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► To cite this version:

D. Witte, L. Bernd, J. Bruns, G. Gosheger, J. Harges, et al.. Limb-salvage reconstruction with MUTARS hemipelvic endoprosthesis: A prospective multicenter study. *EJSO - European Journal of Surgical Oncology*, 2009, 35 (12), pp.1318. 10.1016/j.ejso.2009.04.011 . hal-00556302

HAL Id: hal-00556302

<https://hal.science/hal-00556302>

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Accepted Manuscript

Title: Limb-salvage reconstruction with MUTARS[®] hemipelvic endoprosthesis: A prospective multicenter study

Authors: D. Witte, L. Bernd, J. Bruns, G. Gosheger, J. Harnes, E. Hartwig, B. Lehner, I. Melcher, W. Mutschler, M. Schulte, P-U Tunn, W. Wozniak, A. Zahlten-Hinguranage, F. Zeifang

PII: S0748-7983(09)00141-3

DOI: [10.1016/j.ejso.2009.04.011](https://doi.org/10.1016/j.ejso.2009.04.011)

Reference: YEJSO 2831

To appear in: *European Journal of Surgical Oncology*

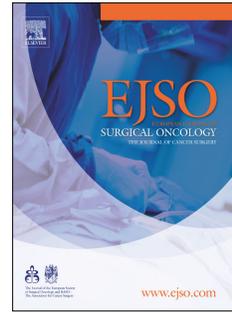
Received Date: 21 November 2008

Revised Date: 22 April 2009

Accepted Date: 24 April 2009

Please cite this article as: Witte D, Bernd L, Bruns J, Gosheger G, Harnes J, Hartwig E, Lehner B, Melcher I, Mutschler W, Schulte M, Tunn P-U, Wozniak W, Zahlten-Hinguranage A, Zeifang F. Limb-salvage reconstruction with MUTARS[®] hemipelvic endoprosthesis: A prospective multicenter study, *European Journal of Surgical Oncology* (2009), doi: [10.1016/j.ejso.2009.04.011](https://doi.org/10.1016/j.ejso.2009.04.011)

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Abstract

Background: Limb-sparing surgery with hemipelvic megaprosthesis replacement is often limited by the high rate of associated complications. The aim of this evaluation was to assess clinical and oncological findings with respect to type, treatment and outcome of post-operative complications.

Methods: First results of 40 patients treated with individual MUTARS® hemipelvic endoprotheses were evaluated in a prospective multicenter study.

Results: The mean follow-up period of the 27 male and 13 female patients was 24 months (range 1-61). The diagnosis was, in 29 cases, a primary bone or soft tissue sarcoma, in 11 patients, a metastasis. Clinical evaluation showed a mean Enneking score of 50 % (range 10-70%). The oncological outcome revealed 25 patients (62.5%) alive with no evidence of disease. Seventeen of them had a primary tumour, eight a metastatic malignancy. Seven patients (17.5%) had died of their disease and eight (20%) were still alive but had developed a metastases and/or had had a recurrence of the primary tumour. The one- and two-year overall survival rate of the patients was 89% (± 0.10) and 81% (± 0.19), respectively. Post-operative complications occurred in 75% of the patients, predominantly wound-related disorders. The rate of implant revision was 22.5% with three septic and six aseptic cases of implant loosening. The estimated three-year-survival rate of the implant was 61.4% [CI95%: 0.36;0.87].

Conclusions: Periacetabular endoprosthesis replacement showed an acceptable functional and oncological outcome but had a high complication rate owing, predominantly, to infection. The indication for hemipelvic prosthesis in patients with a metastatic disease must be considered seriously.

Key words: pelvic tumour, limb-salvage, custom-made megaprosthesis, hemipelvic endoprosthesis, postoperative complications, pelvic reconstruction

Introduction

The reconstruction of pelvic bone defects in orthopaedic oncology remains a challenge. Limb-salvage treatment by means of endoprosthetic replacement or biological reconstruction has become more common in the past two decades. Improvements in combined multimodal therapy,¹⁻³ better imaging, advanced surgical techniques and new prosthetic design,⁴⁻¹⁵ as well as favoured acceptance by the patients, often lead to limb-sparing procedures instead of classical hemipelvectomy. Biological reconstructive procedures, such as the use of autografts,¹⁶ allografts,^{17,18} iliofemoral and ischiofemoral arthrodeses or pseudarthroses,¹⁹ are often followed by leg length discrepancy and loss of hip-joint motion and show a high rate of complications.^{20,21} Type II resections according to the tumour classification of Enneking and Dunham,²² which take the periacetabular area into consideration, result in extended bone and soft-tissue defects. Although endoprosthetic replacement should preserve hip function, complications are well-known in terms of infection, endoprosthetic loosening and/or dislocation as well as reduced soft-tissue compliance.⁴⁻¹⁵

The aim of this prospective multicenter study was to evaluate first results of the MUTARS®-custom-made hemipelvic megaprosthesis with regard to clinical and oncological outcome and complications in patients with a malignant pelvic tumour.

Material and Methods

Prosthesis

The MUTARS® system (Implantcast, Buxtehude, Germany) has been used in tumour centres in Germany, Austria and Poland since 1998 for the reconstruction of severe pelvic defects after tumour resection. Anchorage principles of the individual implants are stem fixation in the iliac bone with wide collar support and the possibility of additional fixation with cancellous bone screws (Fig 1). Additionally, a mesh tube (Trevira®) for muscle and tendon fixation is available. Basic requirements for preoperative planning are the CT scan, with slices of 1-2 mm in regions of interest and the conversion of the resulting data into a 3D-model. After the surgeon has planned the resection margins with respect to joint axes and spatial implant fixation, a stereolithographic pelvic model is manufactured followed by a wax model of the adapted prosthesis with final casting and finishing. Therefore, cooperation between the surgeon and the collaborating company is essential for accurate preoperative planning. The implant is made of CoCrMo alloy in the cementless and cemented version.

Patients and Methods

Patients were seen within the first two years after surgery at least every six months and then annually. Informed consent was given by all patients. Specific tumour and therapy-related data was drawn from the clinical, radiological and histopathological findings. Tumour-related aspects were assessed in terms of tumour entity and size at surgery, neoadjuvant therapy and oncological outcome (NED: no evidence of disease of a primary tumour or a primary metastatic disease; AWM: alive with metastasis of a primary tumour; AWR: alive with recurrence of a primary disease; AWM and AWR: alive with metastasis of a primary pelvic tumour and with recurrence; DOD: died of disease).

Clinical evaluation

The clinical outcome was assessed using the Enneking score.²³ Limb-salvage procedures in the pelvic region were classified according to Enneking's and Dunham's classification system.²²

Postoperative complications

Postoperative complications were divided into five typical groups according to the classification described by Zeifang.²⁰ Type A (local wound-related complications): wound infection, fistulas, seromas, impaired wound healing, skin necrosis and infected haematomas; Type B (implant failure): fracture, loosening or dislocation of implant; Type C (systemic complications): pulmonary embolism, cardiovascular failure, thrombosis, catheter infections; Type D (other): nerve damage, leg-length discrepancy, lymphoedema, decubitus, ulcers, etc.; Type E (local tumour recurrence). Nerve lesions as negative side effects of radical tumour-resection surgery were not regarded as a complication. The complications were graded by severity and

treatment according to Ruggieri²⁴ and classified as “minor” (grades I and II) or “major” (grades III to V).

Radiological evaluation

The radiological evaluation was based on postoperative imaging compared with that at follow-up regarding the occurrence of implant failure or new osteolysis or radiolucent lines. Ethical approval was obtained by the local ethics commission.

Statistical analysis

Survival analysis based on Kaplan-Meier²⁵ survival curves was performed from the date of surgery to the time of death or latest follow-up date. Surviving patients were censored at the last date of follow-up. Moreover, the survival-analysis was used to evaluate survival rates of the implants with revision of the pelvic component for any reason. The distributions of the evaluated parameters are described by mean and standard deviation. An association between different clinical parameters was tested by the Spearman rank correlation. A probability value (p) of less than 0.05 was considered statistically significant.

Results

Patients` demographics

Between September 1998 and June 2003 Implantcast manufactured a total of 47 individual hemipelvic megaprotheses. The implantations took place in 18 hospitals in Germany, Austria and Poland. Forty patients, 27 male and 13 female, with a mean age of 47.8 years (range 11 to 73, SD \pm 17), who were treated in eight major university tumour centres in Germany and in Poland, were included in this study. The follow-up period was one to 61 months with an average of 24 months (SD \pm 15) including two patients who died of their metastasized disease one and five months after surgery, respectively, and one patient who died after three months owing to a recurrence of the original disease.

Tumour type and resection technique

The histologically proven diagnosis was, in 29 cases a primary bone or soft-tissue tumour and in 11 patients a metastasis (Table 1).

Neoadjuvant treatment was performed in 22 patients (14 were treated with chemotherapy, 6 with radiotherapy and 2 with combined radio-/ chemotherapy). At surgery, the average size of the tumour was 9.4 cm (range 3 to 24 cm, SD \pm 5), measured by means of the largest cross-sectional dimension. In 7 cases, the tumour was resected in region IIa according to Dunham,²² in 13 patients in region IIb and in 20 cases in region IIc. Wide resection margins were achieved in 33 cases, while 6 patients (4 patients with a primary metastatic tumour and 2 with a primary malignant tumour) underwent marginal, one patient intralesional resection (primary malignant tumour). The correlation between a marginal or intralesional resection of a primary

tumour and the occurrence of a metastasis was statistically significant ($p=0.04$, $r=0.37$).

Clinical assessment

Patients showed a mean Enneking Score of 50% (10-70, SD \pm 19.2) at the last follow-up examination at a mean of 24 months (range 1-61) after surgery. The best postoperative results regarding isolated parameters were achieved with respect to reduction of pain (mean of 3.2 of 5 points) and walking ability (mean of 2.7 of 5 points), although the most obvious impairment was the use of a walking frame (mean 1.7 of 5 points). The results of the Enneking Score revealed no statistically significant difference between patients with a primary tumour entity or a metastasis ($p=0.6$), although patients with a metastasis reached an average of 54% and a smaller standard deviation (\pm 11.6) compared to patients with primary tumours (48% \pm 21.4).

Complications

Postoperative complications occurred in 30 of 40 patients, of whom 22 required further revision surgery.

Type A complications

The most frequent complication was a wound-related disorder, this occurring in 17 of 40 cases with 12 wound infections, three skin necrosis and two haematomas. All 17 patients underwent major revision surgery. In three cases a deep wound infection or fistula was followed by septic loosening and removal of the prosthesis one, two or 26 months after implantation and was treated with removal of the implant. We could not find any correlation between age at surgery ($p=0.525$, $r=0.146$), tumour size ($p=0.405$,

$r=0.2$) or neoadjuvant therapy ($p=0.74$, $r=0.06$) and the occurrence of wound complications.

Type B complications

Aseptic implant failure, screw breakage, implant loosening and dislocation occurred in 9 of 40 cases with three minor (two loosening and breakage of the cranial screw, one dislocation of the implant) and six major complications. The six patients with major implant failure complications showed an aseptic loosening of the iliac fixation and, at a mean of 21.5 months (1-38, SD \pm 14) after implantation, surgery was carried out, in four cases to replace the implant and, in two patients, to remove of prosthesis. No correlation between aseptic implant failure and either age at surgery ($p=0.742$, $r=0.06$), tumour size ($p=0.861$, $r=0.03$) or neoadjuvant therapy ($p=0.8$, $r=0.03$) could be found.

Type C complications

Systemic complications were observed in three cases (deep-vein thrombosis in two patients and one occlusion of the common iliac artery).

Type D complications

Complications including leg-length discrepancy, ulcers or lymphoedema occurred in 25 cases.

Type E complications

Nine of the 40 patients suffered from a tumour recurrence after a mean of 10 months (2-23, SD \pm 6.2). In one patient a secondary hemipelvectomy was performed whereas, in the other 8 cases, a local excision was carried out. Two of the nine

patients with local recurrence showed a marginal surgical resection and died of their disease, while the resection specimen for the other seven patients was classified as “wide”. We could not find a correlation between resection margin and tumour recurrence ($p=0.7$, correlation coefficient $r=0.1$).

Implant survival

The three septic and six aseptic implant failures revealed an overall explantation rate of 9 of 40 patients. Kaplan-Meier curves were performed for prosthesis revision for any reason (Fig 2). The Kaplan-Meier overall survival probability of the prosthesis at one year was 89.3% [confidence interval CI95%:0.79;0.99], at two years 78.1% [CI95%: 0.61;0.95] and 61.4 % [CI95%: 0.36;0.87] at 3 years. The median lifetime of prosthesis was 38.1 months.

Oncological outcome

At the time of the last follow-up examination, 25 patients were alive with no evidence of disease (NED), either of a primary tumour (17 cases) or of a metastatic disease (8 cases). Seven patients had died owing to an underlying malignancy (DOD); three of them had a metastasized disease, two patients had died as a result of a recurrent and metastasized chondrosarcoma one and three months after surgery. One patient had died of a newly diagnosed recurrence of synovial sarcoma five months after surgery and one patient died owing to a metastasized osteosarcoma seven months after surgery.

Three patients were still alive but had had a recurrence (AWR) of their primary malignant disease, four patients were alive but had developed a recurrence and a metastasis of the primary pelvic tumour (AWM and AWR). One patient was still alive but had developed a metastasis of the primary pelvic tumour (AWM). The one-

and two-year overall survival rate was 89% (± 0.10) and 81% (± 0.19), respectively (Fig 3). The mean overall survival time of the patients with a pelvic metastasis was 33 months [CI95%: 23.0;43.3], for patients with a primary tumour 54 months [CI95%: 47.9;60.7] ($p=0.204$ log rank test).

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Discussion

In the operative treatment of malignant tumours in the pelvis, limb-salvage surgery, combined with chemo- or radiotherapy, showed similar survival, recurrence and complication rates as well as an improvement in the quality of life of the patients when compared to hindquarter amputation.²⁶⁻²⁸

Complication rate

Hemipelvic endoprosthetic replacement in terms of saddle or custom-made prostheses was developed to restore bone defects and hip function but is often associated with a high complication rate.

Clinical outcome

In our series, acceptable functional results, with a mean Enneking Score of 50% (10-70, SD \pm 19.2) could be achieved after a mean of 24 months prospective follow-up examination (range 1-61 months). The retrospective investigations in the literature showed similar results (Table 2). Ozaki reported a mean MSTS score (1987) of 37% and concluded that the lack of soft-tissue coverage and the large dead space may be the reason for the not satisfying functional outcome.⁷ Dai⁴ and Wirbel⁹ reviewed 70% or more of the patients with good and/or excellent function, while Abudu⁸ reported a mean MSTS score (1993) of 70% of normal.

Wound related complications

A major complication after prosthetic pelvic reconstruction is a wound-related infection often a result of the necessarily large wound cavity, long operating time and the adjuvant immunosuppressive therapy. Despite the postoperative antibiotic treatment we feel that a second-look surgery should be routinely considered. The

overall infection rate of 30% was similar to the rates reported in other studies (13-32%, Table 2). In our patients the revision rate of the implant owing to deep infection was 7.5%. Other studies (Table 2) reported rates from 3.6% to 25%. Jeys²⁹ revealed tibial and pelvic prosthetic replacement, radiation therapy and the use of paediatric expandable prostheses to be significant factors for infection in patients treated for an orthopaedic oncological condition. In our patients, there was no statistically significant difference in the occurrence of wound complications and the age at surgery, neoadjuvant therapy or tumour size. Promising future perspectives are studies which describe silver-coated prostheses in animal models and humans.^{30,31} Further studies will have to examine the toxicological side-effect in humans.

Implant related complications due to aseptic loosening or dislocation

The fixation of the megaprosthesis in the pelvic bone still remains a major problem. We used the MUTARS® prosthesis with stem fixation with a wide collar support in the ilium in addition to cancellous bone screws. In two patients a cranial screw and/or breakage occurred which did not require surgery, however. Six patients (15%) showed an aseptic loosening of the iliac fixation following revision of the implant, whereas the reviewed investigations revealed an aseptic loosening of the prosthesis in 0 to 22% of the patients (Table 2). Other pelvic implants are designed to restore the anterior pelvic ring with pubic fixation. Dai⁴ reported one patient with aseptic loosening of the pubic fixation, but he indicated the importance of restoring the three linking areas of the implant (sacrum, pubic rami and ischium). Guo⁵ used dual fixation of the pelvic prosthesis to the ilium and pubis but also reported about 7% pubic-fixation breakage. He concluded that it is not necessary to restore the anterior pelvic girdle after breakage of the pubic fixation. Other studies also revealed a loosening and/or breakage of the pubic fixation in 7 to 25% (Table 2).

Dislocation occurred in only 2.5% of the cases and was less frequent than reported in other studies (3.6% to 20%, Table 2).

The study was limited by the short-term follow-up and lack of control for comparison between different reconstruction methods. However, they are the results of a prospective evaluation of, for the first time, a large number of patients, this being made possible by the multicentric study design.

Oncological outcome

From the oncological point of view the outcome of the patients with a primary pelvic tumour should be differentiated from that of patients with a metastasis. In our study the survival did not differ significantly ($p=0.204$). Three of the seven patients died as a result of a metastatic pelvic tumour, four patients of a primary recurrent and/or metastasized disease. Bruns¹² reported that even with metastatic lesions, a five-year survival of patients who have been treated with hemipelvic endoprosthetic replacement is possible. We would recommend this surgical procedure mainly for patients who are suffering from a solitary metastasis of a tumour with a wide resection margin and who have a good life expectancy.

Local recurrence or distant metastases and resection margins

The recurrence rate of 18% is similar to that reported in other studies (0 to 33%, Table 2). We could show a significant relation between resection margin and occurrence of a metastasis ($p=0.04$) but not in the case of an occurrence of a recurrent disease ($p=0.7$). In the treatment of pelvic tumours, there are no major anatomical barriers for tumour expansion. Frequently, in limb-sparing surgery, a “wide” resection margin cannot be achieved as well as it can be in extremity tumours. It could be shown, that in the treatment of chondrosarcoma,³² the incidence of wide

margins is much higher following a hemipelvectomy than after limb-sparing resection. Therefore, close radiological and clinical follow-up examinations should be standard procedure. In case of unclear surgical margins during the surgery, especially in large tumours, we would recommend a two-stage procedure. The prosthesis should be implanted in a second surgery when the surgical margins are well-known.

Conclusions

Internal hemipelvectomy and reconstruction of pelvic defects with hemipelvic endoprosthesis are associated with a high rate of complications, mainly due to infection. Therefore, each case should be discussed critically and alternative procedures should also be considered. Indication for surgery with a hemipelvic endoprosthesis must be taken seriously in specialised tumour centres.

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Diagnosis	Number
Primary tumour disease	29
Chondrosarcoma	15
Osteosarcoma	4
Ewing` s Sarcoma	3
Giant Cell Tumour	2
Chordoma	1
Leiomyosarcoma	1
Synovial Sarcoma	1
Malignant fibrous Histiocytoma	1
PNET (primitive neuroectodermal tumour)	1
Metastasis	11
kidney	7
thyroid	2
mamma	1
rectum	1

Table 1: List of diagnosis, n = 40

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Study (year)	Number of patients	Reconstruction system	Diagnosis (primary/metastatic tumour)	Mean follow up (months, range)	Died of disease	Complications	Function (% \pm standard deviation)
Current study	40	Custom-made, hemipelvic prosthesis, no pubic fixation	29/11	24 (1-60), prospective	18%	Infection 30%, septic implant removal 15%, aseptic implant removal 8%, recurrence 18%, dislocation 2.5%	MSTS (1993) 50% \pm 19
Dai et al. (2007) ⁴	10	Custom-made, hemipelvic prosthesis, pubic fixation	7/3	34 (21-48)	40%	Infection 30%, breakage/loosening of pubic fixation 10%, recurrence 30%, dislocation 20%	70% good function
Guo et al. (2007) ⁵	28	Modular hemipelvic prosthesis, pubic fixation	22/4	30 (10-59)	29%	Infection 32%, deep infection 14%, septic implant removal 3.6%, loosening of pubic fixation 7%, recurrence 25%, dislocation 3.6%	MSTS (1993) 62% (range 30-83)
Ozaki et al. (2002) ⁷	12	Custom-made, hemipelvic prosthesis, pubic fixation	12/0	57 (26-77)	25%	Deep infection 25%, septic implant removal 25%, loosening of pubic fixation 25%, recurrence 33%, dislocation 8.3%	MSTS (1987) 37%
Muller et al. (2002) ⁶	9	Custom-made, megaprosthesis, pubic fixation	6/3	62 (40-102)	33%	Infection 22%, septic implant removal 22%, aseptic implant removal 22%, recurrence	11% good function

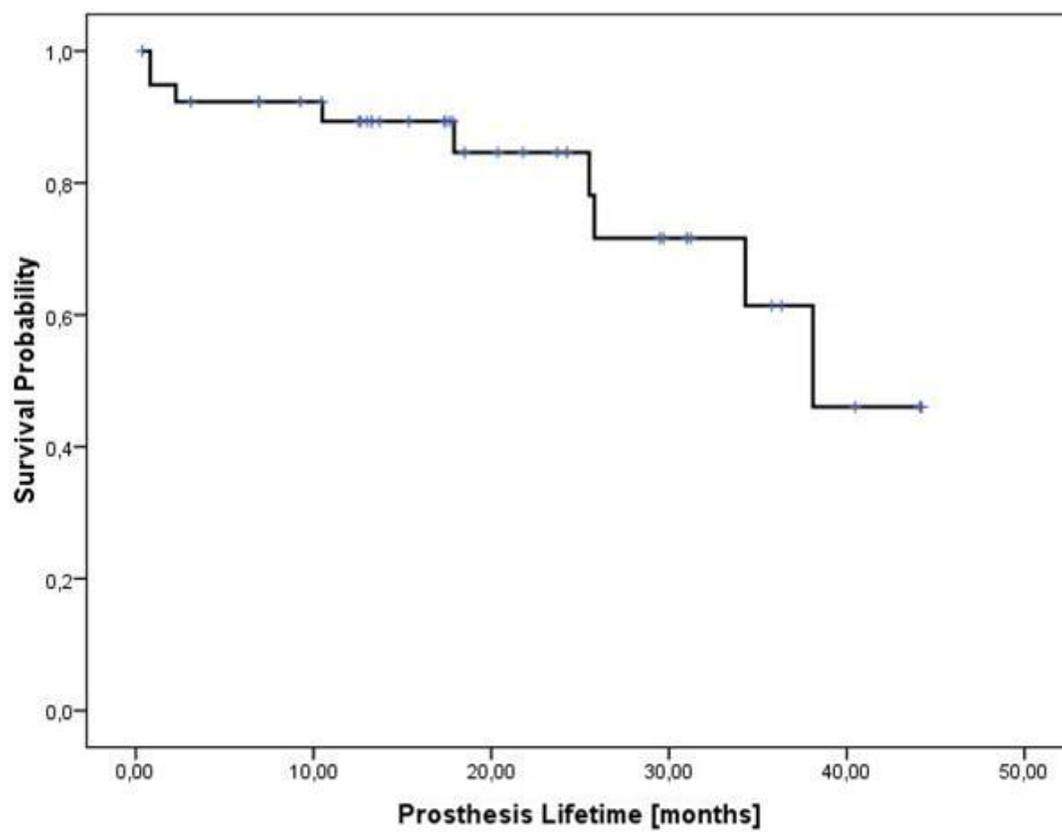
						0%, dislocation 11%	
Wirbel et al. (1999) ⁹	39	37 hemipelvic prosthesis, 2 saddle prosthesis, pubic fixation	39/0	58 (15-110)	51%	Infection 26%, septic implant removal 5%, aseptic implant removal 5%, recurrence 23%, dislocation 15%	77% good/ excellent function
Abudu et al. (1997) ⁸	35	Custom-made, hemipelvic prosthesis, no pubic fixation	32/3	84 (12-312)	40%	Deep infection 26%, septic removal of prosthesis 14%, aseptic removal of prosthesis 3%, recurrence 24%, dislocation 17%	MSTS (1993) 70% (range 50-90)
Bruns et al. (1997) ¹²	15	Custom-made, hemipelvic prosthesis, pubic fixation	11/4	maximum 60	60%	Infection 13%, septic removal of implant 13%, recurrence 11%	MSTS (1978) 50,7%
Windhager et al. (1996) ¹¹	21	9 Saddle prosthesis, 6 custom-made prosthesis and others	21/0	41 (12-190)	33%	Infection 21%, dislocation 7%	MSTS (1987) 15.5 points
Gradinger et al. (1991) ¹⁰	9	Adaptable prosthetic system, pubic fixation	7/2	27 (12-36)	44%	Infection 22%, loosening of pubic fixation 11%, recurrence 56%, dislocation 11%	56% good results

Table 2: Review of the literature according to hemipelvic reconstruction, complication rate and oncological outcome

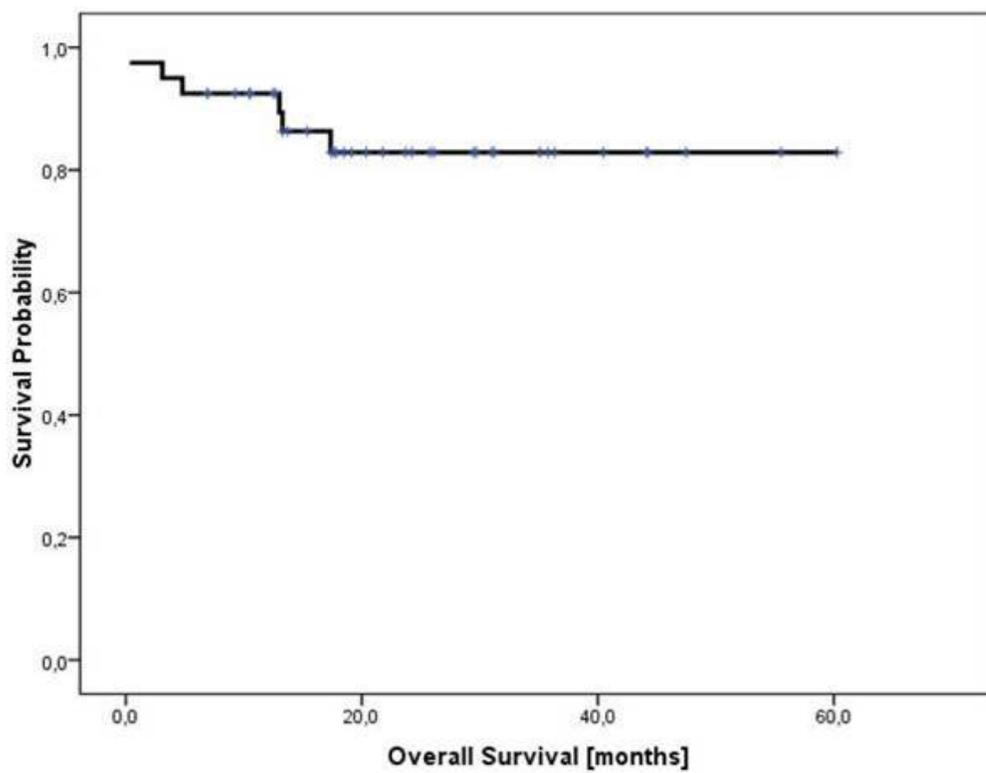
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