



**EMSOS Study:
Total Femur Replacement: Functional Outcome, Clinical Results and Gait Analysis**

Study protocol

Inclusion criteria

- patients that received a total femur replacement, implanted for oncological or non-oncological indications
- reconstruction performed with a total femur endoprosthesis (Implantcast MUTARS, Stryker GMRS, Zimmer Biomet, custom-made or other)
- index operation at year 1990 or after
- no age (at index operation) limitation
- minimal follow-up: 6 months (or less if the patient died)
- provide surgery and/or complication data, even if patient is lost in follow-up or not possible to provide clinical performance / scores' info (e.g. died, underwent hip disarticulation)

Output data

- surgical outcome
 - o local tumor control at resection (oncological indications)
 - o intraoperative complications
- oncological outcome (oncological indications)
 - o local recurrence
 - o metastasis
 - o survival
 - o general outcome (MSTS, SF-12)
- endoprosthesis outcome
 - o clinical performance (Harris Hip Score, Oxford Knee Score)
 - o range of motion (hip and knee joint)
 - o complications (Henderson Failure Classification, Type I to V)
 - o direct comparison of various implants
 - o competing risk analysis
- specific functional outcome (Gait Analysis)



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Legend for the Excel Table Datasheet

General data	
Country	Country
City	City
Hospital	Hospital / University
Patient / tumor data	
DOB	patient's date of birth, format: mm/yyyy
Index OP date	date at index surgery, format: mm/yyyy
Age at resection	years
Gender	M / F
Indication for TFR	Oncological / Non oncological (O / N)
Side	L / R
Diagnosis	Diagnosis at index operation (histologically confirmed for oncological cases)
<i>For oncological cases:</i>	
Tumor localization	please specify
Tumor size	mm (at index operation)
Metastasis at diagnosis	metastases at diagnosis, y/n If y, state where (lung, nodes, bone...)
Radiotherapy	0 – no 1 – preoperative 2 – postoperative 12 – pre- and postoperative 3 – intraoperative
Chemotherapy	0 – no 1 – preoperative 2 – postoperative 12 – pre- and postoperative



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Surgery data	
Soft tissue resection	Planned - please specify
Trevira tube	y/n
Endoprosthesis	Endoprosthesis type: Mut – Implantcast MUTARS Stry – Stryker GMRS Bio – Biomet CM – custom made O – other (state which)
EP length	length of TFR endoprosthesis, format: mm
Tibial component	0 – cementless 1 – cemented
Expanding endoprosthesis	y/n
Complications	
Tumor resection	W – wide M – marginal I – intralesional
I-OP complications	Intraoperative nerve injury, arterial injury... please specify
Classification of failure	(Henderson, 2011) format "no" or "describe in detail"
1	soft tissue failure
2	aseptic loosening – early (<2y after implantation) or late (>2y after implantation)
3	structural failure
4	infection – early (<2y after implantation) or late (>2y after implantation); if y, state microorganism
5	tumor progression
Postoperative complications (other)	describe in detail
Reoperations	
Number	Number of revisions/reoperations (including disarticulations)
Reason	State the reason and type for each reoperation and the time (months) from index operation



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Specific scores and outcome

MSTS	Musculoskeletal Tumor Rating Scale (MSTS) at the last follow-up - MSTS questionnaire attached - possible MSTS result: 0 to 30
SF-12	SF-12 at the last follow-up - SF-12 questionnaire attached - possible SF-12 result: 0 to 56
Harris Hip Score	Harris Hip Score at the last follow-up - Harris Hip Score questionnaire attached - possible Harris Hip Score result: 0 to 100
Oxford Knee Score	Oxford Knee Score at the last follow-up - Oxford Knee Score questionnaire attached - possible Oxford Knee Score result: 0 to 48
Range of motion	format: extension to flexion (ROM with goniometer!) KNEE and HIP example: if knee extension contracture 10° and flexion 80°, write "10 to 80 "
Follow-up	follow-up from index operation until the last control, format: months - Lost in follow-up: LIF
Date last follow-up	last follow-up date, format: mm/yyyy
<i>For oncological cases:</i>	
Local recurrence	known local recurrence till the last follow-up format: y/n - If y, how many months after index surgery
Late METs	late metastasis, known to the last follow-up format: y/n - If y, state when (months) and where (lung, nodes, bone...)
Final outcome	NED – no evidence of disease AWD – alive with disease DOD – died of disease RIP – died of other cause, not related to index tumor LIF – lost in follow-up
Comment	if needed

GAIT ANALYSIS

Gait laboratory	available in your institution + possibility to perform Gait analysis on the "alive with limb, walking" patients - y/n
Video	[alternative:] Video documentation of the gait of the patients (which will be analyzed as a remote gait analysis in Graz) - possibility to record video? y/n

Specific gait analysis protocols/instructions will be sent separately.



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Attachment 1

Musculoskeletal Tumor Rating Scale (MSTS):
lower extremity

Score	<i>Pain</i>	<i>Function</i>	<i>Emotional acceptance</i>	<i>Supports</i>	<i>Walking</i>	<i>Gait</i>
5	none	no restriction	enthused	none	unlimited	normal
4	(intermediate)	(intermediate)	(intermediate)	(intermediate)	(intermediate)	(intermediate)
3	modest	recreational restriction	satisfied	brace	limited	minor cosmetic
2	(intermediate)	(intermediate)	(intermediate)	(intermediate)	(intermediate)	(intermediate)
1	moderate	partial restriction	accepts	one cane or crutch	inside only	major cosmetic
0	severe	total restriction	dislikes	two canes or crutches	not independent	major handicap

CALCULATE: Score / 30



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Attachment 2.

12-item Short-Form Health Survey (SF-12 Score)

	1 point	2 points	3 points	4 points	5 points
1. <i>General health</i>	Poor	Fair	Good	Very good	excellent
2. <i>Moderate activities</i>	Limited a lot	Limited a little	Not limited at all		
3. <i>Climb several flights of stairs</i>	Limited a lot	Limited a little	Not limited at all		
4. <i>Accomplished less (physical)</i>	All of the time	Most of the time	Some of the time	A littel of the time	None of the time
5. <i>Limited in kind of work</i>	All of the time	Most of the time	Some of the time	A littel of the time	None of the time
6. <i>Pain - interference</i>	Extremely	Quite a bit	Moderately	A little bit	Not at all
7. <i>Accomplished less (emotional)</i>	All of the time	Most of the time	Some of the time	A littel of the time	None of the time
8. <i>Did work less carefully</i>	All of the time	Most of the time	Some of the time	A littel of the time	None of the time
9. <i>Calm and peaceful</i>	None of the time	A littel of the time	Some of the time	Most of the time	All of the time
10. <i>Energy or vitality</i>	None of the time	A littel of the time	Some of the time	Most of the time	All of the time
11. <i>Downhearted and blue</i>	All of the time	Most of the time	Some of the time	A littel of the time	None of the time
12. <i>Social limitations</i>	All of the time	Most of the time	Some of the time	A littel of the time	None of the time

Question 1-3 referring to the present; Question 4-12 referring to the past 4 weeks.

CALCULATE: Score / 56



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Attachment 3.

Harris Hip Score

Function	Definition	Points
Pain	None or ignores it	44
	Slight, occasional, no compromise in activities	40
	Mild pain, no effect on average activities, rarely moderate pain with unusual activity	30
	Moderate Pain, tolerable but makes concession to pain. Some limitation of ordinary activity or work. May require occasional pain medication	20
	Marked pain, serious limitation of activities	10
	Totally disabled, crippled, pain in bed, bedridden	0
Limp	None	11
	Slight	8
	Moderate	5
	Severe	0
Support	None	11
	Cane for long walks	7
	Cane most of the time	5
	One crutch	3
	Two canes	2
	Two crutches or not able to walk	0
Distance Walked	Unlimited	11
	Six blocks	8
	Two or three blocks	5
	Indoors only	2
	Bed and chair only	0
Sitting	Comfortably in ordinary chair for one hour	5
	On a high chair for 30 minutes	3
	Unable to sit comfortably in any chair	0
Enter public transportation	Yes	1
	No	0



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Stairs	Normally without using a railing	4
	Normally using a railing	2
	In any manner	1
	Unable to do stairs	0
Put on shoes and socks	With ease	4
	With difficulty	2
	Unable	0
Absence of deformity	Less than 30° fixed flexion contracture	YES/NO
	Less than 10° fixed abduction	
	Less than 10° fixed internal rotation in extension	(all yes = 4;
	Limb length discrepancy less than 3.2 cm	less than 4 =0)
Range of motion	211-300° (normal: Flexion 140°, Abduction 40°, Adduction 40°, External Rotation 40°, Internal Rotation 40°)	5
	161-210°	4
	101-160°	3
	61-100°	2
	31-60°	1
	0-30°	0

CALCULATE: Score /100



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Attachment 4.

Oxford Knee Score

How would you describe the pain you have usually from your knee?	None Very mild Mild Mild moderate Severe	4 3 2 1 0
Have you had any trouble with washing and drying yourself all over because of your knee?	No trouble at all Very little trouble Moderate trouble Extremely difficult Impossible to do	4 3 2 1 0
Have you had any trouble getting in and out of a car or using public transport because of your knee?	No trouble at all Very little trouble Moderate trouble Extremely difficult Impossible to do	4 3 2 1 0
If you were to kneel down could you stand up afterwards?	Yes, easily With little difficulty With moderate difficulty With extreme difficulty No, impossible	4 3 2 1 0
Have you been limping when walking because of your knee?	Rarely/Never Sometimes or just at first Often, not just at first Most of the time All of the time	4 3 2 1 0
Have you felt that your knee might suddenly give way or let you down?	Rarely/Never Sometimes or just at first Often, not just at first Most of the time All of the time	4 3 2 1 0
Have you been able to do your own household shopping on your own?	Yes, easily With little difficulty With moderate difficulty With extreme difficulty No, impossible	4 3 2 1 0
For how long have you been able to walk before the pain from your knee became severe (with or without a stick)?	No pain, even after more than 30 minutes 16-30 minutes 5-15 minutes	4 3 2 1



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	Around the house only Unable to walk at all	0
Have you been able to walk down a flight of stairs	Yes, easily With little difficulty With moderate difficulty With extreme difficulty No, impossible	4 3 2 1 0
After a meal (sat at a table) how painful has it been for you to stand up from a chair because of your knee?	Not at all painful Slightly painful Moderately painful Very painful Unbearable	4 3 2 1 0
How much pain from your knee interfered with your usual work (including housework)?	Not at all A little bit Moderately Greatly Totally	4 3 2 1 0
Have you been troubled by pain from your knee in bed at night?	No nights Oly 1 or 2 nights Some nights Most nights Every nights	4 3 2 1 0

CALCULATE: Score /48