, reconstruction, and implantation of the TMPH endoprosthesis, good functional outcomes could be expected.

What is already known on this topic?

The proximal humeral resection and reconstruction with endoprosthesis is a common procedure for treating malignant or benign aggressive bone tumor involving the proximal humerus. However, the endoprosthesis used were made from various countries. Results have been reported in literatures with moderate to good outcome. In the past, the endoprosthesis itself has never been made in Thailand.

What this study adds?

With collaboration from many institutions in Thailand, the TMPH endoprosthesis of the proximal humerus can be used successfully. This is the first article to report on the outcome of the TMPH endoprosthesis.

Potential conflicts of interest

None.

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ผลการใช้งานของข้อไหล่ หลังการผ่าตัดใส่โลหะเอนโดโพรสเทซิสทดแทนกระดูกต้นแขนส่วนบนชนิดที่ผลิตในประเทศไทย

ปิยะ เกียรติเสวี, ภาสนันต์ สุคันธนาค, พงศ์ศิริ เปียคง, ดำเนินสันต์ พฤกษากร, ธนินนิตย์ ลีรพันธ์, กฤษณ์ เจริญลาภ, กวิน การุณรัตนกุล, มารุต วงษ์คำช้าง, กฤษณ์ไกรพ์ สิทธิเสรีประทีป

ภูมิหลัง: *การผ่าตัดโดยการตัดกระดูกต้นแขนส่วนบนออก แล้วใส่แทนที่ด้วยโลหะเอนโดโพรสเทซิสในผู้ป่วยมะเร็งหรือเนื้องอกของกระดูกนั้น เป็นวิธีการรักษามาตรฐานและเป็นที่ยอมรับกันในปัจจุบัน แต่การผ่าตัดในประเทศไทยยังต้องอาศัยการนำโลหะเข้าจากต่างประเทศมาโดยตลอด คณะผู้นิพนธ์จึงได้ริเริ่มออกแบบและผลิตโลหะเอนโดโพรสเทซิสทดแทนกระดูกต้นแขนส่วนบนโดยใช้ชื่อว่า Thai modular proximal humeral (TMPH) endoprosthesis และเริ่มใช้จริงเป็นครั้งแรกในปี พ.ศ. 2557*

วัตถุประสงค์: *เพื่อศึกษาผลระยะสั้นหลังการผ่าตัดเปลี่ยนกระดูกต้นแขนส่วนบนด้วยโลหะเอนโดโพรสเทซิสชนิดที่ผลิตในประเทศไทย ในแง่มุมการใช้งานหัวไหล่หลังผ่า อัตราการรอดชีวิต อัตราการกลับเป็นซ้ำ และผลแทรกซ้อนหลังการผ่าตัด*

วัสดุและวิธีการ: *ในระหว่างเดือนมีนาคม พ.ศ. 2557 และ มีนาคม พ.ศ. 2558 ผู้ป่วย 10 ราย ได้รับการผ่าตัดเปลี่ยนกระดูกต้นแขนส่วนบนด้วยโลหะเอนโดโพรสเทซิสที่ผลิตในประเทศไทย (TMPH endoprosthesis) จากสถาบันร่วมวิจัย คือ โรงพยาบาลเลิดสิน จำนวน 6 ราย โรงพยาบาลมหาราชนครเชียงใหม่จำนวน 3 ราย และโรงพยาบาลจุฬาลงกรณ์จำนวน 1 ราย ผู้ป่วยทั้ง 10 ราย มีอายุเฉลี่ยที่ 52 ปี (17-78) ระยะตัดกระดูกต้นแขนส่วนบนเฉลี่ย 13 เซนติเมตร (9-17) ติดตามดูอาการเฉลี่ย 9.7 เดือน (0.6-19.5) ในผู้ป่วยทั้งหมด และ 14.5 เดือน (8.7-19.5) สำหรับผู้ป่วยที่รอดชีวิต เก็บบันทึกข้อมูลคะแนนการใช้งานแขนของผู้ป่วยหลังผ่าตัดโดย MSTS score ภาพถ่ายทางรังสี และเก็บบันทึกภาวะแทรกซ้อนต่าง ๆ หลังการผ่าตัด*

ผลการศึกษา: *ผู้ป่วย 3 ราย เสียชีวิตจากโรคมะเร็งที่ระยะเวลาเฉลี่ย 2.6 เดือน (2.1-4.1) หลังการผ่าตัด ผู้ป่วย 1 รายเสียชีวิตจากโรคประจำตัวของผู้ป่วยเองที่เวลา 0.6 เดือนหลังผ่าตัด จากการศึกษาไม่พบภาวะแทรกซ้อนหลังการผ่าตัด ทั้งเรื่องการติดเชื้อหลังผ่าตัด การเคลื่อนหลุดของเหล็กชนิดเอนโดโพรสเทซิส การกลับเป็นซ้ำของมะเร็ง และภาวะแทรกซ้อนจากโลหะชนิดนี้ คะแนนการใช้งานแขนของผู้ป่วยหลังผ่าชนิด MSTS score เฉลี่ยเท่ากับ 22 คะแนน (18-25) ผู้ป่วยสามารถกางไหล่ไปด้านข้างด้วยตัวเองได้เฉลี่ย 42 องศา (20°-80°) ถ้ามีผู้ช่วยกางไหล่สามารถกางได้ 104 องศา (45°-170°) ผู้ป่วยสามารถยกไหล่ไปด้านหน้าได้เองเฉลี่ย 45 องศา (25°-85°) ถ้ามีผู้ช่วยสามารถยกไหล่ไปด้านหน้าได้เฉลี่ย 102 องศา (45°-170.5°)*

สรุป: *ผลการรักษาหลังการผ่าตัดใส่โลหะเอนโดโพรสเทซิสทดแทนกระดูกต้นแขนส่วนบนชนิดที่ผลิตในประเทศไทยเป็นที่น่าพอใจอย่างยิ่ง เพราะหลังผ่าตัดผู้ป่วยสามารถใช้งานแขนได้ดี และมีภาวะแทรกซ้อนน้อยมากเมื่อเทียบกับการศึกษาอื่น อย่างไรก็ตามยังคงต้องมีการศึกษาติดตามผลในระยะยาวด้วยจำนวนผู้ป่วยที่มากกว่านี้ต่อไป*