

VILNIUS UNIVERSITY

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**TOTAL KNEE ARTHROPLASTY – THE INFLUENCE OF  
PREOPERATIVE PATIENT FACTORS ON PAIN, FUNCTION  
AND QUALITY OF LIFE**

Summary of doctoral dissertation  
Biomedical sciences, Medicine (06 B)

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VILNIAUS UNIVERSITETAS

TOMAS SVEIKATA

**KELIO SĄNARIO ENDOPROTEZAVIMAS – PRIEŠOPERACINIŲ  
PACIENTO VEIKSNIŲ ĮTAKA POOPERACINIAM KELIO SĄNARIO  
SKAUSMUI, FUNKCIJAI IR GYVENIMO KOKYBEI**

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## **1. ABBREVIATIONS**

Ahlback joint	Ahlbäck classification of osteoarthritis of the knee joint
ASA class	American Society of Anesthesiologists physical status class
BMI	Body mass index
CI	Confidence interval
Charnley class	Classification used to assess patients level of activity
MCS	Mental health composite score
OA	Osteoarthritis
OMERACT-OARSI	Outcome Measures in Rheumatology and Osteoarthritis Research Society International
PCS	Physical health composite score
PROM	Patient reported outcome measure
ROM	Range of motion
SD	Standard deviation
SF-12	Short From 12 item Health Survey
TKA	Total knee arthroplasty
WHO	World Health Organisation
WOMAC	Western Ontario and McMaster Universities' proposed Osteoarthritis Index

## **2. INTRODUCTION**

### **2.1. Background**

Osteoarthritis (OA) is one of the most common diseases affecting the musculoskeletal system in elderly people and has a substantial impact on patients quality of life (QoL)(1). Age is the strongest predictor of the development and progression of osteoarthritis, as such a number of people suffering from OA is expected to continue to increase over the coming years due to the ageing population and increasing obesity(2). A primary total knee arthroplasty (TKA) is an effective treatment for an end stage knee osteoarthritis(3–5). TKA is aimed to provide long lasting joint which relieves pain and improves patient's physical function(6). Since the introduction of modern TKA in 1970's, the surgical techniques, the instrumentation, the implant technologies have changed dramatically and those improvements greatly benefited to postoperative outcomes. Knee arthroplasty has moved from a salvage operation, performed in extreme cases, to an intervention designed to improve the quality of life in patients who might otherwise cope without the intervention. However, a significant patient population (10-20%) is still experiencing unsatisfactory results (7). There is no clinical, radiographic or laboratory explanation for their dissatisfaction. This patients group, referred to as the "looks good but feels bad" group remains a mystery to knee surgeons (8).

Therefore a traditional indicators of surgical success such as stating the range of knee motion (ROM), the implant position on x-ray and implant survival may not mirror the patient's postoperative experience. Patient-reported outcome measures (PROMs) have become a corner-stone of outcome assessment after joint surgery (9). Numerous PROMs are used to measure the TKA outcome from the patient's perspective. Usually one generic and one specific questionnaire are used because they measure different but complementary aspects of patient outcomes(10). The Medical Outcome Short Form 36 (SF-36) Health Survey and the Western Ontario and McMaster

Universities Osteoarthritis Index (WOMAC) is the most used combination in the literature (5).

WOMAC is a joint specific instrument for measuring clinical outcome in patients treated for knee osteoarthritis (11).

The SF-36 score is a generic health measure of patient's overall physical and mental wellbeing(12).

Various patient-related factors can be associated with poor outcome after TKA, including age, sex, obesity, education, social support and mental status(13–16). It is important to identify those preoperative risk factors in order to understand why some people fail to benefit from TKA.

## **2.2. The aim of the study**

The aim of this study was to prospectively evaluate the influence of preoperative patient factors on patient reported outcome one year after total knee arthroplasty.

## **2.3. Objectives of the study**

- 1.1. To evaluate knee pain, function, general physical and mental health status of patients before total knee arthroplasty and to compare among patient groups differing by age, sex, education level, social support level, BMI, place of residence, co-morbidities according to Charnley and stage of knee osteoarthritis according to Ahlback.
- 1.2. To evaluate knee pain, function, general physical and mental health status of patients one year after total knee arthroplasty and to compare among patient groups differing by age, sex, education level, social support level, BMI, place of residence, co-morbidities according to Charnley and stage of knee osteoarthritis according to Ahlback.
- 1.3. To compare WOMAC and SF-12 scores change among patient groups differing by age, sex, education level, social support level, BMI, place of

- residence, co-morbidities according to Charnley and stage of knee osteoarthritis according to Ahlback.
2. To find out preoperative patient factors which predict knee pain and function in one year following total knee arthroplasty.
  3. To find out the proportion and which patients do not respond to total knee arthroplasty according to OMERACT-OARSI set of responder criteria.

#### **2.4. The scientific novelty of the study and implementation into the practice**

TKA has demonstrated improvements in OA patient's pain and function. Unfortunately, not all patients are satisfied with the results(17) . The incidence of dissatisfaction or suboptimal outcome after TKA varies in the literature. Variations of reported outcomes may be due to the different kinds of questionnaires used and lack of consensus amongst physicians regarding how they should be applied(18,19). Until now no research has been done to evaluate the influence of patient factors on the TKA outcome using PROMs in Lithuania. Every surgeon is responsible for the results of the intervention, so we need to have all possible information regarding the factors influencing postoperative outcomes. It is important before surgery to identify patients at risk of reporting an unsatisfactory TKA outcomes. If risks are identified and addressed in time the post-operative results could be improved. It is impossible to rely on the data taken from studies done in countries with different economy, culture and traditions.

### **3. MATERIALS AND METHODS**

#### **3.1. Study Design and Settings**

The prospective observational study was performed at the Republican Vilnius University Hospital, Vilnius, Lithuania, from October 2012 to April 2014.

The study protocol was approved by the Regional Ethical Committee of the Vilnius Regional Bioethics Committee, Vilnius, M.K. Ciurlionio 21/27, LT-03101, Lithuania. (Nr. 158200-14-738-254)

The cohort consisted of patients from the orthopaedic department of Republican Vilnius University Hospital.

The patients scheduled for primary TKA were screened for inclusion. All enrolled patients gave a written consent. Flowchart of study cohort is shown in Figure 1.

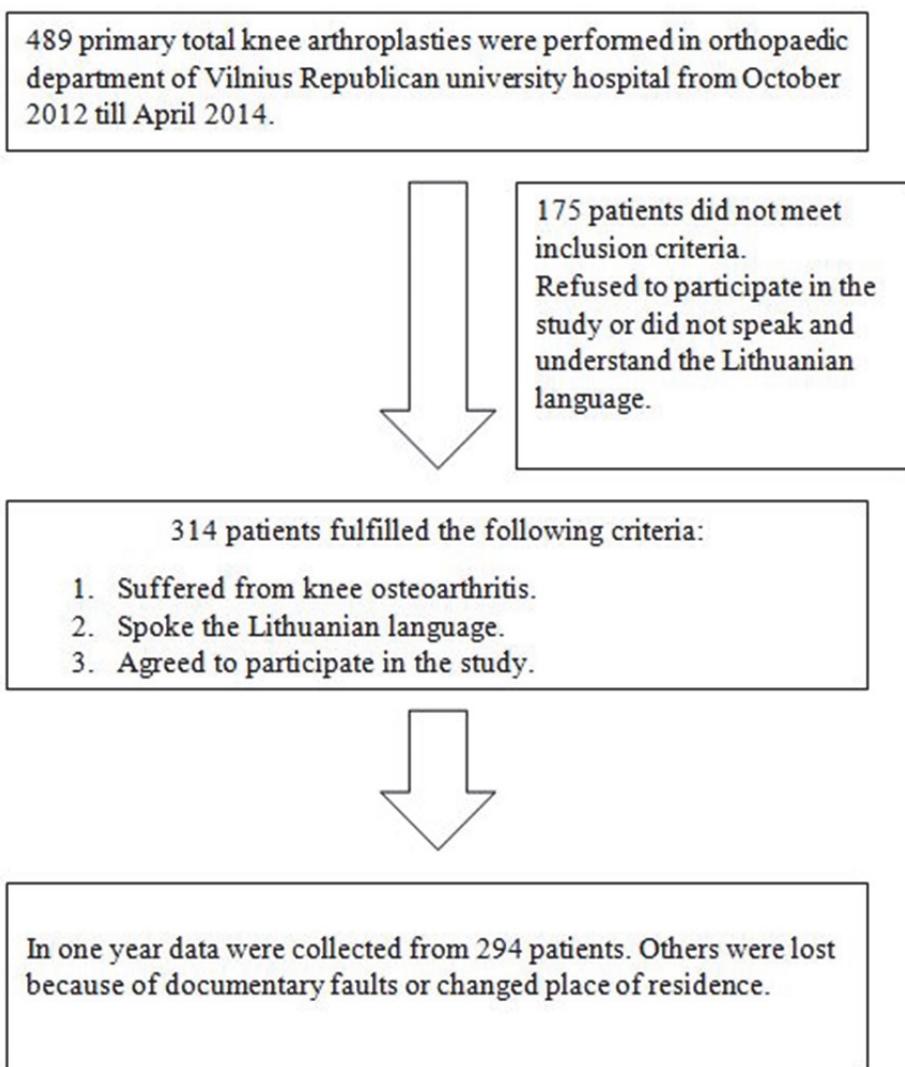


Fig. 1. Flowchart of study cohort

Three hundred fourteen participants were enrolled in the trial. Two hundred ninety four patients completed the study.

Preoperative patient's data was obtained on the day of their preoperative evaluation. Collected information included sex, age, educational level, social support, height and weight was measured (from which body mass index (BMI) was calculated), residence place, co-morbidities. We devided all patients in to two groups according to age (younger than 75 and 75 and older). Usually the elderly are lumped together, grouping everyone over the age of 65. But a 65-year-old's experience of life is much different from a 90-year-old's. The mean age of our cohort was 71. Older adult population is divided into three life-stage subgroups: the young-old (approximately 65–74), the middle-old (ages 75–84), and the old-old (over age 85)(20). We took a cut-off between young-old and middle-old life-stage subgroups. Body Mass Index (BMI) is a simple index of weight-for-height that is commonly used to classify underweight, overweight and obesity in adults (21). It is defined as the weight in kilograms divided by the square of the height in metres ( $\text{kg}/\text{m}^2$ ). We used WHO's recommendation for splitting patients in groups according to BMI: I.  $\text{BMI}<30$  (patients with normal weight and over-weight), II.  $\text{BMI } 30\text{--}34.9$  (obese patients class I), III.  $\text{BMI}\geq 35$  (obese patients class II and class III). Patient's educational level was coded as either low (secondary school or vocational training) or high (University). According to living place patients were grouped in to rural and urban. Social support was determined by their marital and living status (lived alone or with somebody). The patients underwent radiographic examination (AP and lateral standing) and were grouped according to Ahlback osteoarthritis stages (22). According to walking ability patients were grouped to A, B, C Charnley classes (23).

Patients filled up two validated and originally authorized Lithuanian translations of questionnaires: the Western Ontario and McMaster's Universities osteoarthritis Index (WOMAC) and the Short Form - 12 (SF-12) before and one year after TKA.

The WOMAC is a disease-specific instrument with 3 dimensions that measure pain, joint stiffness and physical function. It consists of 24 items (5 for pain, 2 for stiffness and 17 for function). Point values from 0 to 4 are assigned to each response and scores are totaled for each category. The maximum score is 20 points for pain, 8 for stiffness and 68 points for physical function. Higher scores indicate greater difficulty (24). We transformed WOMAC scores to a 0 to 100 point scale for each domain (with 100 being the best score).

The SF-12 score is a generic health measure of a patient's overall physical and mental wellbeing. Physical and Mental Health Composite scores (PCS and MCS) are calculated using the scores of twelve questions and range from 0 to 100, where a zero score indicates the lowest level and 100 indicates the highest level of health(12).

All TKA were made using cemented implants without resurfacing patella and all patients underwent similar rehabilitation program.

Preoperative and in one year clinical outcome scores were analyzed as well as the change in score between preoperative and latest score.

### **3.2. Study Subjects**

**3.2.1** Comparing preoperative, postoperative and score change of WOMAC and SF-12 questionnaires among groups differing by preoperative patient factors.

The first aim of this study was to compare knee pain, function, general physical and mental health of patients before and one year after TKA between groups differing by age, sex, BMI, education, social support level, residence place, amount of co-morbidities and grade of knee osteoarthritis.

Patients were grouped according to these preoperative factors and their knee and general health was evaluated using WOMAC and SF-12. The evaluation of statistical and clinically meaningful differences of knee pain, function and general healthscores among groups was done. Differences in the WOMAC

scores of 9 points on a 100-point scale have been shown to be perceptible to patients and are clinically meaningful(6,25,26).

**3.2.2** Influence of patient factors on knee pain and function after TKA according to one year WOMAC scores change.

The multiple linear regression model was used to determine the preoperative predictors of pain and functionchange in one year following TKA.

### **3.2.3** Measuring the patient's response to TKA

To find out what patients can be classified as responders to TKA, we used OMERACT-OARSI set of responder criteria(27). OMERACT-OARSI criteria are based on pain and function as measured by WOMAC. This set is as follows: if the patient has an improvement in pain or function  $\geq 50\%$  and absolute change  $\geq 20$  then, he is a responder. If the patient does not reach these criteria but has an improvement in at least two of the three following criteria he will also be a responder: 1. Pain  $\geq 20\%$  and absolute change  $\geq 10$ ; 2. Function  $\geq 20\%$  and absolute change  $\geq 10$ ; 3. Patient's global assessment of the disease  $\geq 20\%$  and absolute change  $\geq 10$ . Set of responder criteria is demonstrated in Figure 2.

The estimates of OMERACT-OARSI criteria stratified by WOMAC preoperative tertiles of knee pain severity and function according to Escobar et al.(28).

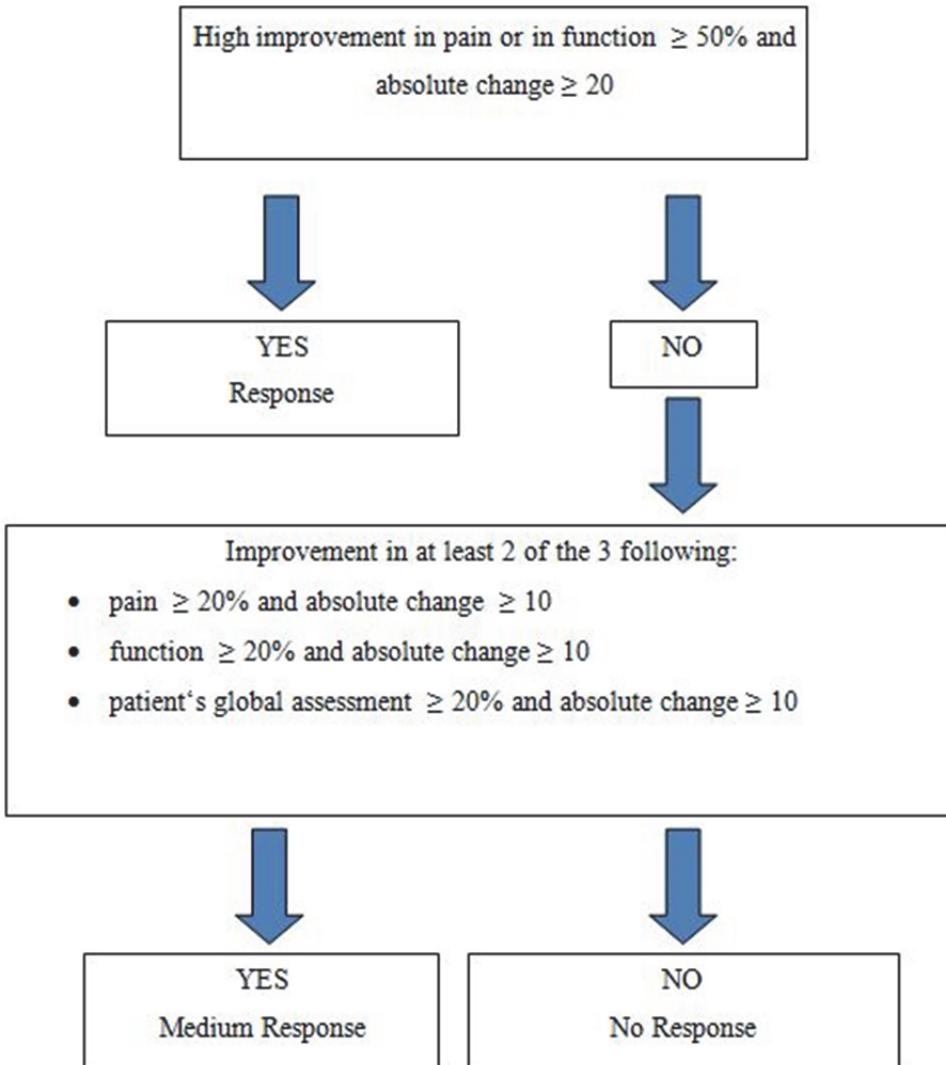


Figure 2. OMERACT-OARSI set of responder criteria.

### 3.3. Statistical analysis

The independent variables were age, sex, BMI ( $<30$ ;  $30-34.9$ ;  $\geq 35.0$ ), level of education (low and high), social support (married/living with someone and otherwise), number of co-morbidities according to Charnley, stage of knee osteoarthritis according to Ahlback, residence place (urban or rural). The effect of each independent variable was analyzed separately for the WOMAC and SF-12. For statistical analysis we used IBM SPSS Statistics 24. To compare two parametric data we used Welch's t-test, for multiple comparisons – ANOVA, with Bonferroni post-hoc test and comparing non-parametric data we

used Mann-Whitney test for two and Kruskal-Wallis test for multiple groups. Multiple linear regression was used to estimate the influence of preoperative factors on the outcomes according to WOMAC and SF-12. A p-value of < 0.05 was considered to be statistically significant.

#### 4. RESULTS

Of the 314 patients enrolled, 294 completed the study. There were 20 participants who failed to show up for postoperative follow up and were excluded from the study. The main characteristics of the study group population and evaluation of knee pain, function according to WOMAC and general health status according to SF-12 before and after TKA are shown in table 1-2 and figures 3-4.

Table 1. Characteristics of participants (n=294).

	All n=314	Included n=294	Excluded n=20
Sex			
Females n (%)	259 (82.5)	243 (82.7)	16 (80.0)
Age		Males 71.02 (9.19) Females 70.82 (8.10)	
mean (SD)	70.71 (8.25)	70.86 (8.28)	68.55 (7.57)
Agegroups n (%)			
<75 year	214 (68.2)	198 (67.3)	16 (80.0)
75 and older	100 (31.8)	96 (32.7)	4 (20.0)
BMI			
mean (SD)	33.04 (6.16)	33.00 (6.20)	33.57 (5.59)
BMI category n (%)			
<30	107 (34.1)	102 (34.7)	5 (25.0)
30-34.9	102 (32.5)	94 (32.0)	8 (40.0)
≥35	105 (33.4)	98 (33.3)	7 (35.0)
Educationallevel n (%)			
Low	206 (65.6)	191 (65.0)	15 (75.0)
High	108 (34.4)	103 (35.0)	5 (25.0)
Socialsupport n (%)			
livingalone	102 (32.5)	94 (32.0)	8 (40.0)
livingwithsomebody	212 (67.5)	200 (68.0)	12 (60.0)
Livingplace n (%)			
Rural	62 (19.7)	52 (17.7)	10 (50.0)
Urban	252 (80.3)	242 (82.3)	10 (50.0)

Table 2. Whole cohort's preoperative and postoperative WOMAC and SF-12 mean values

	Included n=294	Excluded n=20	P value
<b>Preoperative</b>			
<b>Womacmean (SD)</b>			
Pain	53.32 (17.99)	53.25 (13.60)	0.987
Stiffness	51.55 (24.07)	47.30 (20.11)	0.258
Function	47.71 (18.61)	44.40 (12.15)	0.324
Total	49.17 (16.99)	46.40 (11.66)	0.136
<b>SF-12 mean (SD)</b>			
PhysicalCompositescores	33.82 (7.83)	31.82 (6.05)	0.142
MentalHealthCompositescores	46.14 (10.31)	44.11 (6.80)	0.157
<b>1 year postoperative</b>			
<b>Womacmean (SD)</b>			
Pain	90.73 (9.82)	-	-
Stiffness	90.03 (13.23)	-	-
Function	86.30 (10.54)	-	-
Total	87.63 (9.82)	-	-
<b>SF-12 mean (sd)</b>			
PhysicalCompositescores	44.98 (7.42)	-	-
MentalHealthCompositescores	49.37 (7.48)	-	-

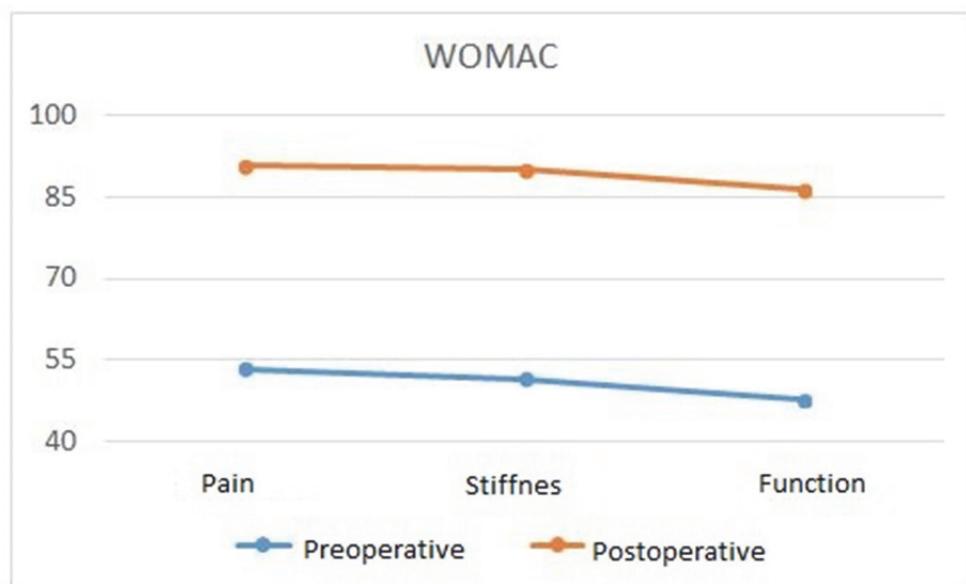


Figure 3. Knee pain, stiffness, function according to WOMAC before and one year after TKA

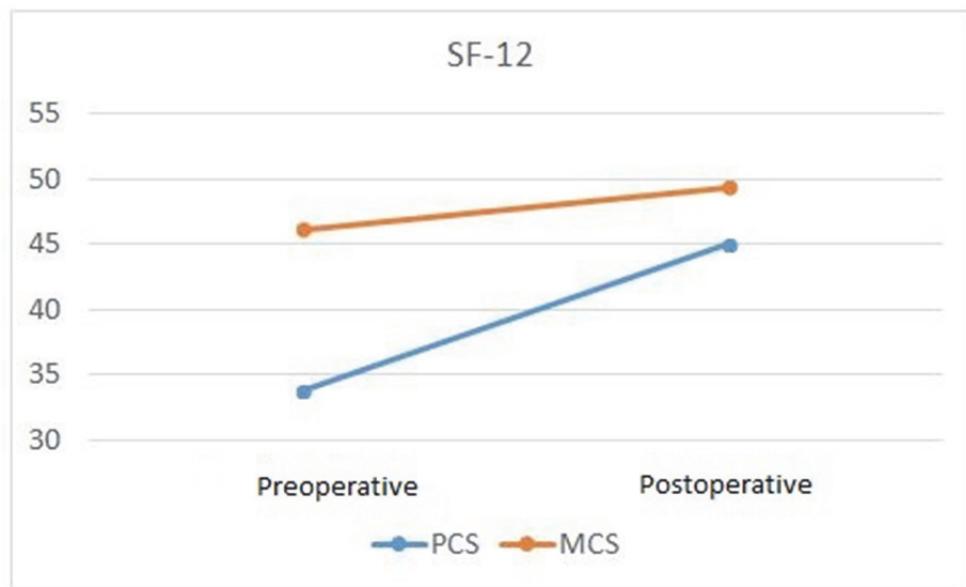


Figure 4. General health status according to SF-12 before and one year after TKA (PCS – Physical Component Summary; MCS – Mental Component Summary)

#### **4.1. Comparing WOMAC and SF-12 results between groups differing by patient factors**

At the time of surgery, women reported statistically and clinically significant more pain ( $p=0.001$ ), and worse knee function ( $p=0.002$ ) as measured by WOMAC. Also, women scored lower on MCS ( $p=0.025$ ) according to SF-12. The preoperative characteristics by sex are presented in Table 3.

Table 3. Preoperative WOMAC and SF-12 scores according to patient's sex

	Preoperative: Sex						
	Male			Female			
WOMAC scores	Md*	Mean ± SD	CI**	Md*	Mean ± SD	CI**	P value
Pain	65	61.37 ± 17.44	[56.47; 66.28]	50	51.63 ± 17.68	[49.39; 53.86]	0.001
Stiffness	63	59.84 ± 23.38	[53.27; 66.42]	50	49.81 ± 23.90	[46.79; 52.83]	0.004
Function	62	56.18 ± 20.74	[50.34; 62.01]	44	45.93 ± 17.67	[43.70; 48.17]	0.002
Total	60	57.63 ± 18.82	[52.33; 62.92]	46	47.40 ± 16.06	[45.37; 49.43]	0.001
<b>SF-12</b>							
PCS	36.47	35.60 ± 8.34	[33.26; 37.95]	32.77	33.44 ± 7.69	[32.47; 34.42]	0.073
MCS	49.80	49.07 ± 9.13	[46.50; 51.64]	45.45	45.52 ± 10.45	[44.20; 46.84]	0.025

\* – Median; \*\* - 95% confidence interval PCS – physical health score MCS – mental health score

One year after TKA men demonstrated better knee pain ( $p=0.023$ ), function ( $p=0.005$ ) scores according to WOMAC and better physical health ( $p=0.049$ ) and mental health ( $p=0.020$ ) according to SF-12. The results are shown in table 4.

Table 4. Postoperative WOMAC and SF-12 scores according to patient's sex

	Postoperative: Sex						
	Male			Female			
WOMAC scores	Md*	Mean ± SD	CI**	Md*	Mean ± SD	CI**	P value
Pain	95	93.53 ± 6.95	[91.57; 95.48]	95	90.14 ± 10.24	[88.85; 91.44]	0.023
Stiffness	100	93.59 ± 8.95	[91.07; 96.10]	88	89.29 ± 13.86	[87.54; 91.04]	0.061
Function	90	90.08 ± 6.28	[88.31; 91.84]	88	85.51 ± 11.08	[84.11; 86.91]	0.005
Total	92	91.16 ± 5.62	[89.58; 92.74]	90	86.89 ± 10.35	[85.58; 88.20]	0.003
<b>SF-12</b>							
PCS	47.20	46.84 ± 6.55	[44.99; 48.68]	45.20	44.59 ± 7.55	[43.64; 45.54]	0.049
MCS	51.69	51.53 ± 6.88	[49.59; 53.46]	48.95	48.92 ± 7.54	[47.97; 49.87]	0.020

\* – Median; \*\* - 95% confidence interval PCS – physical health score MCS – mental health score

Women got more benefit from surgery than men according to WOMAC pain score change ( $p=0.001$ ). The results are shown in table 5.

Table 5. WOMAC and SF-12 score change according to patient's sex

	Difference: Sex						
	Male			Female			
WOMAC scores	Md*	Mean ± SD	CI**	Md*	Mean ± SD	CI**	P value
Pain	30	32.16 ± 16.32	[27.57; 36.75]	40	38.52 ± 18.71	[36.15; 40.88]	0.011
Stiffness	37	33.75 ± 20.85	[27.88; 39.61]	38	39.48 ± 24.64	[36.37; 42.59]	0.101
Function	31	33.90 ± 19.34	[28.46; 39.34]	41	39.57 ± 19.21	[37.15; 42.00]	0.057
Total	30	33.53 ± 17.34	[28.65; 38.41]	41	39.49 ± 17.65	[37.26; 41.72]	0.029
SF-12							
PCS	11.96	11.23 ± 8.84	[8.74; 13.72]	11.18	11.14 ± 8.42	[10.08; 12.21]	0.947
MCS	1.88	2.46 ± 7.59	[0.32; 4.59]	2.35	3.40 ± 9.56	[2.19; 4.61]	0.584

\*– Median; \*\* - 95% confidence interval PCS – physical health score MCS – mental health score

Comparing preoperative WOMAC and SF-12 scores between groups differing in age, older patients felt less pain ( $p=0.035$ ) and demonstrated better mental health ( $p=0.023$ ). The results are shown in table 6.

Table 6. Preoperative WOMAC and SF-12 scores according to patient's age

	Preoperative: Age						
	Under 75			75 and older			
WOMAC scores	Md†	Mean ± SD	CI**	Md†	Mean ± SD	CI**	P value
Pain	50	51.72 ± 17.55	[49.26; 54.18]	55	56.61 ± 18.53	[52.86; 60.37]	0.035
Stiffness	50	49.71 ± 24.27	[46.31; 53.11]	50	55.34 ± 23.32	[50.62; 60.07]	0.052
Function	48	47.44 ± 18.09	[44.90; 49.97]	46	48.27 ± 19.73	[44.27; 52.27]	0.928
Total	48	48.47 ± 16.54	[46.16; 50.79]	49	50.47 ± 17.88	[46.99; 54.24]	0.312
SF-12							
PCS	33.47	33.71 ± 7.58	[32.65; 34.78]	33.32	34.04 ± 8.36	[32.34; 35.73]	0.742
MCS	45.68	45.19 ± 10.74	[43.68; 46.69]	48.23	48.10 ± 9.11	[46.25; 49.94]	0.023

\*– Median; \*\* - 95% confidence interval PCS – physical health score MCS – mental health score

Younger patients improved more than older ones. They demonstrated more change in WOMAC pain domain ( $p=0.001$ ) and mental function ( $p=0.040$ ) scores according to SF-12.

There were no statistical differences between the results of age groups one year after TKA. The results are shown in table 7.

Table 7. WOMAC and SF-12 change score according to patient's age

	Difference: Age						
	Under 75			75 and older			
WOMAC scores	Md*	Mean ± SD	CI**	Md*	Mean ± SD	CI**	P value
Pain	40	39.12 ± 18.52	[36.52; 41.71]	32.50	33.91 ± 17.89	[30.28; 37.53]	0.011
Stiffness	38	40.43 ± 24.12	[37.05; 43.81]	37	34.47 ± 23.65	[29.68; 39.26]	0.061
Function	40.50	39.35 ± 19.33	[36.64; 42.06]	38	37.02 ± 19.29	[33.11; 40.93]	0.333
Total	41	39.54 ± 17.74	[37.05; 42.02]	37	36.23 ± 17.54	[32.67; 39.78]	0.133
<hr/> SF-12							
PCS	12.03	11.80 ± 8.28	[10.64; 12.96]	10.48	9.84 ± 8.77	[8.06; 11.62]	0.063
MCS	2.73	4.00 ± 9.65	[2.65; 5.36]	1.08	1.64 ± 8.18	[-0.01; 3.30]	0.040

\*— Median; \*\* - 95% confidence interval PCS – physical health score MCS – mental health score

More educated patients felt less pain( $p=0.010$ ) and demonstrated statistically and clinically better knee function ( $p<0.001$ ) than less educated patients before TKA according to WOMAC. After TKA less educated patients improved more in knee pain ( $p=0.032$ ) and function ( $p<0.001$ ) according to WOMAC score change. One year after TKA patients from both groups demonstrated similar WOMAC and SF-12 results. The results are shown in tables 8 and 9.

Table 8. Preoperative WOMAC and SF-12 scores according to patient's education level

	Preoperative: Level of Education						
	Low §			High			
WOMAC scores	Md*	Mean ± SD	CI**	Md*	Mean ± SD	CI**	P value
Pain	50	51.41 ± 18.05	[48.84; 53.99]	55	56.84 ± 17.42	[53.44; 60.25]	0.010
Stiffness	50	51.78 ± 24.49	[48.28; 55.27]	50	51.13 ± 23.39	[46.56; 55.70]	0.896
Function	41	44.75 ± 19.14	[42.02; 47.48]	53	53.77 ± 16.30	[50.02; 56.39]	<0.001
Total	45	46.77 ± 17.53	[44.27; 49.28]	55	53.62 ± 15.03	[50.68; 56.56]	<0.001
<b>SF-12</b>							
PCS	33.24	33.43 ± 7.77	[32.32; 34.54]	33.47	34.54 ± 7.94	[32.99; 36.09]	0.246
MCS	46.61	46.31 ± 10.06	[44.87; 47.74]	45.82	45.83 ± 10.80	[43.72; 47.94]	0.703

\* – Median; \*\* - 95% confidence interval PCS – physical health score MCS – mental health score §Elementary or less.

Table 9. WOMAC and SF-12 score change according to patient's education

	Difference: Level of Education						
	Low §			High			
WOMAC scores	Md*	Mean ± SD	CI**	Md*	Mean ± SD	CI**	P value
Pain	40	39.11 ± 18.00	[36.54; 41.68]	35	34.27 ± 18.95	[30.57; 37.98]	0.032
Stiffness	38	37.57 ± 24.04	[34.14; 41.00]	38	40.17 ± 24.20	[35.44; 44.90]	0.415
Function	43	41.30 ± 19.23	[38.55; 44.04]	34	33.56 ± 18.55	[29.94; 37.19]	0.001
Total	42	40.57 ± 17.71	[38.05; 43.10]	36	34.53 ± 17.11	[31.19; 37.88]	0.006
<b>SF-12</b>							
PCS	11.66	11.31 ± 7.52	[10.24; 12.39]	11.25	10.87 ± 10.07	[8.90; 12.84]	0.696
MCS	1.91	3.24 ± 8.44	[2.03; 4.44]	2.96	3.23 ± 10.62	[1.15; 5.31]	0.825

\* – Median; \*\* - 95% confidence interval PCS – physical health score MCS – mental health score §Elementary or less.

Socialy supported patients demonstrated better general physical function ( $p=0.008$ ) one year after TKA according to SF-12. The results are shown in table 10.

Table 10. Postoperative WOMAC and SF-12 scores according to patient's social support

	Postoperative: Social support						
	Yes			No			
WOMAC scores	Md <sup>*</sup>	Mean ± SD	CI <sup>**</sup>	Md <sup>*</sup>	Mean ± SD	CI <sup>**</sup>	P value
Pain	95	91.10 ± 8.98	[89.85; 92.35]	95	89.95 ± 11.42	[87.61; 92.29]	0.874
Stiffness	94	90.19 ± 13.46	[88.31; 92.06]	88	89.71 ± 12.77	[87.10; 92.33]	0.601
Function	88	87.16 ± 9.53	[85.83; 88.49]	88	84.47 ± 12.28	[81.95; 86.98]	0.164
Total	90	88.34 ± 9.12	[87.06; 89.61]	89.50	86.13 ± 11.07	[83.86; 88.40]	0.184
SF-12							
PCS	46.47	45.76 ± 6.87	[44.81; 46.72]	44.01	43.31 ± 8.27	[41.62; 45.00]	0.008
MCS	49.72	49.31 ± 7.44	[48.27; 50.35]	49.36	49.51 ± 7.60	[47.95; 51.06]	0.833

\*– Median; \*\* - 95% confidence interval PCS – physical health score MCS – mental health score

The cohort's preoperative WOMAC scores according to BMI are presented in Table 11. Patients with  $BMI \geq 35\text{kg}/\text{m}^2$  (group III) had significantly worse preoperative WOMAC pain and function scores compared to patients with  $BMI < 30\text{kg}/\text{m}^2$  (group I) ( $p=0.002$ ) and  $BMI = 30-34.9\text{kg}/\text{m}^2$  (group II) ( $p=0.010$ ) ( $p=0.033$ ). Patients with  $BMI < 30$  (group I) demonstrated better physical function than patients with  $BMI = 30-34.9$  (group II) ( $p=0.035$ ) and with  $BMI \geq 35$  (group III) ( $p=0.034$ ) according to SF-12.

Table 11. Preoperative WOMAC and SF-12 scores according to patient's BMI

	Preoperative: BMI							
	<30 (I)			≥35 (III)				
WOMAC scores	Md*	Mean ± SD	CI**	Md* Mean ± SD	CI**	Md* Mean ± SD	CI**	P value
Pain	55	56.23 ± 18.26	[52.64; 59.81]	55 54.79 ± 7.79	[51.14; 58.43]	45 48.88 ± 17.21	[45.43; 52.33]	Ivs.II 0.540 Ivs.III 0.002 IIVs.III 0.010
Stiffness	50	52.58 ± 23.58	[47.95; 57.21]	50 55.44 ± 3.83	[50.56; 60.32]	38 46.75 ± 24.25	[41.89; 51.61]	Ivs.II 0.459 Ivs.III 0.088 IIVs.III 0.019
Function	53	51.17 ± 20.13	[47.21; 55.12]	49 48.77 ± 7.92	[45.10; 52.44]	41 43.10 ± 16.77	[39.74; 46.46]	Ivs.II 0.361 Ivs.III 0.002 IIVs.III 0.033
Total	53	52.26 ± 18.25	[48.78; 55.95]	49 50.46 ± 6.24	[47.13; 53.78]	44 44.62 ± 15.45	[41.52; 47.72]	Ivs.II 0.426 Ivs.III 0.001 IIVs.III 0.016
SF-12								
PCS	34.68	35.35 ± 7.83	[33.82; 36.89]	33.09 32.99 ± 8.01	[31.35; 34.64]	32.74 33.01 ± 7.49	[31.51; 34.52]	Ivs.II 0.035 Ivs.III 0.034 IIVs.III 0.986
MCS	47.48	47.29 ± 9.35	[45.46; 49.13]	46.35 46.30 ± 0.54	[44.14; 48.46]	45.19 44.78 ± 10.61	[42.58; 46.98]	0.223

\* – Median; \*\* – 95% confidence interval PCS – physical health score MCS – mental health score BMI – body mass index

Patients with  $\text{BMI} \geq 35$  (group III) improved more than patients with  $\text{BMI} < 30$  (group I) according to WOMAC pain domain change score ( $p=0.025$ ) and more than patients with  $\text{BMI} < 30$  (group I) ( $p=0.010$ ) and with  $\text{BMI} = 30-34.9$  (group II) ( $p=0.025$ ) according to WOMAC function domain change score. Results are shown in table 12. Patients from all three BMI groups demonstrated similar WOMAC and SF-12 results one year after TKA.

There were no differences in WOMAC and SF-12 preoperative, postoperative and change scores between groups stratified according to place of residence and co-morbidities according to Charnley. Patients with Ahlback knee osteoarthritis grades III ( $p=0.010$ ) and IV ( $p=0.022$ ) improved more than patients with grade I according to SF-12 physical score change.

Table 12. WOMAC and SF-12 change score according to patient's BMI

	Difference: BMI									
	<30 (I)			30-34.9 (II)			≥35 (III)			
	Md*	Mean ± SD	CI**	Md*	Mean ± SD	CI**	Md*	Mean ± SD	CI**	P value
WOMAC scores										
Pain	35	35.20 ±18.10	[31.64; 38.75]	35	35.85 ±18.37	[32.09; 39.61]	45	41.22 ±18.47	[37.52; 44.93]	Ivs.II Ivs.III Ivs.III
Stiffness	38	38.79 ±23.25	[34.23; 43.36]	37	34.53 ±24.38	[29.54; 39.53]	38	41.95 ±24.35	[37.07; 46.84]	Ivs.II Ivs.III Ivs.III
Function	32.50	35.97 ±18.60	[32.32; 39.62]	37.5	36.81 ±20.17	[32.68; 40.94]	44	43.02 ±18.62	[39.29; 46.75]	Ivs.II Ivs.III Ivs.III
Total	36	36.10 ±16.91	[32.78; 39.42]	38	36.59 ±18.36	[32.83; 40.35]	44.50	42.70 ±17.29	[39.24; 46.17]	Ivs.II Ivs.III Ivs.III
SF-12										0.016
PCS	9.42	9.90 ±7.80	[8.37; 11.43]	11.77	11.83 ±9.41	[9.90; 13.76]	12.88	11.83 ±8.16	[10.19; 13.46]	0.180
MCS	2.39	2.84 ±7.73	[1.32; 4.36]	2.11	2.44 ±10.32	[0.33; 4.55]	2.06	4.41 ±9.58	[2.48; 6.33]	0.626

\* - Median; \*\* - 95% confidence interval PCS – physical health score MCS – mental health score

## 4.2. Preoperative predictors of WOMAC pain and function score change

The multiple linear regression models are presented in tables 13-14.

Table 13. Preoperative predictors of postoperative WOMAC pain status

Change WOMAC pain			
	Coef	95% CI	p-value
Age	-0.06	-0.21; 0.09	0.466
Sex			
Male	Ref.		
Female	-1.35	-4.50; 1.80	0.400
BMI	-0.04	-0.24; 0.16	0.697
Social support			
No	Ref.		
Yes	0.46	-2.07; 2.99	0.720
Level of Education			
Higher	Ref.		
Lower	-0.37	-2.80; 2.05	0.762
Residence			
Urban	Ref.		
Rural	0.96	-2.07; 3.99	0.532
Preop. WOMAC pain	-0.90	-0.97; -0.83	<0.001
Charnley class			
A	Ref.		
B	-0.94	-3.73; 1.86	0.511
C	-1.46	-5.34; 2.42	0.459
AHLBACK			
1+2	Ref.		
3+4	1.19	-1.09; 3.47	0.305
SF-12			
Preop. PCS	0.10	-0.06; 0.26	0.205
Preop. MCS	0.10	-0.01; 0.22	0.080

Table 14. Preoperative predictors of postoperative WOMAC functional status

Change WOMAC function			
	Coef	95% CI	p-value
Age	-0.13	-0.29; 0.03	0.113
Sex			
Male	Ref.		
Female	-2.35	-5.70; 0.99	0.167
BMI	-0.05	-0.26; 0.16	0.652
Social support			
No	Ref.		
Yes	1.74	-0.95; 4.42	0.204
Level of Education			
Higher	Ref.		
Lower	-0.62	-3.24; 2.00	0.642
Residence			
Urban	Ref.		
Rural	1.28	-1.93; 4.49	0.433
Preop. WOMAC function	-0.93	-1.01; -0.85	<0.001
Charnley class			
A	Ref.		
B	-1.95	-4.92; 1.03	0.198
C	-1.83	-5.94; 2.28	0.382
AHLBACK			
1+2	Ref.		
3+4	0.62	-1.81; 3.05	0.614
SF-12			
Preop. PCS	0.09	-0.08; 0.26	0.302
Preop. MCS	0.14	-0.01; 0.26	0.034

The preoperative WOMAC pain score was the strongest determinant of the postoperative WOMAC pain score in one year ( $p<0.001$ ).

The preoperative WOMAC function ( $p<0.001$ ) and SF-12 mental health scores ( $p=0.034$ ) were the strongest determinants of the WOMAC function score in one year after TKA.

### 4.3. Responders to TKA

Patients stratified into 3 groups according to OMERACT-OARSI set of responder criteria (table 15).

Table 15. Patients according to response to TKA and their preoperative WOMAC score

		Total (n=294)
Responder	Number (%)	Preop. WOMAC global mean (SD)
No	31 (10.5)	72 (15)
Medium	38 (12.9)	68 (7)
Response	225 (76.5)	43 (13)

We put together in one group responders and medium responders according to OMERACT-OARSI.

Responders and nonresponders to TKA stratified into three groups according to WOMAC pain and function baseline severity tertiles. The results are demonstrated in table 16.

Table 16. Responders and nonresponders according to WOMAC baseline severity tertiles

Responder	Preop. WOMAC pain			Preop. WOMAC function		
	<35 (low)	35-55 (medium)	>55 (high)	<32 (low)	32-45.5 (medium)	>45.5 (high)
Yes	12.9%	54.0%	33.1%	20.9%	31.6%	47.5%
No	0%	16.1%	83.9%	0%	9.7%	90.3%

## **5. CONCLUSIONS**

- 1.1. Preoperatively men demonstrated better WOMAC knee pain, function and SF-12 mental function scores than women.

Older patients demonstrated better WOMAC knee pain and SF-12 mental scores.

Patients with high education demonstrated better WOMAC knee pain and function scores.

Less obese patients demonstrated better WOMAC knee pain, function and SF-12 physical function scores.
- 1.2. One year after TKA men demonstrated better than woman WOMAC knee pain, function and better SF-12 physical and mental function scores.

Socially supported patients demonstrated better SF-12 physical function score.
- 1.3. Women demonstrated higher WOMAC pain score change than men.

Younger patients demonstrated higher WOMAC pain and SF-12 mental higher WOMAC pain and function score change. Patients with end stages of osteoarthritis according to Ahlback demonstrated higher SF-12 physical function score change.
2. The preoperative WOMAC pain score was the strongest determinant of the postoperative WOMAC pain score one year after TKA.

The preoperative WOMAC function and SF-12 mental health scores were the strongest determinants of the WOMAC function score one year after TKA.

Lower preoperative knee pain, function scores and better mental health function results in greater change.
3. Eleven percent (11 %) of patients experienced no improvement in pain and function one year after surgery. Most of them did demonstrated high WOMAC pain and function scores before surgery.

## **6. PRACTICAL RECOMMENDATIONS**

1. PROM data should be collected before surgery.
2. In order to create realistic patient expectations before the surgery take measures to identify those patients who are at high risk of experiencing no improvement in knee pain and function. Outcomes could be improved for a majority of patients by addressing identified risk factors before TKA.
3. Consider before TKA taking pro-active therapeutic measures for patients identified with depression.
4. One year after TKA identify non-responders using PROM's and invite them for thorough clinical and radiographic examination.

## **7. LIST OF PUBLICATIONS ON THE TOPIC OF THE DISSERTATION**

1. The main characteristics of the patients hospitalized for the knee joint endoprosthesis due to knee primary osteoarthritis (Medicinos teorija ir praktika, 2015)
2. Influence of preoperative knee function on TKA results (Laboratorinė medicina, 2016)
3. Age, sex, body mass index, education and social support influence functional results after total knee arthroplasty (Geriatric Orthopaedic Surgery and Rehabilitation, 2016)

## **8. LIST OF PRESENTATIONS ON THE TOPIC OF THE DISSERTATION**

1. Total knee arthroplasty in the elderly (The 8<sup>th</sup> Morphology Scientific Conference 2015)
2. Influence of preoperative factors on TKA outcome (The 13-th congress of Lithuanian society of orthopaedic and trauma surgeons, 2016)
3. What do surgeons know about evolution? (3-rd international congress of evolutionary medicine, 2016)
4. Influence of patient factors on the TKA outcomes at 12 month follow-up (Nordic Orthopaedic Federation congress 2016)
5. How does gender and socioeconomic status affect patients self evaluation before and after TKA? (EFORT 17<sup>th</sup> Annual congress, 2016)

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- Member of the Lithuanian Joint Replacement Society
- Member of Lithuanian Society of Foot and Ankle Surgeons
- Member of European Society of Foot and Ankle Surgeons

## **12. RESUME IN LITHUANIAN**

### **Įvadas.**

Kelio sąnario osteoartritas (OA) yra viena iš dažniausių žmonių neįgalumo priežasčių išsivysčiusiose šalyse. Dauguma osteoartritu sergančių pacientų yra vyresnio amžiaus ir moterys serga dažniau nei vyrai. Vėlyvoje osteoartito stadijose, kada konservatyvus gydymas, tai yra reabilitacija bei medikamentinis gydymas tampa nebe efektyvus, atliekama kelio sąnario endoprotezavimo operacija. Ilgėjant gyvenimo trukmei didėja kelio sąnario osteoartrito paplitimas, taigi auga kelio sąnario endoprotezavimo operacijų skaičius. Nepaisant evoliucijos medicinoje, tai yra pažangos chirurginėje technikoje, anesteziologijoje, pooperacinėje priežiūroje, reabilitacijoje, implantų dizaine, literatūros duomenimis iki 20 procentų pacientų išlieka nepatenkinti pooperacioniais kelio sąnario endoprotezavimo rezultatais. Įvairūs veiksniai daro įtaką pooperacioniam rezultatui. Dažnai neužtenka klinikinio ištyrimo ar rentgenografinio bei kompiuterinės tomografijos tyrimų, kad nustatyti nepatenkinamo pooperacionio rezultato priežastį. Pacientų savęs vertinimo klausimynai (PROMs) tapo labai svarbiu įrankiu pooperacioniam rezultatui vertinti.

### **Tyrimo tikslas.**

Įvertinti priešoperaciinių paciento veiksnį įtaką rezultatams po kelio sąnario endoprotezavimo, naudojant savęs vertinimo klausimynus.

### **Tyrimo uždaviniai.**

- 1.1. Įvertinti priešoperacinį kelio sąnario skausmą, funkciją, bendrą paciento fizinę ir psichinę sveikatą bei rezultatus palyginti tarp pacientų grupių, sudarytų pagal sociodemografinius veiksnius.

- 1.2. Ivertinti pooperacinių kelio sąnario skausmą, funkciją, bendrą paciento fizinę ir psichinę sveikatą bei rezultatus palyginti tarp pacientų grupių, sudarytų pagal sociodemografinius veiksnius.
- 1.3. Ivertinti kelio sąnario skausmo, funkcijos, bendros paciento fizinės ir psichinės sveikatos pokyčius per pirmus metus po kelio sąnario endoprotezavimo bei rezultatus palyginti tarp pacientų grupių, sudarytų pagal sociodemografinius veiksnius.
2. Nustatyti priešoperacinius paciento veiksnius, kurie daro didžiausią įtaką kelio sąnario skausmo ir funkcijos kitimui per 12 mėnesių po kelio sąnario endoprotezavimo.
3. Nustatyti nepatenkintus kelio sąnario endoprotezavimo rezultatais pacientus, naudojant savęs vertinimo klausimynus.

### **Ligonai ir tyrimo metodika.**

2012–2014 metais Respublikinės Vilniaus universitetinės ligoninės ortopedijos ir traumatologijos centre buvo atliktas perspektyvusis tyrimas, į kurį įtraukta 314 pacientų, atvykusiu pirminei kelio sąnario endoprotezavimo operacijai. Tyrimui atlikti gautas Lietuvos bioetikos komiteto leidimas.

Surinkti pacientų duomenys; tai yra amžius, lytis, išsilavinimas, socialinė aplinka, gyvenamoji vieta, ūgis, svoris. Pagal ūgi ir svorį apskaičiuotas kūno masės indeksas (KMI). Pagal KMI pacientai suskirstyti į grupes : I ( $KMI < 30$ ), II ( $KMI = 30-34,9$ ), III ( $KMI \geq 35$ ). Pacientų mobilumas vertintas pagal Charnley A, B, C klasses. Visiems pacientams atliktos 2-ų krypčių kelio sąnario rentgenogramos ir nustatyta viena iš keturių osteoartrito stadija pagal Ahlback. Pagal amžių pacientai skirstyti į 2 grupes ( $< 75$  ir  $\geq 75$ ), pagal išsilavinimą į turinčius aukštajį išsilavinimą ir žemesnį nei aukštasis. Pacientai skirstyti į miesto ir kaimo gyventojus pagal gyvenamąją vietą. Pagal socialinę aplinką pacientai skirstyti į dvi grupes: I. Gyvena su šeimos nariais ir II. Gyvena vieni.

Pacientai užpildė validuotus ir originaliai išverstus į lietuvių kalbą WOMAC ir SF-12 klausimynus. WOMAC yra ligai specifinis klausimynas. Jis skirtas vertinti paciento sergančio osteoartritu kelio sąnario būklę.

SF-12 klausimynas skirtas vertinti bendrą paciento sveikatą. Visiems pacientams endoprotezuoti kelio sąnariai, naudojant cementinio tvirtinimo pirminius endoprotezus nekeičiant girnelės. 1-ą pooperacinę dieną pradėtas reabilitacinis gydymas. Ligoninėje pacientai gydyti nuo 5 iki 7 dienų. Gydymas tėstas reabilitacijos ligoninėje.

Po 1 metų po operacijos pacientai pakartotinai užpildė WOMAC ir SF-12 klausimynus. Palygintas kelio sąnario skausmas, funkcija bei bendra pacientų fizinė ir psichinė sveikata tarp pacientų grupių, sudarytų pagal priešoperacinus sociodemografinius veiksnius, nustatyti pacientų priešoperacioniai veiksnių, kurie darė didžiausią įtaką kelio sąnario skausmo ir funkcijos kitimui per pirmus metus po kelio sąnario endoprotezavimo bei nustatyti pacientai, kurie po metų išliko nepatenkinti kelio sąnario endoprotezavimo rezultatais, naudojant OMERACT-OARSI kriterijus.

## **Rezultatai ir išvados.**

- 1.1. Prieš operaciją vyrai geriau nei moterys vertino kelio sąnario skausmą ( $p=0,001$ ) ir funkciją ( $p=0,002$ ) pagal WOMAC.

Vyresni pacientai geriau vertino kelio sąnario skausmą ( $p=0,035$ ) pagal WOMAC ir bendrą psichinę sveikatą pagal SF-12 ( $p=0,023$ ).

Pacientai, turintys aukštajį išsilavinimą geriau vertino kelio sąnario skausmą ( $p=0,010$ ) ir funkciją ( $p<0,001$ ) pagal WOMAC. Pacientai, kurių mažesnis kūno masės indeksas I grupė ( $<30$ ) ir II grupė (30-34,9), geriau vertino kelio sąnario skausmą ( $p=0,002$ ) ( $p=0,010$ ) ir funkciją ( $p=0,002$ ) ( $p=0,033$ ) nei pacientai iš III ( $\geq 35$ ) grupės pagal WOMAC. Pacientai, kurių mažesnis kūno masės indeksas I grupė ( $<30$ ) geriau vertino bendrą fizinę sveikatą nei pacientai iš II (30-34,9) ( $p=0,035$ ) ir III ( $\geq 35$ ) ( $p=0,034$ ) grupių pagal SF-12.

- 1.2. Vieneri metai po kelio sąnario endoprotezavimo vyrai geriau nei moterys vertino kelio sąnario skausmą ( $p=0,023$ ), funkciją ( $p=0,005$ ) pagal WOMAC ir bendrą fizinę ( $p=0,049$ ) ir psichinę sveikatą ( $p=0,020$ ) pagal SF-12.
- Pacientai gaunantys socialinę pagalbą vieneri metai po kelio sąnario endoprotezavimo geriau vertino bendrą fizinę sveikatą pagal SF-12 ( $p=0,008$ ).
- 1.3. Per pirmus metus po kelio sąnario endoprotezavimo moterys patyrė didesnį kelio sąnario skausmo sumažėjimą negu vyrai vertinant WOMAC pooperacinių ir priešoperacinių reikšmių skirtumą ( $p=0,011$ ).
- Jaunesni pacientai demonstravo didesnį skausmopagal WOMAC ( $p=0,011$ ) ir psichinės sveikatos pokytį pagal SF-12 ( $p=0,040$ ).
- Pacientai, kurių kūno masės indeksas  $\geq 35$  (III grupė) demonstravo didesnį skausmo pokytį nei pacientai kurių KMI  $<30$  (I grupė) ( $p=0,025$ ) ir didesnį kelio sąnario funkcijos pokytį nei pacientai kurių KMI $<30$  (I grupė) ( $p=0,010$ ) ir kurių KMI=30-34,9 (II grupė) ( $p=0,025$ ). Mažiau išsilavinę pacientai demonstravo didesnį skausmo ( $p=0,032$ ) ir funkcijos ( $p=0,001$ ) pokytį pagal WOMAC nei turintys aukštajį išsilavinimą. Pacientai kuriems diagnozuotos III ir IV stadijos kelio osteoartritas pagal Ahlback demonstravo didesnį bendros fizinės sveikatos pagerėjimą pagal SF-12 lyginant su pacientais, kuriems diagnozuotas I-os stadijos osteoartritas pagal Ahlback ( $p=0,010$ ) ( $p=0,022$ ).
2. Priešoperacinis kelio sąnario skausmas pagal WOMAC daro didžiausią įtaką skausmo pokyčiui per pirmus metus po kelio sąnario endoprotezavimo ( $p<0,001$ ). Priešoperacinė kelio sąnario funkcija pagal WOMAC ( $p<0,001$ ) ir bendra psichinė sveikata pagal SF-12 ( $p=0,034$ ) daro didžiausią įtaką kelio sąnario funkcijos pokyčiui.
- Prastesnis prieš operacinis kelio sąnario skausmo ir funkcijos vertinimas pagal WOMAC ir geresnė psichinė sveikata pagal SF-12 daro įtaką didesniams skausmo ir funkcijos pagerėjimui per pirmuosius pooperacionius metus.
3. Vertinant kelio sąnario skausmo ir funkcijos pokytį per pirmus pooperacionius metus ir taikant OMERACT-OARSI vertinimo kriterijus, vienuolika procentų pacientų buvo nepatenkinti kelio sąnario endoprotezavimo rezultatu. Dauguma

pacientų, kurie išliko nepatenkinti pooperaciniu rezultatu, labai gerai vertino kelio sąnario skausmą ir funkciją pagal WOMAC prieš operaciją. 84 proc. iš jų priešoperacinį kelio sąnario skausmą vertino daugiau nei 55 balais ir 90 proc. kelio sąnario funkciją vertino daugiau nei 45,5 balais pagal WOMAC.

### **13. TRUMPA INFORMACIJA APIE AUTORIŪ**

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<b>Išsilavinimas</b>	
- 1977-1988	Kauno J. Jablonskio vidurinė mokykla
- 1989-1995	Lietuvos sveikatos mokslų universitetas
- 1995-1996	Pirminė rezidentūra Vilkaviškio rajono ligoninėje
- 1996-2000	Ortopedijos traumatologijos rezidentūra Vilniaus Universitete
<b>Darbopatirtis</b>	
-2000-2003	Vilniaus Šv. Jokūbo ligoninė, gydytojas ortopedas traumatologas
-Nuo 2003	Respublikinė Vilniaus Universitetinė Ligoninė, gydytojas ortopedas traumatologas
-Nuo 2005	Baltijos ir Amerikos klinika, gydytojas ortopedas traumatologas
-Nuo 2013	Vilniaus miesto klinikinė ligoninė, gydytojas ortopedas traumatologas

### **Narystė**

- Lietuvos traumatologų ortopedų draugija
- Lietuvos sąnarių endoprotezuotojų asociacija
- Lietuvos pėdos chirurgijos draugija
- Europos pėdos ir čiurnos chirurgų draugija