

BIENNIAL REPORT

2009-2010



Sint Maartenskliniek
RD&E

Sint Maartenskliniek Research, Development and Education

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SINT MAARTENSKLINIEK RESEARCH, DEVELOPMENT AND EDUCATION

General introduction

Although Research has always been a part of the core-business of the St. Maartenskliniek, in 2010 it has been 5 years that the “new” Department of Research, Development & Education has come into existence. A 5 years term is usually the rise for looking back. In the period 2005-2010 a boost of initiatives is seen to ground interventions on a solid scientific basis. This is reflected in the number and quality of publications.

In this same period, the field of healthcare itself has changed also. In the former Biennial there was a prelude to this. With the effects of the recent economical crisis still present, developments are accelerated. Insurance companies and governmental agencies stress the unbearable growth of costs in healthcare in future even more. One of the foreseen remedies is a total reorganization of the healthcare system in which specialization in service delivery is the main topic. For the St. Maartenskliniek this implies further specialization and concentration on its core-business. Specialization implies research and market leadership.

By now, it is common practice that each and every general hospital provides a broad range of health care services no matter costs involved. In near future, it is foreseen that general hospitals will need to choose which services they will offer based on economical considerations and proven expertise.

On the other hand, specialized hospitals need to grow and to combine research, education and vocational training for all health professionals. Thus, this development provides opportunities for research to grow. However, insurances companies and the government need to understand that in such a system, costs involved with research and development become more visible and concentrated. As long as “evidence based medicine” is requested and is used to weed out ineffective interventions from healthcare, costs of services will rise in specialized hospitals.

Therefore, looking back, we might conclude that the St. Maartenskliniek, has placed itself in a favorable position to grow and specialize further by investing in Research and Research infrastructure in the past 5 years.

We hope that the results of research may inspire all who are interested and hope that they will be incorporated in regular medicine. Therefore we invite everyone to use and copy all that is in this Biennial and contact our staff with any question they might have to spread the results.

Kind regards,

Jacques van Limbeek MD, PhD, MMI

Epidemiologist

Director of the Department of Research, Development & Education

St. Maartenskliniek, Nijmegen

MOVEMENT ANALYSIS LABORATORY

Introduction

The Sint Maartenskliniek is a specialized hospital for disorders of posture and movement and for behavioral dysfunctions as a result of brain damage. For a better and successful treatment and therapy for patients in the Sint Maartenskliniek a detailed analysis of posture and movement is required. Our movement analysis laboratory provides additional and detailed information of posture and movement to our clinicians.

Many of the information obtained in our movement analysis laboratory cannot be seen by the clinician's eye. For example, we can measure the force and pressure under the foot and muscle activity (EMG) during walking. All the information is presented with respect to data of healthy control subject so that clinicians can directly visualize abnormalities. Hence, the detailed information helps clinicians to diagnose the exact problem or helps to evaluate the effectiveness of a treatment or therapy.

In 2008 a lab coordinator was appointed and together with a staff of six special trained physiotherapists she conducts the clinical (gait) assessments. The lab coordinator takes care of the measurements and provides the detailed information to the clinicians.

In addition to clinical assessments, the lab is also used for research on the human motor control.

EQUIPMENT

- Vicon system for 3D motion analysis
- Zerowire 16 channel electromyography (EMG) system
- Cosmed fitmate pro Cardio Pulmonary Exercise Testing
- Force plates (Kisler, Bertec, AMTI) to measure the forces applied to the ground
- RsScan pressure platform to measure plantar pressure
- Precision 3D photo scanner to acquire the 3D plantar foot shape

Many of these systems can be used at the same time. For example, the Vicon system can be combined with EMG, force plates, accelerometers and goniometers. Gait assessments are performed during over ground locomotion and/ or treadmill walking. A large sized treadmill is used for the measurement of O₂ uptake capabilities of spinal cord injured persons during wheelchair propulsion. In addition to the conventional equipment of movement analysis laboratory, we also develop equipment and assessment methods for our PhD projects. The experimental setups for the evaluation of sitting and standing balance performance are successful examples.

COLLABORATION

Our laboratory works in close collaboration with the laboratory of the Department of Rehabilitation Medicine of the Radboud University Medical Centre Nijmegen.

1

REHABILITATION STUDIES

The rehabilitation studies conducted in Nijmegen can best be described as follows:

“Research directed toward exploring and studying ways to influence central adaptation and compensation processes that form the physiological and neuropsychological basis for functional recovery” after neurological insult. The studies have an applied clinical character and are generally conducted within the Rehabilitation Center at the Sint Maartenskliniek. Occasionally, more fundamental investigations may be initiated. In these studies Research, Development & Education cooperates with the department of rehabilitation at the University Medical Center Sint Radboud.

Rehabilitation in Nijmegen has been set up as a network. One rehabilitation staff, comprising personnel of the Sint Maartenskliniek, the University Medical Center Sint Radboud, the Canisius Wilhelmina Hospital as well as the Rivierland Hospital in Tiel and the Maas Hospital in Boxmeer, provides the health care. Parallel to this patient care, health care research is performed within the network. The main goal of this research is to answer hypotheses arising from clinical practice, through patient-oriented research into the mechanisms of adaptation and compensation after neurological damage. Moreover, the effectiveness of clinical care processes and treatments aimed at fostering adaptation and compensation is evaluated. The findings may lead to new clinical treatments or to modifications of existing treatments.

All publications not linked to major research lines, can be found in the total output list at the end of the report.

1.1 COGNITIVE REHABILITATION

Cognitive disorders after brain injury constitute a serious obstacle to rehabilitation. They lead to significant functional impairments, interfere with the quality of life of brain-injured survivors, and add to caregivers burden. Therefore, the treatment of cognitive disorders is of paramount importance in rehabilitation. This had led to the development of several treatment methods in the field of "cognitive rehabilitation". Clinically, cognitive rehabilitation is a process whereby brain injured people work together with health professionals to remediate or alleviate cognitive deficits arising from neurological insult (B. Wilson, 1996). This comprehensive definition of cognitive rehabilitation characterizes the subject of investigation of this research line. Herein, the evaluation of treatment methods for cognitive deficits in the domains of executive functioning, perception, memory, mental speed and sustained mental effort is undertaken. In every domain, review studies are performed and new, cutting-edge training methods are given to groups of brain-injured patients, and their effectiveness is investigated in randomized controlled trials. If these trials require the development of novel assessment instruments, new tests, observation scales and questionnaires are also developed and evaluated. The research line also comprises research into neuropsychiatric disturbances (in particular depression) that are frequently observed following brain lesions. These disturbances in neurological patients present unique challenges, when related to the specificity of the population studied. The evaluation of assessment as well as treatment methods for these neuropsychiatric disturbances in neurological patients is also a main objective of this research line.

AUGMENTED COGNITIVE BEHAVIOURAL THERAPY IN POST-STROKE DEPRESSION AND ANXIETY

PERIOD	2010-2014		
PARTICIPANTS	J. Kootker A. Geurts L. Fasotti S. Rasquin C. van Heugten	UMCN UMCN/SMK SMK/DCC Adelante Maastricht University	Neuropsychologist, Researcher Physiatrist Neuropsychologist Neuropsychologist Neuropsychologist
SPONSOR	ZonMW, Restore 4 Stroke program		
PURPOSE	In the present project a rehabilitation protocol for post stroke depression and anxiety (PSDA) will be developed. This protocol will be tested on its' effectiveness. The global aim of the present study is to provide a standardized, augmented cognitive behavioral treatment for depression and anxiety symptoms after stroke. This treatment is aimed at reducing depression and anxiety symptoms, increasing activities, attaining personal goals and preventing the relapse of symptoms.		
METHODOLOGY	A multicentre randomized controlled trial will be performed. Two groups of stroke patients will be formed (total n=106). Patients will be randomly assigned to either the augmented CBT intervention, or a computerized cognitive training intervention. Outcome measures will be anxiety and depression symptoms (primary), quality of life, goal attainment scaling, participation in social activities and life satisfaction. Assessment of these parameters will take place before the start of the treatment, directly after treatment and at 6 and 12 months follow up.		
PROGRESS	Currently the treatment protocol development is in its final stages. Furthermore, medical ethical approval has been applied for. Next to that, participating centers will be recruited.		
RESULTS	The first preliminary results are expected at the end of 2012.		
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ERRORLESS LEARNING IN GOAL MANAGEMENT TRAINING

PERIOD	2010-2014		
PARTICIPANTS	D. Bertens	DCC	Student Neuro- & Rehabilitation Psychology
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	R. Kessels	DCC/UMCN	Clinical Neuropsychologist
	D. Boelen	SMK/UMCN	Psychologist
SPONSOR	Nationaal Initiatief Hersenen en Cognitie (National Initiative Brain and Cognition)		
PURPOSE	<p>Many brain-injured patients referred for outpatient rehabilitation have difficulties with planning, problem-solving and reasoning. Goal management training (GMT) is a successful treatment for these problems. It entails learning and applying an algorithm, in which a daily task is subdivided into multiple steps. Main aim of the present study is to examine if using an errorless learning (EL) approach (preventing the occurrence of errors) contributes to the efficacy of GMT in the execution of IADL tasks.</p>		
METHODOLOGY	<p>The study is set up as a double blind randomized controlled trial, in which the efficacy of GMT with an EL approach (GMT+EL) will be compared with standard GMT (without EL). In both the GMT+EL and the standard GMT conditions a group of 30 patients will be examined. Main outcome measure will be the performance in 2 individually chosen IADL tasks before and after treatment, using a standardized scale and a goal attainment scale.</p>		
PROGRESS	<p>Currently, an application for the ethics committee approval is being written. The editing of the treatment protocol is in a final stage.</p>		
RESULTS	<p>First preliminary results are expected in 2012.</p>		
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EFFECTIVENESS OF COGNITIVE AND GRADED ACTIVITY TRAINING ON POST-STROKE FATIGUE. A MULTI-CENTER STUDY

PERIOD	2007-2011		
PARTICIPANTS	L. Fasotti A. Geurts A. Zedlitz	SMK/RU UMCN/SMK RU/SMK	Neuropsychologist Physiatrist Neuropsychologist
SPONSOR	ZonMw		
PURPOSE	<p>Excessive fatigue after stroke is a common and chronic complaint with estimated prevalence rates between 28-73% even in stroke patients who seem to recover well. This may lead to impairments in daily functioning. And up to date no evidence based treatments are available. In the Sint Maartenskliniek, a pilot study on a treatment yielded positive results on fatigue and psychological distress after treatment. The purpose of this study was therefore to qualitatively adapt the protocol and evaluate the cognitive treatment with and without Graded Activity Training in a randomized multi-center trial.</p>		
METHODOLOGY	<p>In a multi-center trial 96 stroke patients will participate in this waiting-list controlled randomized controlled trial. Each patient will be submitted to a first measurement at admission. Then, every patient will be placed on a waiting list for three months (the so-called qualification period) and a second measurement will take place, just before random assignment to one out of two treatment conditions: (a) the full COGRAT training, (b) the cognitive part of COGRAT only. At the end of treatment, and 6 months after the end of treatment (follow-up) every participant will be assessed again.</p> <p>The assessments comprise fatigue complaints lists, registrations of physical activity (with actometers), neuropsychological tests, and psychosocial questionnaires on coping, attributions, self-efficacy, and social support.</p>		
PROGRESS	<p>Of the 231 patients screened, 88 completed the waiting list period. Of these patients 73 finished treatment, and follow-up measurements of 68 patients are available.</p>		
RESULTS	<p>Both treatments yielded positive results, directly after treatment and at six month follow-up. However, in the COGRAT group significantly more patients attained a clinically significant reduction of fatigue after treatment and follow-up than in the group receiving cognitive therapy alone.</p>		
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1.2 SPEECH AND LANGUAGE PATHOLOGY

The *Ontwikkelcentrum Spraak- en Taaltechnologie* (OSTT; Dutch acronym for Centre of Expertise for the Application of Speech and Language Technology in Speech and Language Pathology as well as Rehabilitation) is based on a collaboration of the Sint Maartenskliniek (Department of Research, Development, and Education), Radboud University Nijmegen (Faculty of Arts), and Radboud University Nijmegen Medical Centre (Dept. of Rehabilitation). In 2005, the OSTT was assigned the status of 'Centre of Expertise' by the Dutch Ministry of Health, Welfare and Sports (VWS).

Speech and language disorders are known to hamper people in their communication and hence, impede their participation in society. The OSTT is a centre of excellence which aims at applying speech and language technology for both general rehabilitation patients and patients with communication disabilities as a result of speech and language pathology. Within the area of speech and language technology, the OSTT aims at:

1. Conducting studies into the feasibility, efficacy and effectiveness of applications
2. Developing diagnostic and therapeutic instruments
3. Improving cooperation among stakeholders
4. Monitoring trends and new developments
5. Educating students and professionals

USING TELEHEALTH TO IMPLEMENT THE DUTCH AND ADAPTED REDUCED SYNTAX THERAPY IN CLINICAL PRACTICE

PERIOD	2010-2011		
PARTICIPANTS	P. Holtus	SMK	Speech Therapist
	H. Kolk	RU	Neuropsychologist
	J. van Limbeek	SMK	Epidemiologist
	A. Rietveld	RU/SMK	Phonetician, Statistician
	M. Ruiter	SMK/RU	Speech-Language Pathologist
SPONSOR	ZonMw		
PURPOSE	<p>The Dutch and adapted version of Reduced Syntax Therapy (REST) has been shown to improve functional communication in chronically agrammatic speakers of Dutch (Ruiter, 2008; Ruiter, Kolk, & Rietveld, 2010). REST therapy enhances a normal - but previously infrequently used - linguistic operation of the dominant hemisphere: the production of ellipses. Ellipses are syntactic frames in which slots for grammatical morphology tend to be lacking (e.g., everybody inside). In the current project, the Dutch and adapted version of Reduced Syntax Therapy will be implemented in clinical practice by means of a telehealth system.</p>		
METHODOLOGY	<p>A web-based therapy programme allows persons with aphasia to train the continuous production of ellipses independently. As a consequence, the face-to-face sessions with the speech therapist can be fully allocated to the generalization of the elliptical style to communicative settings of daily life.</p>		
PROGRESS	<p>The development of the web-based application of REST therapy is in progress. The project ends in 2011.</p>		
RESULTS	<p>Not yet available.</p>		
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PUBLICATIONS	<p>Ruiter, M.B., Kolk, H.H. and Rietveld, T.C. Speaking in ellipses: the effect of a compensatory style of speech on functional communication in chronic agrammatism. <i>Neuropsychological Rehabilitation</i> 2010; 20: 3, 423-458.</p>		

HUMAN LANGUAGE TECHNOLOGY AND COMMUNICATIVE DISABILITIES: REQUIREMENTS AND POSSIBILITIES FOR THE FUTURE

PERIOD	2008-2010		
PARTICIPANTS	M. Ruiter	SMK/RU	Speech-Language Pathologist
	D. Lembrechts	MODEM	Speech Therapist, Coordinator
	H. Strik	RU	Phonetician, Speech Technologist
	T. Rietveld	SMK/RU	Phonetician, Statistician
	E. Krahmer	UVT	Scientist
	H. van Hamme	KUL	Scientist
	L. Beijer	SMK	Speech-Language Pathologist
	V. de Jong	Dedicon	Project Manager R&D
SPONSOR	Nederlandse Taalunie (Dutch Language Union)		
PURPOSE	For some years now, the Dutch Language Union has been active in promoting the development of human language technology (HLT) applications for users of Dutch with communication disabilities. The reason is that HLT products and services may enable these users to improve their verbal autonomy and communication skills. We sought to identify a minimum common set of HLT resources that is required to develop tools for a wide range of communication disabilities.		
METHODOLOGY	In order to reach this goal, we investigated the specific HLT needs of communicatively disabled people and related these needs to the underlying HLT software components. By analyzing the availability and quality of these essential HLT resources, we were able to identify which of the crucial elements need further research and development to become usable for developing applications for communicatively disabled users of Dutch.		
PROGRESS	Report in press.		
RESULTS	Although multiple-usability was used as a criterion in this study, we sought to present the results in such a way that other criteria could also be used in analyzing the results obtained.		
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PHONE NUMBER	+31 24 3659670		

AN AUDITORY DISCRIMINATION TEST (ADT) AS A PRELUDE FOR WEB BASED SPEECH THERAPY

PERIOD	2009-2010		
PARTICIPANTS	L. Beijer	SMK	Speech-Language Pathologist
	A. Rietveld	SMK/RU	Methodologist, Phonetician
	A. van Stiphout	SMK	Speech-Language Pathologist
SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>Web based speech training for adult dysarthric patients, such as E-learning based Speech Therapy (EST) puts considerable demands on auditory discrimination abilities. Despite the vital role of auditory discrimination in web based speech training, a tool that assesses this ability for speech dimensions that are considered relevant in speech training, does not exist for Dutch and most other languages. For this reason, an auditory discrimination test (ADT) was developed in order to provide a tool to establish adequate auditory speech discrimination in neurological patients as a minimum requirement for web based training.</p>		
METHODOLOGY	<p>Two studies were conducted.</p> <p>The first study concerns the development of five subtests, each addressing auditory discrimination of a relevant speech dimension: articulation, intensity (loudness), overall-pitch, speech rate and intonation. Each subtest contains 15 test items. The test was performed by 36 healthy controls. On the basis of the results test items that were considered sensitive to diminished auditory discrimination were identified.</p> <p>The second study concerns the comparison of 14 matched pairs of neurological and healthy participants. Items that did not meet the condition for sensitivity in the first study were not taken into account in the analyses.</p>		
PROGRESS	Currently a paper is completed and was submitted.		
RESULTS	<p>Neurological patients perform poorer than their matched healthy controls on all subtests: score percentages are lower and reaction times are longer, although this difference does not reach statistical significance for all subtests. Cognitive deficits and larger (neurologically induced?) hearing deficits in the neurological group might have contributed to these results.</p>		
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ORTHOGRAPHIC TRANSCRIPTION AND INTELLIGIBILITY SCALE RATINGS OF SEMANTICALLY UNPREDICTABLE SENTENCES AS A MEASURE FOR SPEECH INTELLIGIBILITY

PERIOD	2009-2010		
PARTICIPANTS	L. Beijer	SMK	Speech-Language Pathologist
	R. Clapham	SMK	Speech-Language Pathologist
	A. Rietveld	SMK/RU	Methodologist, Phonetician
SPONSOR	Sint Maartenskliniek		
PURPOSE	Evaluating the suitability of orthographic transcription and intelligibility scale ratings of Semantically Unpredictable Sentences (SUS) as a measure for speech intelligibility for clinical outcome research in dysarthric speakers with Parkinson's disease (PD).		
METHODOLOGY	<p>Two studies were conducted.</p> <p>In the first study interrater reliability for both orthographic transcription and intelligibility scale ratings of a SUS set was evaluated in ten trained listeners (speech and language pathologists). The listeners had to score ten SUS realized by a speakers with PD. Interrater reliability was adequate for orthographic transcription but not for scale ratings.</p> <p>In the second study a latin square design was employed to establish main effects for 'SUS-set', 'rater' and 'speaker'. Five speakers with PD each realized five sets of 30 SUS. Each set contained 3 different types of SUS: D6 (declarative, 6 words), D13 (declarative, 13 words), Q (questions, 6 words). The same ten listeners who participated in study 1 transcribed SUS of five speakers according to an orthogonal array design, in order to avoid learning effects. For orthographic transcription scoring in both studies a decision tree was used. Only key words (nouns, verbs, prepositions) were scored.</p>		
PROGRESS	Currently a paper is completed and was submitted.		
RESULTS	Orthographic transcription of SUS-D6 were not affected by 'rater' or 'SUS set', but were affected by 'speaker'. These results pointed out that the five developed sets of D6 sentences were equivalent with respect to potential intelligibility. In addition, D6 sentences were sensitive to degree of speech intelligibility. They were not affected by 'rater'. This combination of outcomes led to the conclusion that semantically unpredictable sentences of the D6 type is suitable for clinical outcome research. This was not the case for SUS-D13 and SUS-Q.		
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EVALUATING USER SATISFACTION OF WEB BASED SPEECH TRAINING VERSUS FACE-TO-FACE SPEECH TRAINING

PERIOD	2010-		
PARTICIPANTS	L. Beijer A. Rietveld A. Geurts	SMK SMK/RU SMK/UMCN	Speech-Language Pathologist Methodologist, Phonetician Physiatrist
SPONSOR	Sint Maartenskliniek		
PURPOSE	Evaluating user satisfaction E-learning based Speech Therapy (EST) versus face-to-face speech training in dysarthric speakers due to stroke and Parkinson’s disease. Three patient groups are involved: stroke patients in the sub acute phase, chronic stroke patients and chronic patients with Parkinson’ disease. Correlations between speech intelligibility improvement through EST and valuation of web based training will be established.		
METHODOLOGY	A split plot design with ‘patient group’ as a between-subject factor and ‘time’ as a within-subject factor is employed.		
PROGRESS	In progress.		
RESULTS	To be obtained.		
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PHONE NUMBER	+31 24 3659718		
PUBLICATIONS	<p>Beijer, L.J., Rietveld, T.C., Hoskam, V., Geurts, A.C. and De Swart, B.J. Evaluating the feasibility and the potential efficacy of e-learning-based speech therapy (EST) as a web application for speech training in dysarthric patients with Parkinson’s disease: a case study. <i>Telemedicine and e-Health</i> 2010; 16: 6, 732-738.</p> <p>Beijer.L.J., Rietveld, A.C.M., Van Beers, M., Slangen, R., Van den Heuvel, H., De Swart, B.J. M. and Geurts, A.C.H. E-learning based Speech Therapy (EST): a web application for speech training. <i>Telemedicine and e-Health</i> 2010; 16: 2, 177-180.</p> <p>Beijer.L.J., Rietveld, A.C.M., Hoskam, V., Geurts, A.C.H. and De Swart, B.J.M. Evaluating the feasibility and the potential efficacy of E-learning based Speech Therapy (EST) as a web application for speech training in dysarthric patients with Parkinson’s Disease: a case study. <i>Telemedicine and e-Health</i> 2010; 16: 6, 732-738.</p>		

COMMUNICATION ASSESSMENT & INTERVENTION SYSTEM FOR CHILDREN WITH (SEVERE) MULTIPLE DISABILITIES WHO RELY ON AUGMENTATIVE AND ALTERNATIVE COMMUNICATION (CAIS)

PERIOD	2007-2011		
PARTICIPANTS	A. Rietveld	RU/SMK	Phonetian, Statistician
	H. Klatter-Folmer	RU	Senior Researcher
	A. Kilkens	SMK	Speech-language Pathologist
SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>Children with (severe) multiple disabilities often have enormous difficulties with communication and language development. In order to adequately assess and treat these children, we need evidence based communication instruments that are especially designed for this complex population. For this reason, CAIS - Communication Assessment & Intervention System for children with multiple disabilities who rely on Augmentative and Alternative communication - has been developed. This new instrument integrates both assessment and intervention and is focused on (proto-)imperative behavior (the insertion of a person as a means for attaining objects or other goals).</p>		
METHODOLOGY	<p>CAIS is based on an extensive review of the literature, clinical experience and multiple pilot studies; the latter have been conducted in order to gather data on feasibility and validity of CAIS (for example the observer agreement of the scoring scale for (proto-)imperative behavior). We are currently conducting a study to examine the effect of CAIS on the (proto-) imperative behavior of children with (severe) multiple disabilities.</p>		
PROGRESS	<p>Three speech therapists from the Sint Maartenskliniek are involved in the effect study. These therapists have been extensively trained in CAIS. Until now (September 2010- December 2010) seventeen children have been included in the study. These children receive their therapy either at the Sint Maartenskliniek or a day-care center. Their therapy sessions are being videotaped, and treatment integrity and changes in the quality of the (proto-)imperative behavior of these children will be measured.</p>		
RESULTS	Not available yet.		
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1.3 MOTOR REHABILITATION

Motor rehabilitation is an important part of the rehabilitation process, which contributes substantially to the improvement of the independence of patients in daily life. Clinically, motor rehabilitation aims to foster functional recovery and participation. The main focus of the research on motor rehabilitation is to optimize the rehabilitation of the patients groups treated in the Rehabilitation Center of the Sint Maartenskliniek such as patients with a stroke, amputation, spinal cord injury, and children with cerebral palsy. To contribute to the improvement of the rehabilitation process, research studies are performed to evaluate and improve existing interventions on motor problems. Moreover, new interventions are developed and evaluated in randomized controlled trials to investigate their effectiveness. For the evaluation of interventions, new measurement equipment, protocols, questionnaires, and clinical tests are developed, improved, and evaluated. In addition, guidelines are developed based on systematic reviews. More fundamental studies are performed only if it is expected that their results can contribute to clinical practice.

MARTIAL ARTS TECHNIQUES TO REDUCE FALL SEVERITY

PERIOD	2004-2010		
PARTICIPANTS	B. Groen	SMK	Movement Scientist
	V. Weerdesteyn	SMK/UMCN	Health Scientist
	B. Nienhuis	SMK	Biomedical Engineer
	J. van Limbeek	SMK	Epidemiologist
	J. Duysens	SMK/UMCN/KUL	Neurophysiologist
SPONSOR	Sint Maartensliniek Prothese en Orthese Makerij Nijmegen Organization for Healthcare Research in the Netherlands (ZonMw)		
PURPOSE	Hip fractures among elderly are a major health problem. As hip fractures are often caused by a fall, they may be prevented by falling safely. This project focuses on limiting fall severity by means of using martial arts (MA) fall techniques. Its main purpose was to explore the potential usefulness of martial arts training for hip fracture prevention in the elderly.		
METHODOLOGY	The project consisted of several experiments. The MA techniques were compared with a natural fall technique to determine whether the MA techniques could reduce the fall severity and to gain knowledge about the working mechanisms. Furthermore, it was investigated whether older individuals are able to learn these techniques, and whether the MA fall training itself is safe. In all experiments, the maximum hip impact force and fall kinematics were measured.		
PROGRESS	This project is completed.		
RESULTS	The MA techniques could reduce the hip impact force by 27% in experienced martial artists. A reduction in hip impact velocity and the roll after impact seemed to play a role in reducing the hip impact force. However, arm impact and trunk orientation seemed not to be essential. Both young and older individuals were able to learn the MA techniques within a short training period. Finally, the MA training seemed to be safe, even for persons with osteoporosis, if appropriate safety measures are taken.		
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PUBLICATIONS

PhD thesis

Groen, B. *Martial arts techniques to reduce fall severity*. Radboud University Nijmegen, 2010.

Articles

Van Swigchem, R., Groen, B.E., Weerdesteyn, V. and Duysens, J. The effects of time pressure and experience on the performance of fall techniques during a fall. *Journal of Electromyography and Kinesiology* 2009; 19: 521-531.

Groen, B.E., Smulders, E., Duysens, J., Van Lankveld, W. and Weerdesteyn, V. Could martial arts fall training be safe for persons with osteoporosis?: a feasibility study. *BMC Research Notes* 2010; 3: 1, 111.

Groen, B.E., Smulders, E., De Kam, D., Duysens, J. and Weerdesteyn, V. Martial arts fall training to prevent hip fractures in the elderly. *Osteoporosis International* 2010; 21: 2, 215-221.

IMPROVEMENT OF THE CLINICAL GAIT ANALYSIS

PERIOD	2008-2012		
PARTICIPANTS	B. Groen	SMK	Movement Scientist
	A. van der Zijden	SMK	Biomedical Engineer
	N. Keijsers	SMK	Movement Scientist
	B. Nienhuis	SMK	Biomedical Engineer
	J. Duysens	SMK/UMCN/KUL	Neurophysiologist
SPONSOR	Sint Maartenskliniek		
PURPOSE	In clinical practice, 3D-gait analysis is used for treatment decision making and treatment evaluation. A primary requirement of the 3D-gait analysis for use in clinical practice is the reliability of the collected gait data. An important source of error is the incorrect placement of markers on anatomical landmarks. The purpose of this study was to improve the 3D clinical gait analysis.		
METHODOLOGY	First, the sensitivity to errors in marker placement was assessed in 3D gait analyses using different models (OLGA and VCM). Healthy adults performed six gait sessions. For the first session, the standard marker set was used. For the following sessions, marker displacements of 10 mm were applied. Gait data were collected with a 3D motion capturing system (Vicon) in combination with a force plate (Kistler). Based on the results, a tool was developed to increase the reliability of marker placement.		
PROGRESS	A manuscript regarding the sensitivity to errors in marker placement in 3D gait data is to be submitted for publication. The tool to increase reliability is developed and evaluated and will be implemented in clinical practice.		
RESULTS	The VCM and OLGA model used in 3D gait analysis are both sensitive to errors of 10 mm in marker placement, but the sensitivity was reduced when using the OLGA model. Thigh, knee and shank marker displacement in anterior/posterior caused the largest errors in the joint kinematics. The tool to increase the reliability of marker placement was developed. The evaluation showed that it improved the inter observer reliability for the knee varus/valgus kinematics.		
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EFFECTS OF THE MARTIAL ARTS FALL TECHNIQUE ON THE FEMORAL FRACTURE RISK

PERIOD	2009-2013		
PARTICIPANTS	A. van der Zijden	SMK/UMCN	Biomedical Engineer
	B. Groen	SMK	Movement Scientist
	E. Tanck	UMCN	Movement Scientist
	B. Nienhuis	SMK	Biomedical Engineer
	V. Weerdesteyn	SMK/UMCN	Movement Scientist
	N. Verdonschot	UMCN/UT	Biomedical Engineer
SPONSOR	Sint Maartenskliniek		
PURPOSE	Hip fractures are a major health issue. The Sint Maartenskliniek is focusing on reducing the femoral fracture risk by providing Martial Arts (MA) fall training for healthy elderly and osteoporotic patients. In this study, the effects of the MA fall technique on the impact force and failure force of the femoral bone are examined, in order to determine the effect of the MA fall technique on the femoral fracture risk.		
METHODOLOGY	Experienced judokas performed sideways falls in our laboratory. They performed two fall techniques: the MA fall and a natural fall arrest strategy. Motion data and force data were recorded to determine fall loading conditions and maximum impact forces. Computer models of femoral bones were used to predict the failure force for each fall loading condition. The ratio between impact force and failure force was calculated to determine the effect of the MA fall technique on the femoral fracture risk.		
PROGRESS	The first nine judokas participated in the fall experiment. Analysis of the motion and force data is in progress. The computer model of the femoral bone has been developed and will be validated for fall loading conditions in the near future.		
RESULTS	Preliminary results show that martial arts fall techniques decrease the impact forces at the hip during sideways falling.		
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MODIFIED CONSTRAINT-INDUCED MOVEMENT THERAPY FOR CHILDREN WITH UNILATERAL SPASTIC CEREBRAL PALSY: THE PIRATE GROUP INTERVENTION

PERIOD	2006-2010		
PARTICIPANTS	P. Aarts	SMK	Occupational Therapist
	A. Geurts	SMK/UMCN	Physiatrist
	P. Jongerius	SMK	Physiatrist
	J. van Limbeek	SMK	Epidemiologist
	Y. Geerdink	SMK	Occupational Therapist
	M. van Hartingsveldt	UMCN	Occupational Therapist
SPONSOR	Johanna Kinder Fonds Sint Maartenskliniek		
PURPOSE	To evaluate a new treatment for children with a unilateral spastic cerebral palsy between 2.5 and 8 years old. In this intervention the principle of CIMT (constraint-induced movement therapy) and bimanual training combined in a child friendly 'Pirate Group' treatment (mCIMT-BiT).		
METHODOLOGY	The effectiveness of the mCIMT-BiT on the spontaneous use of the affected arm and hand was compared to that of treatment as usual for the same period was studied in a Randomized Controlled Trial. A group of 52 children with unilateral cerebral palsy (MACS I,II or III) were included and randomly assigned to either the mCIMT_BiT group (n=28) or the control group (n=24).		
PROGRESS	The study is concluded and various papers published.		
RESULTS	All the primary (Assisting Hand Assessment and Abilhand Kids) as well as the secondary outcome variables, with the exception of the Melbourne Assessment of Unilateral Upper Limb Function showed an improvement in the mCIMT-BiT group; these improvements were maintained at 8 weeks following the treatment. The capacity and performance scores for the upper limb showed a significantly greater improvement for the mCIMT-BiT group in comparison to the treatment as usual group, which was also the case 8 weeks following the therapy. When the concept of developmental disregard was evaluated, the new therapy only produced a slight reduction.		
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PUBLICATIONS

PhD thesis

Aarts, P. B. *Modified constraint-induced movement therapy for children with unilateral spastic cerebral palsy: the Pirate group intervention*. Radboud University Nijmegen, 2010.

Articles

Aarts, P.B., Jongerius, P.H., Geerdink, Y.A. and Geurts, A.C. Validity and reliability of the VOAA-DDD to assess spontaneous hand use with a video observation tool in children with spastic unilateral cerebral palsy. *BMC Musculoskeletal Disorders* 2009; 10: 145.

Aarts, P.B., Jongerius, P.H., Geerdink, Y.A., Van Limbeek, J. and Geurts, A.C. Effectiveness of Modified Constraint-Induced Movement Therapy in Children With Unilateral Spastic Cerebral Palsy: A Randomized Controlled Trial. *Neurorehabilitation and Neural Repair* 2010; 24: 6, 509-518.

LOWER LIMB PROSTHESEOLOGY AND ACTIVITY MONITORING

PERIOD	2007-2012		
PARTICIPANTS	C. Hofstad	SMK	Movement Scientist
	R. van der Ploeg	SMK	Physiotherapist
	P. Peters	SMK	Physiotherapist
	F. Schiltz	SMK	Physiotherapist
	N. Keijsers	SMK	Movement Scientist
	A. de Fretes	SMK	Physiatrist
SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>To provide more insight in the rehabilitation process of patients with a lower limb amputee, the rehabilitation process will be described in several phases. The first aim is to develop these phases, which are called treatment modules. A characteristic of good clinical practice is that it uses measurement instruments that are reliable, valid, and responsive to intervention. Therefore, this project aims to introduce clinimetrics in lower limb prosthesiology and ambulatory monitoring.</p>		
METHODOLOGY	<p>Based on the literature and clinical practice, the different phases and relevant clinimetrics are described. Ambulatory monitoring has been used to assess the number of consecutive steps in daily life by patients with a lower limb amputation and aged matched controls. A method to assess the number of consecutive steps was developed. The number of consecutive steps was correlated with questionnaires that assess lower limb amputee activity level (SIGAM and MFCL).</p>		
PROGRESS	<p>Different phases in the rehabilitation process have been described and will be implemented in clinical practice in 2011. 15 patients with a lower limb amputation and 8 control subjects have been measured in daily life for 2 days. A manuscript will be written.</p>		
RESULTS	<p>The algorithm to determine the number of consecutive steps had in 70% of the data a difference of less than 3 steps. Maximal walking distance in individuals with lower limb amputation is limited and many do not reach a walking distance of 50 m. The SIGAM scale and MFCL classification appeared to be a rough indicator for maximal walking distance and walking aid usage in daily life.</p>		
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PUBLICATIONS	<p>Hofstad, C.J., Weerdesteyn, V., Van der Linde, H., Nienhuis, B., Geurts, A.C. and Duysens, J. Evidence for bilaterally delayed and decreased obstacle avoidance responses while walking with a lower limb prosthesis. <i>Clinical Neurophysiology</i> 2009; 120: 5, 1009-1015.</p>		

ARM-LEG COUPLING AND REFLEX MODULATION IN SPINAL CORD INJURED INDIVIDUALS

PERIOD	2008-2010		
PARTICIPANTS	D. de Kam	SMK/UMCN	Movement Scientist, Physical Therapist
	H. Rijken	SMK	Physical Therapist
	B. Nienhuis	SMK	Biomedical Engineer
	D. van Kuppevelt	SMK	Physiatrist
	J. Duysens	SMK/UMCN/KUL	Neurophysiologist
SPONSOR	Internationale Stiftung für Forschung in Paraplegie		
PURPOSE	Recent studies have shown that arm movements can increase muscle activity in the legs during passive recumbent stepping. Although it would be relevant for rehabilitation, less is known about the effect of arm movements on muscle activity in active legs. The purpose of this study was to determine the effect of arm movements on leg muscle activity during active recumbent stepping in healthy subjects and in spinal cord injured individuals.		
METHODOLOGY	Ten healthy subjects and 9 spinal cord injured individuals were included in the study. Leg muscle activity was recorded during sub maximal recumbent stepping. Conditions with actively involved arms were compared to conditions without arm movements.		
PROGRESS	This study is in the data analysis and manuscript preparation phase.		
RESULTS	In healthy subjects muscle activity in ankle flexors and extensors and in the lateral hamstrings increased when arms became actively involved. No effect was found in the extensor of the knee. In patients there was an increase of muscle activity as well, however, the effects were less pronounced than in healthy controls.		
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1.4 PARTICIPATION IN EXTERNAL RESEARCH PROJECTS

1

USE OF BRAIN SIGNALS AND COMPUTER TECHNOLOGY IN REHABILITATION

PERIOD	2008-2013		
PARTICIPANTS	M. Severens B. Nienhuis J. Duysens P. Desain	SMK SMK SMK/UMCN/KUL DCC	Cognitive Neuroscientist Biomedical Engineer Neurophysiologist Neuroscientist
SPONSOR	SmartMix (Ministry of Economic Affairs)		
PURPOSE	Using brain signals to control a device is called Brain Computer Interfacing (BCI). In this project we will focus on two applications of BCIs. The first will be for communication or control of domotics. The second application is the use of a BCI in the rehabilitation of gait. The idea is that patients can control a locomotor device (such as the Locomat) with their own brain signals, which may improve the rehabilitation process.		
METHODOLOGY	The brain signals will be measured with ElectroEncephaloGraphy (EEG), first in healthy subjects, later on in patients. For the first application, the brain signals that are evoked by attention to tactile stimuli will be used to control the BCI. For the second application, brain signals that are associated with (imagination of) walking movements will be used to control a locomotor device (such as the locomat).		
PROGRESS	For the domotics or communication application, we first studied the brain signals evoked by different types of tactile stimulation in healthy subjects. Furthermore, several BCI pilot studies with tactile stimulation have been performed with healthy subjects. Next, a more extensive study with online feedback will be performed in both healthy subjects and patients. Furthermore we will start with investigating the brain signals evoked by (imagined) walking movements.		
RESULTS	The results of the first study suggested that different tactile stimulation sites should not be too close together. The BCI pilot studies showed that the performance of such a BCI varies for different types of stimulation and subjects. Average classification performance is about 70%.		
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NIRS BASED BCI FOR THE REHABILITATION OF GAIT

PERIOD	2008-2012		
PARTICIPANTS	K. Koenraadt	SMK	Movement Scientist
	N. Keijsers	SMK	Movement Scientist
	J. Duysens	SMK/UMCN/KUL	Neurophysiologist
SPONSOR	Smart Mix (Ministry of Economic Affairs)		
PURPOSE	<p>fMRI studies have shown that brain areas are activated when subjects imagine themselves walking. In the current project, this knowledge will be extended to NIRS (Near-InfraRed Spectroscopy) and to the rehabilitation of gait. Currently there are devices (Locomat; Lopes) available, which assist locomotion in subjects, who are unable to activate their muscles sufficiently. Ideally one would like such devices to be controlled by brain activity (BCI; Brain Computer Interface). This cannot be done with fMRI but NIRS would be ideal.</p>		
METHODOLOGY	<p>NIRS is a relatively new technique in the field of neuro-imaging. Therefore, fundamental issues have to be studied. First, we studied the positioning of our NIRS optodes on the head using Transcranial Magnetic Stimulation (TMS). Another study focused on the effect of the frequency of movements on the amplitude of the responses measured with NIRS.</p>		
PROGRESS	<p>Following the first two studies we performed, we gained more insight in the way to measure brain activity using NIRS. We will extend our research on brain activity following hand movements to movements of the lower extremity and imagined movements. Furthermore, we will more and more focus on the application of a NIRS based BCI in patients. The step to online-analysis of the NIRS signals has already been made and tested in a demonstration.</p>		
RESULTS	<p>We determined that the NIRS signals retrieved from the TMS position did not resulted in larger responses compared to the conventional localization method. We also found that increasing the frequency of a hand movement did not resulted in larger hemodynamic responses, as suggested by previous studies. Movements with alternating frequencies seemed to result in the highest NIRS response amplitude.</p>		
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AWARE SHOE

PERIOD	2007-2012		
PARTICIPANTS	V. Beerepoot	RU	Electrical Engineer
	L. Boves	RU	Phonetician
	N. Keijsers	SMK	Movement Scientist
	B. Nienhuis	SMK	Biomedical Engineer
SPONSOR	SenterNovem IOP		
PURPOSE	In many diseases, it is important that potentially dangerous behavior can be assessed and maybe even more important immediate feedback can be given in order to persuade patients to adapt their behavior. The goal of this project is to develop a system that can assess the posture and movements of a patient in a user friendly way and provide the user with information about their behavior.		
METHODOLOGY	The newly developed system will consist of a PDA and two accelerometers. The PDA will capture the data of the accelerometers and will classify posture and movements. To develop the classification model, 10 subjects have been tested in controlled situation and during two days wearing body attached sensors and sensors loosely attached to the clothes (belt and in the pocket). A hidden Markov model was developed to assess the 5 basic daily life activities (lying, sitting, standing, walking, and bicycling).		
PROGRESS	An article has been submitted. A study will be started that evaluates the benefit of the system to increase daily life activity in rehabilitation patients.		
RESULTS	The loose sensor configuration is sufficiently accurate for detection of standing, walking, sitting, bicycling and lying in natural daily life conditions. Although the results are sufficient, further improvement related to the orientation of the pocket sensor is feasible. One should be cautious using classification models in daily life which are developed in controlled simulated daily life environments.		
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2

STUDIES ON RHEUMATIC CONDITIONS AND THEIR TREATMENT

The primary aim of research initiated by researchers of the Department of Rheumatology of the Sint Maartenskliniek is to improve treatment outcomes and to reduce the consequences of rheumatic diseases on the quality of life of patients. Development and evaluation of treatments and research on optimal timing and phasing of evidence-based interventions are the central foci of research. Researchers and care providers (rheumatologists, pharmacists, allied healthcare professionals) work closely together in setting up and answering research questions relevant for clinical practice.

The vast majority of research projects initiated by the Department of Rheumatology is embedded in PhD project. PhD-projects are initiated in close collaborations with various research partners; among others UMC St Radboud, University Medical Center Utrecht, Leiden University Medical Center and the Netherlands Institute for health services research (Nivel).

2.1 EPIDEMIOLOGICAL STUDIES

This research line includes a wide variety of studies focusing on the identification of prognostic factors for the course of rheumatic diseases and their treatment; the development and evaluation of psychometric qualities of outcome measures, and summarizing the results in the literature about the efficacy of interventions. Knowledge about prognostic factors for the course and outcome of rheumatic diseases is necessary to identify patients at risk for unfavorable outcome. Two examples of studies in this research line are a study into the diagnostic and prognostic value of ultrasonography in patients with osteoarthritis of the knee and a study into the role of psychological factors in patients with various diagnoses referred to the Department of Rheumatology of the Sint Maartenskliniek. Finally, the efficacy of non-pharmacological treatment is summarized by means of systematic reviews. Results of those reviews are implemented in the multidisciplinary treatment offered by the Department of Rheumatology.

IMPLEMENTATION OF THE DAS28 IN CLINICAL PRACTICE

PERIOD	2009-2010		
PARTICIPANTS	A. van der Maas	SMK	Resident Rheumatology
	C. van den Ende	SMK	Senior Researcher Allied Healthcare
	A. den Broeder	SMK	Rheumatologist
SPONSOR	Alifax		
PURPOSE	<p>The use of frequent disease monitoring in RA has been shown to be effective in reducing disease activity. As a measure for disease activity the DAS28 (disease activity score) can be used. The DAS28 is a combined index consisting of the following elements: the number of tender joints (out of 28 selected joints), the number of swollen joints, erythrocytes sedimentation rate (ESR) and the degree of disease activity (as perceived by the patient). Implementation of DAS28 in clinical practice is hampered by the time involved to assess the DAS28. The aim of this project is to examine the loss of accuracy of DAS28 if an automated analyzer is used to determine ESR.</p>		
METHODOLOGY	<p>Data of two samples of patients will be analyzed. In 125 patients visiting the Department of Rheumatology because of a rheumatic disorder ESR was determined by means of three different methods (conventional Westergren method (Starrsed Comapct Analyzer) and by using two different automated analyzers (Alifax Roller Test-1; Vesmatic 200).</p>		
PROGRESS	Project has been completed.		
RESULTS	<p>ESR measured by automated analyzers like Alifax show acceptable ICC but LoA are large compared to the Westergren ESR. The Alifax Roller Test-1TH is very rapid but DAS28 misclassification is considerable and even as large as when using the ESR of the previous visit.</p>		
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COPING FLEXIBILITY QUESTIONNAIRE: DEVELOPMENT AND VALIDATION

PERIOD	2008-2009		
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	A. Eijsbouts	SMK	Rheumatologist
	T. van Helmond	SMK	Psychologist
	R. Geenen	UU	Psychologist
	C. van den Ende	SMK	Senior Researcher Allied Healthcare
SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>The ability to modify coping responses according to situational demands has been referred to as coping flexibility. Experimental and cross-sectional studies have demonstrated positive associations of coping flexibility with psychological adjustment outcomes, and coping flexibility has been found to attenuate the negative impact of pain and disability on psychological well-being. Although coping flexibility appears beneficial for adjustment, the construct has hardly been examined in the context of chronic disease. Coping flexibility, may be beneficial for adjustment in the context of a progressive and unpredictable course of chronic rheumatic diseases. The aim of this study was to develop and initially validate a self-report measure that assesses coping flexibility.</p>		
METHODOLOGY	<p>Study participants were 147 outpatients with chronic rheumatic diseases (73% female, mean age 59 (range 20-79) years). Principal axis factoring analysis with oblique rotation was applied and internal consistency was determined. To investigate the initial validity of the coping flexibility questionnaire (COFLEX), hypothesized correlations with psychological and physical adjustment outcomes, pain, and coping strategies were examined.</p>		
PROGRESS	This study is submitted for publication.		
RESULTS	<p>Factor analysis yielded a two factor model of coping flexibility with acceptable internal consistency: versatility, the capability of switching between assimilative and accommodative coping strategies according to personal goals and situational demands ($\alpha=.88$) and reflective coping, the capability of generating and considering coping options, and appraising the suitability of a coping strategy in a given situation ($\alpha=.70$). Versatility was correlated with adaptive ways of coping and psychological adjustment, but not with physical adjustment and pain. Reflective coping was correlated with both adaptive and maladaptive ways of coping, but it was not correlated with adjustment outcomes. In conclusion, the current study suggests acceptable internal consistency of the COFLEX. Preliminary evidence of the validity of the versatility dimension is indicated,</p>		

while the validity of reflective coping could not be firmly established. The associations of versatility with favorable adjustment to the disease warrants future confirmatory and validity research in larger samples of patients with chronic rheumatic diseases.

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GERONTOREUMATOLOGY: ELDERLY WITH A RHEUMATOLOGY DIAGNOSIS

PERIOD	2008-2010		
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	J. Goossens	SMK	Rheumatology Nurse
	A. den Broeder	SMK	Rheumatologist
	W. van Lankveld	SMK	Psychologist, Senior Researcher
SPONSOR	Sint Maartenskliniek		
PURPOSE	Elderly patients referred to the rheumatologist are prone to generic and age related health hazards. As yet, the prevalence of these health hazards is unknown. The first step to improve treatment for these patients is to study the prevalence of a number of generic health hazards.		
METHODOLOGY	Patients aged 75 or older referred to a specialized outpatient service were studied prospectively. Over a period of two years 154 patients were included. The rheumatologist assessed rheumatic diagnosis and co morbidities as well as medication use. The specialized nurse recorded falls, pain, fatigue, and physical activity. Self-report questionnaires were used to assess physical function, depression, loneliness, and treatment need.		
PROGRESS	De study has been completed.		
RESULTS	The sample of patients was characterized by poor physical functioning, high levels of pain and high prevalence of age related health hazards. Co-morbidities were observed in 88% of the patients. At least one fall in the last year was reported in 44% of the patients. In 44% of the patients physical activity was below norms for health enhancing physical activity.		
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EVIDENCE-BASED TAILORED CONSERVATIVE TREATMENT OF KNEE AND HIP OSTEOARTHRITIS: BETWEEN KNOWING AND DOING

PERIOD	2007-2010		
PARTICIPANTS	G. Snijders	SMK	Researcher
	A. den Broeder	SMK	Rheumatologist
	P. van Riel	RU	Rheumatologist
	V. Straten	SMK	Physician Assistant
	F. de Man	SMK	Orthopedic Surgeon
	F. van den Hoogen	SMK	Rheumatologist
	C. van den Ende	SMK	Senior Researcher Allied Healthcare
SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>Insufficient data is available on the efficacy of combined conservative interventions recommended by treatment guidelines for knee/hip osteoarthritis (OA). The aims of this observational cohort study were 1) to estimate the results of an evidence-based 12-week tailored multimodal conservative treatment protocol for patients with knee/hip OA and 2) to identify predictors for response.</p>		
METHODOLOGY	<p>After obtaining data on previous OA related interventions, multimodal treatment was offered to patients with knee and/or hip OA at a specialized outpatient clinic. Treatment with analgesics was tailored using a numeric rating scale (NRS) for pain aiming for $NRS \leq 4$. The following outcome measures were assessed: 1) the proportion of patients fulfilling OMERACT-OARSI responder criteria and 2) the proportion of patients with NRS pain ≤ 4 after 12 weeks.</p>		
PROGRESS	Article in press.		
RESULTS	<p>A total of 183 out of 299 patients was included. OMERACT-OARSI responder criteria were fulfilled at 12 weeks in 47% of patients; 39% reached a NRS pain ≤ 4. The only independent predictor for response was the number of previously used non-steroidal anti-inflammatory drugs (NSAIDs). The majority of patients had not been exposed adequately to conservative treatment modalities for knee and/or hip OA in the past (81%).</p> <p>Conclusion: Evidence-based multimodal conservative treatment using a standardized protocol for knee and/or hip OA is feasible and successful in 47% of patients. Response could largely not be predicted. In addition, basic first-line recommended conservative treatment options have not been adequately utilized prior to referral to secondary care in the vast majority of patients.</p>		
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REPRODUCIBILITY OF ULTRASONOGRAPHY IN OSTEOARTHRITIS OF THE KNEE

PERIOD	2010-2011		
PARTICIPANTS	K. Bevers H. Martens	SMK SMK	Rheumatologist Rheumatologist
SPONSOR	St Maartenskliniek		
PURPOSE	<p>Osteoarthritis (OA) is a common joint disorder, with the knee being one of the most frequently involved sites. With ultrasonography (US) it is possible to also visualise soft tissue structures. Information about these structures will likely give insight in the complex process of development and progression of knee OA. As US is known to be an operator-dependant modality, lack of inter-reader agreement could restrict its use especially in clinical practice. So far, few studies have reported reproducibility data on US in knee OA and no standardised and reproducible knee OA US protocol has been developed.</p>		
METHODOLOGY	<p>Based on results of previous US studies and pathophysiologic concepts of knee OA, the acquisition protocol focused on three domains, comprising mechanical (medial meniscus protrusion), inflammatory (synovial hypertrophy and effusion, bursitis) and degenerative aspects (cartilage thickness). US was performed independently by two rheumatologists in 60 outpatients fulfilling the American College of Rheumatology clinical criteria for knee OA. The acquisition protocol comprised medial meniscus protrusion, synovial hypertrophy, effusion, infrapatellar bursitis and cartilage thickness.</p>		
PROGRESS	Data collection will be completed mid 2011.		
RESULTS	<p>Interobserver agreement (k value) was moderate for protrusion of the medial meniscus (0.54), good for infrapatellar bursitis (0.66) and effusion (0.74), excellent for Bakers' cyst (0.85) and poor for the detection of synovial hypertrophy (-0.08). Interobserver reliability was good for the measurement of medial meniscus protrusion (correlation coefficient 0.80, 95% limits of agreement -1.93 to 1.94 mm) and cartilage thickness (correlation coefficient 0.62 and 0.68, 95% limits of agreement -0.87 to 0.84 mm and -0.77 to 0.96 mm at the medial and lateral condyle respectively).</p>		
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HEALTH SERVICE UTILIZATION OF PATIENTS WITH END-STAGE OA OF THE HIP OR KNEE

PERIOD	2009-2011		
PARTICIPANTS	T. Hoogeboom	SMK	Physiotherapist, Junior Researcher
	C. van den Ende	SMK	Senior Researcher Allied Healthcare
	R. de Bie	UM	Epidemiologist
	A. den Broeder	SMK	Rheumatologist, Senior Researcher
	B. Swierstra	SMK	Orthopedic Surgeon, Senior Researcher
SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>In the Netherlands, multidisciplinary consensus is achieved on the step-wise treatment strategy for patients with hip or knee osteoarthritis. We expect that current practice does not comply to a large extent to these recommendations. It is more likely that the amount of health service utilization (HSU) is associated with patient characteristics. To gain more insight in HSU, we decided to study HSU, determinants on HSU and to assess the appropriateness of HSU in patients with osteoarthritis referred to secondary care.</p>		
METHODOLOGY	<p>The study utilized a cross-sectional postal survey. Patients older than 18 who visit secondary care due to a new episode of complaints because of hip or knee osteoarthritis are eligible for inclusion. HSU will be measured by straightforward questions. Additionally measured variables are pain, functioning, attitudinal-belief variables and fatigue. Data analysis is performed with descriptive analyses, logistic regression analysis and t-tests.</p>		
PROGRESS	Data collection is finished. Data analysis and manuscript finalization are scheduled for 2011.		
RESULTS	403 of the 500 patients returned the questionnaire (>80%). Further analyses follow.		
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2

VALIDITY AND RELIABILITY OF THE SODA IN OSTEOARTHRITIS

PERIOD	2008-2011		
PARTICIPANTS	R. de Ruiter	SMK	Occupational therapist
	L. Rietveld	MKW	Occupational therapist
	J. Westeneng	SMK	Physical Therapist
	M. Stukstette	SMK	Researcher, Physiotherapist
	C. van den Ende	SMK	Senior Researcher Allied Healthcare
SPONSOR	Dutch Arthritis Association		
PURPOSE	<p>The Sequential Occupational Dexterity Assessment (SODA) was developed and validated in the Sint Maartenskliniek to evaluate bimanual functioning in patients with rheumatoid arthritis (RA). Although the SODA was developed and validated in RA, the SODA is national as well as international frequently used to evaluate bimanual functioning in patients with osteoarthritis. Aim of this study is to investigate validity and reliability of the SODA in patients with osteoarthritis of hands.</p>		
METHODOLOGY	<p>To investigate inter observer reliability of the SODA in a subgroup of 50 patients of the NOAH study the assessment of the SODA will be videotaped. The videotaped SODA assessments will be scored independently by two observers. To determine the construct validity of the SODA the association between patients scores on the SODA and the DUTCH-AIMS/AUSCAN will be investigated.</p>		
PROGRESS	Data collection completed.		
RESULTS	Results will be available in 2011.		
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DEVELOPMENT AND VALIDATION OF A DUTCH KNOWLEDGE QUESTIONNAIRE IN PATIËNTS WITH OSTEOARTHRITIS

PERIOD	2010-2011		
PARTICIPANTS	A. Smink	SMK	Movement Scientist
	T. Hoogeboom	SMK	Physiotherapist, Junior Researcher
	C. van den Ende	SMK	Senior Researcher Allied Healthcare
SPONSOR	Sint Maartenskliniek		
PURPOSE	The aim of this study is to develop and validate a Dutch knowledge questionnaire in patients with osteoarthritis. This questionnaire can be used by healthcare providers as a tool to assess patients knowledge of osteoarthritis over time which forms the basis of an education plan.		
METHODOLOGY	Initial items were developed by an expert panel and tested on a sample of patients to assess its legibility. Subsequently, the item pool was completed by 100 adolescents with osteoarthritis. Redundant and duplicate items were removed through analysis of item difficulty, discrimination index, and internal consistency. The final questionnaire will be applied in 75 patients, 50 laymen, and 50 healthcare providers to assess the validity, test-retest and minimal detectable change.		
PROGRESS	This study is still in progress. The final item pool is developed and completed by 98 adolescents with osteoarthritis. After the final item selection, the validity, test-retest and minimal detectable change will be assessed.		
RESULTS	Preliminary results: The expert panel determined 97 initial items and categorized them in four domains; 1) disorder, 2) self management, 3) treatment modalities, 4) other and remarkable. After testing the legibility, 99 potential items were formulated. Ninety-eight patients of the outpatient rheumatology department of the Sint Maartenskliniek hospital in Nijmegen in The Netherlands with symptomatic osteoarthritis completed the item pool.		
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A SYSTEMATIC INVENTORY OF MODELS OF CARE FOR OSTEOARTHRITIS

PERIOD	2008-2011		
PARTICIPANTS	G. van den Bos	AMC	Social Medicine
	J. Dekker	VUMC	Psychologist Allied Healthcare
	C. van den Ende	SMK	Senior Researcher Allied Healthcare
	M. Stukstette	SMK	Researcher, Physical Therapist
SPONSOR	Health Council of the Netherlands		
PURPOSE	<p>Osteoarthritis (OA) is the most common form of musculoskeletal disorders with a significant impact on the individual and society. A wide variety of effective treatment options are available for the treatment of OA which can be divided into conservative treatment interventions (non-pharmacological and pharmacological intervention) and surgical interventions. In osteoarthritis of the hip and/or knee (non)-pharmacological interventions are delivered by a broad range of healthcare services provided in different settings and by different disciplines. The conservative management of OA can be characterized as heterogeneous and suboptimal given the (regional) variation in healthcare utilization, in number of visits to general practitioners, and in patterns of referral to allied healthcare providers. The aim of this project is to make a systematic inventory of models of care facilitating access and guaranteeing quality of care for all patients with osteoarthritis of hip and/or knee.</p>		
METHODOLOGY	Data collection: literature search and semi-structured interviews with experts.		
PROGRESS	Completed		
RESULTS	The results of this project will be used by the Health Council of the Netherlands (Gezondheidsraad); an independent advisory body charged with providing Ministers and Parliament with scientific advice on healthcare matters.		
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COHORT STUDY INTO THE EFFECT OF PSYCHOSOCIAL FACTORS ON PSYCHOLOGICAL DISTRESS IN SCLERODERMA

PERIOD	2008-2013		
PARTICIPANTS	L. Kwakkenbos	SMK	Psychologist
	F. van den Hoogen	SMK	Rheumatologist
	M. Jeurissen	SMK	Rheumatologist
	M. Vonk	UMCN	Rheumatologist
	W. van Lankveld	SMK	Psychologist, Senior Researcher
	C. van den Ende	SMK	Senior Researcher Allied Healthcare

SPONSOR Sint Maartenskliniek

2 PURPOSE Scleroderma has serious negative consequences for the patient, causing elevated levels of depressed mood in 36-65% of the patients. Only recently it has become clear which stressors are important, and which psychological mechanisms are related to distress in scleroderma. However, longitudinal research is needed to determine which psychological variables predict psychological distress after controlling for changes in disease status.

METHODOLOGY Patients with a definite diagnosis of scleroderma from the Sint Maartenskliniek and the UMC Sint Radboud will be asked to participate in the study. Patients receive both written and oral information about the study. After obtaining informed consent, participants complete sets of questionnaires, every 6 months during 3 years.

PROGRESS Inclusion has started in September 2008 and ended in January 2010. In total, 215 patients completed the baseline. Baseline data are currently being analyzed.

RESULTS Results from baseline data will be available mid-2011.

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VALIDATION OF THE DUTCH VERSION OF THE LOWER EXTREMITY FUNCTIONAL SCALE (LEFS)

PERIOD	2009-2012		
PARTICIPANTS	T. Hoogeboom	SMK	Physiotherapist, Junior Researcher
	P. Stratford	McMasters	Senior Researcher
	A. den Broeder	SMK	Rheumatologist
	R. de Bie	UM	Epidemiologist
	C. van den Ende	SMK	Senior Researcher Allied Healthcare
SPONSOR	Sint Maartenskliniek		
PURPOSE	The purpose of this study is to translate the Lower Extremity Functional Scale (LEFS) into Dutch and to evaluate the psychometric qualities of the Dutch version of the LEFS as expressed by internal consistency, reliability, construct validity, discriminant validity and floor and ceiling effects in patients with OA of the hip or knee in secondary care.		
METHODOLOGY	The LEFS questionnaire was translated according to the recommendations of Beaton et al (2000). The readability and understandability of the questionnaire was evaluated in 30 patients. To evaluate the psychometric properties of the questionnaires, 246 people with lower extremity osteoarthritis completed the translated LEFS, the physical function subscale of the SF-36, and the Hip or Knee Osteoarthritis Outcome Score.		
PROGRESS	Data is collected. Data analyses is planned.		
RESULTS	Not available yet.		
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HEALTH STATUS OF PATIENTS DIAGNOSED WITH HIP OR KNEE OSTEOARTHRITIS WHO ALSO REPORT PAIN IN TWO OR MORE OTHER JOINT-GROUPS

PERIOD	2009-2011		
PARTICIPANTS	T. Hoogeboom	SMK	Physiotherapist, Junior Researcher
	B. Swierstra	SMK	Orthopedic Surgeon
	R. de Bie	SMK	Epidemiologist
	A. den Broeder	SMK	Rheumatologist
	C. van den Ende	SMK	Senior Researcher Allied Healthcare
SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>Many patients with OA of the knee or hip have more than one painful joint. So far, research on physical and psychological functioning and on OA therapies focused on patients with OA in a single joint or neglect the effect of OA in other joint-groups. Sparse data are available on the health status of patients with OA of the hip or knee who suffer from complaints in multiple joint groups. This information is important in, for example, the development of OA therapies or research projects. Therefore, this study aims to examine the physical and psychological status of patients with OA of hip or knee who report pain in two of more joint-groups.</p>		
METHODOLOGY	<p>In this cross-sectional postal survey, 403 consecutive patients who recently visited their orthopedic surgeon for a new episode of complaints because of hip or knee OA, returned a questionnaire (response rate 80%). The number of painful joint-groups (i.e. more than half of the time complaints) and physical and psychological factors were assessed by questionnaires. Patient characteristics and measures were compared for single joint-group and multiple joint-group complaints (≥ 2 painful joint-groups) by using T-test statistics.</p>		
PROGRESS	A manuscript is being finalized for international publication.		
RESULTS	Over half of the patients reported complaints in two or more joint-groups and over a third of the patients in ≥ 3 joint-groups. Patients who reported multiple painful joint-groups also reported lower physical and psychological health.		
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2.2 NON-PHARMACOLOGICAL STUDIES

Despite optimal drug treatment, many patients with rheumatic diseases experience loss of physical function often accompanied with loss in social and psychological functioning as well. Therefore, improvement of the efficacy of multidisciplinary treatment by allied healthcare professionals is also an important focus of research of the Sint Maartenskliniek.

At the Department of Rheumatology there is an ongoing process to improve treatment options by implementing recent research findings in clinical practice. Also, research is initiated to contribute to the body of knowledge about the efficacy of newly developed multidisciplinary interventions, such as an intervention to improve medication adherence. Also, treatment programs are being developed and evaluated in patients with osteoarthritis of the hand and patients with generalized arthritis.

IMPROVING BELIEFS ABOUT MEDICATION IN PATIENTS WITH RA

PERIOD 2009-2012

PARTICIPANTS

H. Zwikker	SMK	Researcher
B. van den Bemt	SMK	Pharmacist
C. van den Ende	SMK	Senior Researcher Allied Healthcare
A. den Broeder	SMK	Rheumatologist
F. van den Hoogen	SMK	Rheumatologist

SPONSOR Sint Maartenskliniek

PURPOSE

This study focuses on patients with Rheumatoid Arthritis (RA). Adherence to medication in RA is low. Previously research showed that 33% of the patients with RA do not take their Disease Modifying Anti Rheumatic Drugs (DMARDs) as prescribed. DMARDs reduce disease activity and radiological progression and improve long term functional outcome in patients with RA. Non-adherence to DMARDs can reduce efficacy of treatment.

Previous research showed that beliefs about medication in RA is associated with adherence. The objective of the study is to determine if a short motivational patient-centered intervention for non-adherent patients is more successful in improving beliefs about medication (and adherence) compared to a usual care control group of non-adherent patients. If adherence in non-adherent RA-patients improves, e efficacy of DMARD-treatment can be optimized.

METHODOLOGY

During 18 months 600 RA patients will be selected for study inclusion: 120 non-adherent patients will be randomly assigned to the experimental and control condition. The researcher will be blinded for condition allocation. With a validated questionnaire (Compliance Questionnaire Rheumatology) non-adherent RA-patients using DMARDs will be selected. Beliefs about medication, adherence and several psychological and physical outcomes will be assessed using questionnaires. Also, adherence will be measured using refill rates. The patient completes four measurements: prior to the intervention and 1 week, 6 months and 12 months after the intervention. In addition, the patient reports experienced adverse effects and care utilization every month.

PROGRESS At the moment, 82 patients participate in the randomized controlled trial. In march 2011, we expect that we have included 120 patients.

RESULTS Not yet available.

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INTERDISCIPLINARY ACCEPTANCE REHABILITATION PROGRAMME FOR HIGHLY DISTRESSED PATIENTS WITH ARTHRITIS

PERIOD	2009-2011		
PARTICIPANTS	J. Vriezekolk	SMK	Psychologist, Researcher
	R. Geenen	UU	Psychologist
	A. Eijsbouts	SMK	Rheumatologist
	T. van Helmond	SMK	Psychologist
	F. van den Hoogen	SMK	Rheumatologist
	W. van Lankveld	SMK	Psychologist, Senior Researcher
	C. van den Ende	SMK	Senior Researcher Allied Healthcare
SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>Some patients with rheumatic diseases experience high levels of pain, psychological distress, and poor quality of life despite adequate medical treatment. These patients are often referred to multidisciplinary rehabilitation. A majority of patients referred to rehabilitation at the Sint Maartenskliniek show high levels of psychological distress and illness acceptance was very low. We developed an interdisciplinary acceptance-oriented rehabilitation programme for these highly distressed patients. This new rehabilitation programme comprises comprehensive allied healthcare supplemented by a cognitive-behavioral intervention targeting acceptance and coping flexibility.</p> <p>The aim of this study is to evaluate the potential effectiveness of this rehabilitation programme. In addition, the validity of the assumed mediating psychological processes (i.e., acceptance and coping flexibility) will be explored.</p>		
METHODOLOGY	<p>In this proof-of-concept study (N = 25), the results of the interdisciplinary acceptance-oriented rehabilitation programme will be compared to the results in highly distressed patients who received CMR without a psychological intervention in 2006-2007. The potential effectiveness of the programme will be assessed according to a predefined response rate. Patients with inflammatory rheumatic diseases or osteoarthritis referred to CMR at the Sint Maartenskliniek Nijmegen will be screened for psychological distress, using cut-off scores from previous research. Highly distressed patients admitted to the next acceptance-oriented rehabilitation programme will be asked to participate in the study. Demographic data, disease-related variables, physical and psychosocial functioning of study participants will be assessed by a set of self-report questionnaires at four assessment points: start treatment, mid-treatment, post treatment, and one year after start treatment.</p>		
PROGRESS	All data will be collected by february 2011. Preliminary data analyses are being conducted.		

RESULTS Not yet available.

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SYSTEMATIC REVIEWS: SUMMARIZING RESULT ON EFFECTIVENESS AND PROGNOSTIC FACTORS

PERIOD	2009 -		
PARTICIPANTS	T. Hoogeboom J. Vriezokolk C. van den Ende	SMK SMK SMK	Physiotherapist, Junior Researcher Psychologist, Research Fellow Senior Researcher Allied Healthcare
SPONSOR	Sint Maartenskliniek		
PURPOSE	At the Department of Rheumatology new multidisciplinary treatment programs are being developed and/or customized to the latest evidence to serve patients with rheumatic disorders and complex complaints. Results derived from systematic reviews are considered to provide the highest level of evidence. Also, results from longitudinal studies on prognostic factors of treatment outcome are systematically summarized to provide evidence for the development of new interventions. Therefore, researchers of the Department of Rheumatology are involved in the writing and updating of a number of systematic reviews.		
METHODOLOGY	The following topics are being reviewed for their evidence: 1) Home exercise for rheumatoid arthritis 2) Dynamic exercise therapy for rheumatoid arthritis (un update of a Cochrane Review) (in collaboration with the Department of Rheumatology of the Leiden University Center) 3) The effect of waiting for joint replacement because of osteoarthritis (in collaboration with TNO, Leiden) 4) The longitudinal association between coping and psychological distress.		
PROGRESS	Ongoing		
RESULTS	Results have been presented during scientific conferences and have been submitted and/or accepted for publication by international journals and/or the Cochrane Collaboration.		
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EFFECT OF A MULTIDISCIPLINARY TREATMENT PROGRAMME IN PATIENTS WITH HAND OA (NOAH)

PERIOD	2008-2011		
PARTICIPANTS	M. Stukstette	SMK	Researcher, Physiotherapist
	A. den Broeder	SMK	Rheumatologist
	J. Dekker	VU	Psychologist
	J. Bijlsma	UMCU	Rheumatologist
	C. van den Ende	SMK	Senior Researcher Allied Healthcare
SPONSOR	Dutch Arthritis Association		
PURPOSE	The department of rheumatology of the Sint Maartenskliniek developed a multidisciplinary treatment programme to treat patients with hand AO. The aim of this study is to examine the efficacy of this new developed multidisciplinary intervention in patients with hand OA, to examine the added value of a booster session and to explore the association of patient-related factors with changes in pain and function after multidisciplinary treatment.		
METHODOLOGY	150 patients with hand OA are randomized to the multidisciplinary treatment programme or a waiting time of three months followed by the multidisciplinary treatment programme. After the treatment programme patients are randomized to booster session or no booster session. Participating study centers are the Rheumatology Center of the Sint Maartenskliniek (locations Nijmegen and Woerden) and the University Medical Center Utrecht. Primary outcome measures after three months and one year are the OMERACT OARSÍ responder criteria and the AUSTRALIAN CANADIAN hand index.		
PROGRESS	Data collection completed.		
RESULTS	Results will be available in 2011.		
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EVALUATION OF A MULTIDISCIPLINARY TREATMENT FOR PATIENTS WITH SCLERODERMA AND DISTRESS

PERIOD	2010-2012		
PARTICIPANTS	L. Kwakkenbos	SMK	Psychologist
	F. van den Hoogen	SMK	Rheumatologist
	M. Jeurissen	SMK	Rheumatologist
	M. Vonk	UMCN	Rheumatologist
	A. van Helmond	SMK	Psychologist
	H. Beenackers	SMK	Psychologist
	L. Willems	SMK	Psychologist
	W. van Lankveld	SMK	Psychologist, Senior Researcher
	C. van den Ende	SMK	Senior Researcher Allied Healthcare
SPONSOR	Sint Maartenskliniek		
PURPOSE	Scleroderma has serious negative consequences for patients. Elevated levels of depression are observed in 36- 65% of the patients. There is a growing recognition that these psychological problems should be treated, in addition to regular and ongoing medical and paramedical treatment. The aim of the present study is to evaluate the efficacy of a protocol for cognitive behavioral treatment as a component of multidisciplinary treatment in SSc on psychological distress.		
METHODOLOGY	The effect of the psychological component of multidisciplinary treatment will be evaluated using a multiple-baseline single-case design (N=8). Participants will be recruited from participants in a psychological cohort study. Patients with high levels of psychological distress will be invited to participate in the intervention study. In addition to the psychological treatment, individual physical therapy, occupational therapy and/or specialized nurse care will be provided following evidence-based methods and best practice guidelines.		
PROGRESS	Treatment protocols are developed and its content evaluated by independent psychologists. Patients are currently being recruited for participation in the study.		
RESULTS	Results will be available in 2012.		
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EFFECTS OF PREVENTIVE FALL TRAINING IN OSTEOPOROSIS

PERIOD	2004-2010		
PARTICIPANTS	J. Duysens	SMK/UMCN/KUL	Neurophysiologist
	W. van Lankveld	SMK	Psychologist, Senior Researcher
	F. van den Hoogen	SMK	Rheumatologist
	R. Laan	SMK	Rheumatologist
	M. Franssen	SMK	Rheumatologist
	B. Smits-Engelsman	UMCN/KUL	Neuroscientist, Physiotherapist
	N. Verdonshot	UMCN	Biomechanical Engineer
	V. Weerdesteyn	SMK/UMCN	Movement Scientist
	E. Smulders	SMK	Movement Scientist
SPONSOR	ZonMw		
PURPOSE	<p>Persons with osteoporosis are at risk for fall related fractures, because of decreased bone strength. The Nijmegen falls prevention program (NFPP) has been shown to be effective in reducing falls in community-dwelling elderly. For safety reasons, persons with osteoporosis were excluded from this study. Therefore, the NFPP was adjusted to meet the specific demands and constraints of persons with osteoporosis. The purpose is to evaluate the efficacy of this program.</p>		
METHODOLOGY	<p>Participants were randomly divided in an exercise (n=50) and a control group (n=46). Fall incidence was monitored by means of a fall calendar for 12 months after the intervention period. Laboratory assessments of obstacle avoidance were performed 3 times (before and after the intervention period and after 12 months follow-up). In addition, balance confidence, quality of life and activity level was assessed by means of questionnaires.</p>		
PROGRESS	The study has ended.		
RESULTS	<p>Participants in the exercise group reported significantly less fall incidents (39%) than the control group. Furthermore, their balance confidence improved. No differences were seen in obstacle avoidance performance, quality of life and activity level. However, the quality of life and activity level were already high at baseline. Furthermore, attendance to the program was high (93%) and the participants mentioned the falls prevention program as pleasant and informative.</p>		
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STEP REACTION TIME IN PERSONS WITH RHEUMATOID ARTHRITIS

PERIOD	2009-2010		
PARTICIPANTS	E. Smulders	SMK/UMCN	Movement Scientist
	W. van Lankveld	SMK	Psychologist, Senior Researcher
	V. Weerdesteyn	SMK/UMCN	Movement Scientist
	J. Duysens	SMK/UMCN/KUL	Neurophysiologist
	C. van den Ende	SMK	Senior Researcher Allied Healthcare
SPONSOR	Sint Maartenskliniek		
PURPOSE	The ability to perform quick steps contributes to a reduced fall risk. Manual reaction time is delayed in RA patients, but step reaction has not been investigated. The aim was to compare step reaction performance of RA patients with healthy aged- and gender matched controls. Furthermore, balance confidence, fear of falling and activity level were investigated, since these are known to be related to increased fall risk an delayed reaction time.		
METHODOLOGY	Fifteen RA patients and controls (mean age 60 year) performed the step reaction task. After a visual cue they were instructed to step as quickly in forward direction on a force plate. Furthermore, a manual reaction time task was performed and questionnaires on balance confidence (ABC), fear of falling (SAFFE-nl) and physical activity (SQUASH) were assessed.		
PROGRESS	The study has ended.		
RESULTS	RA patients moved their stepping leg with a lower velocity than the controls, which resulted in increased movement times. Reaction times were not significantly delayed. The results of the manual reaction time were largely comparable with that of the earlier study, with delayed reaction and increased movement times. The RA patients had significantly less balance confidence and more fear of falling. Physical activity was comparable between the groups.		
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IMPLEMENTATION OF A PATIENT-CENTERED STEPPED-CARE APPROACH FOR OSTEOARTHRITIS

PERIOD	2009-2013		
PARTICIPANTS	J. Dekker T. Voorn C. van den Ende S. Bierma-Zeinstra J. Kortland B. Swierstra T. Vliet Vlieland J. Bijlsma H. Schers A. Smink	VUMC UMCN SMK EMC RPB SMK LUMC UMCU UMCN SMK	Psychologist General Practitioner Senior Researcher Allied Healthcare Physiotherapist, Epidemiologist Patient Representative Orthopedic surgeon Physiotherapist Rheumatologist General Practitioner Epidemiologist, Movement Scientist
SPONSOR	Dutch Arthritis Association (Reumafonds) Royal Dutch Society for Physical Therapy (KNGF) Annafonds Sint Maartenskliniek		
PURPOSE	With respect to conservative treatment of hip or knee OA, current guidelines are not specific about the indication for and the timing of the various treatment modalities. Therefore, a multidisciplinary patient-centered treatment strategy is developed and will be implemented in the region Nijmegen, The Netherlands.		
METHODOLOGY	For a successful implementation, a broad range of activities is necessary. Most importantly, tools should be available for patients as well as healthcare providers involved in the treatment of OA of the hip and/or knee. One of the activities that will be arranged, is a care booklet. The outline and content of these activities will be determined by a regional implementation group with experts (consisting representatives of all disciplines involved in the treatment of OA).		
PROGRESS	The GP's of the Nijmegen University Network of General Practitioners (NUHP) are invited by email to participate in the study (n=157). These GP's are asked to invite patients with a new episode of complaints of symptomatic OA of the hip and/or knee to participate in the study. Minimal 250 patients will be included.		
RESULTS	The first result is the care booklet. This booklet will be distributed to patients with OA of the hip or knee by GP's. The care booklet contains general information about OA, the treatment strategy. Moreover, it enhance an active role of the patient.		

Secondly, barriers and facilitators of the implementations in both patients and healthcare providers will be identified. The impact of the patient-centered stepped-care approach on healthcare utilization and outcome of care will be described.

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DEVELOPMENT AND EVALUATION OF A MULTI-DISCIPLINARY CARE PROGRAMME FOR PATIENTS WITH GENERALIZED OSTEOARTHRITIS

PERIOD	2009-2012		
PARTICIPANTS	T. Hoogeboom A. den Broeder C. Kersten-Smit R. de Bie C. van den Ende	SMK SMK SMK UM SMK	Physiotherapist, Junior Researcher Rheumatologist, Senior Researcher Physiotherapist Epidemiologist, Senior Researcher Senior Researcher Allied Healthcare
SPONSOR	Sint Maartenskliniek		
PURPOSE	Around 27% of patients with hip or knee osteoarthritis also have generalized osteoarthritis (GOA). Up to now, the effectiveness of a non-pharmacologic treatment for people with GOA has not been evaluated. Therefore, we aimed to compare the effectiveness of an multi-disciplinary treatment programme to a telephone-based programme on functioning, self-efficacy and quality of life in people with GOA. In addition, we will also evaluate economic costs and examine which subgroup of patients benefits most of both interventions.		
METHODOLOGY	Participants included in the study will be randomly assigned to the multi-disciplinary or the telephone counseling group on the basis of block randomization. We aimed for a single blind study, in which the examiner was blinded for group allocation. Patients receive questionnaires prior and after the interventions (follow-up = 1 year).		
PROGRESS	The study has started in the Maartenskliniek Nijmegen en Woerden and the study inclusion has begun.		
RESULTS	Not yet available.		
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PRELIMINARY EFFECTIVENESS OF A MULTI-DISCIPLINARY CARE PROGRAMME FOR PATIENTS WITH GENERALIZED OSTEOARTHRITIS

PERIOD	2009-2012		
PARTICIPANTS	T. Hoogeboom A. den Broeder L. Rietveld R. de Bie C. van den Ende	SMK SMK MKW UM SMK	Physiotherapist, Junior Researcher Rheumatologist Occupational therapist Epidemiologist Senior Researcher Allied Healthcare
SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>Data on the efficacy of non-pharmacological treatment options for people with generalized osteoarthritis are lacking. We therefore systematically conceptualized a treatment programme tailored to the needs of patients with GOA. To gain more insight on the effects of this multi-disciplinary intervention on the health related quality of life, a high quality clinical study has to be performed. However, before embarking on a large trial, the feasibility of the approach is tested in a pilot study. In this study we aim to evaluate the feasibility and preliminary effectiveness of a multi-disciplinary intervention for patients diagnosed with generalized osteoarthritis.</p>		
METHODOLOGY	<p>Four participants, ≥ 18 years and diagnosed with generalized osteoarthritis, entered the simultaneous replication phased single case study. All patients completed a fourteen itemed questionnaire - on pain, fatigue, physical functioning, kinesiophobia, illness cognitions, illness beliefs and self-efficacy - twice a week over a 19 week period, starting at a random moment after the intake. Also, pre and post measures are performed, to assess fatigue, self-reported and performance-based functioning, self-efficacy and illness cognitions. Feasibility measures are adherence, contentment and occurrence of adverse events.</p>		
PROGRESS	All data is collected. Statistical analyses are planned for 2011.		
RESULTS	Not yet available.		
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ACTIVITY PACING: AN OFTEN USED BUT POORLY UNDERSTOOD NON-PHARMACOLOGICAL TREATMENT IN ARTHRITIS

PERIOD	2009-2011		
PARTICIPANTS	T. Hoogeboom N. Keijsers Y. Neijland C. van den Ende	SMK SMK SMK SMK	Physiotherapist, Junior Researcher Senior Researcher Specialized Nurse Senior Researcher Allied Healthcare
SPONSOR	Sint Maartenskliniek		
PURPOSE	Both activity pacing and promotion of physical activity are recommended treatment strategies for patients with rheumatoid arthritis to improve daily functioning and to reduce pain and fatigue. These strategies appear to be contradictory. In this study, we aimed to gain more insight in patient and disease related characteristics associated with activity pacing. Furthermore, we investigated the relationship between activity pacing and physical activity, as we hypothesized activity pacing might invoke physical inactivity.		
METHODOLOGY	Thirty RA patients (80% female, mean age 59 years (SD=8)) were included in this study. Patients completed a set of questionnaires, wore an accelerometer on the ankle and completed an activity diary for five days. An occupational therapist and specialized nurse classified the participants as adequate or non-adequate pacers. For each patient compliance to the Dutch Physical Activity Norm (DPAN) was determined. Afterwards patients were asked whether they believed they met the DPAN. Physical activity and disease-related characteristics were compared for adequate and non-adequate pacers by using t-test statistics.		
PROGRESS	Manuscript finalization is under progress.		
RESULTS	Adequate pacers (n=14) reported significantly better functioning and less pain during activities. We found no significant differences in the amount of physical activity between adequate and non-adequate pacers. More physical activity was associated with a lower body mass index and less problems in functioning. Three participants met the DPAN, whereas 14 participants thought they did.		
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2.3 PHARMACOLOGICAL STUDIES

Disease activity guided treatment may contribute to the efficiency and efficacy of care by tailoring the dosage of drugs to the response to drugs (e.g. biologicals) in individual patients. In this area of research the Department of Rheumatology, the Department of Pharmacy and the Clinical Chemistry lab closely collaborate in a number of studies to improve the outcome of drug treatment. Furthermore, at the Sint Maartenskliniek a randomized controlled trial is initiated to evaluate the efficacy and safety of doxycycline in patients with osteoarthritis of the knee.

MECHANISMS UNDERLYING FALLS RISK WITH MEDICATION USE

PERIOD	2007-2010		
PARTICIPANTS	J. Hegeman	SMK	Movement Scientist
	B. van den Bemt	SMK	PharmD, Scientist
	V. Weerdesteyn	SMK/UMCN	Movement Scientist
	B. Nienhuis	SMK	Biomedical Engineer
	J. van Limbeek	SMK	Epidemiologist
	J. Duysens	SMK/UMCN/KUL	Neurophysiologist
SPONSOR	Sint Maartenskliniek		
PURPOSE	NSAIDs are drugs that are often prescribed to patients with rheumatic or orthopedic diseases. They seem to be at a greater risk for falls than healthy persons because of their disease, age and medication use. Another medication group associated with increased falls risk are the antidepressants, SSRIs in particular. This project aims to gain more insight in the mechanism and actual risk for falls when using these medications.		
METHODOLOGY	The assessments consisted of obstacle avoidance during walking, postural balance tasks and reaction time tasks. The NSAID-study was a randomized-placebo-controlled trial with healthy seniors (50-70yrs). For the SSRI-study the performance of long-term (>3 months) users on the abovementioned 3 tests was compared with that of healthy age-matched participants (50-70yrs).		
PROGRESS	Final analyses are performed. Three articles are published in peer reviewed journals. Three more articles are in progress.		
RESULTS	Statistical testing revealed no effects of NSAIDs or SSRIs on obstacle avoidance skills, postural balance and manual reaction time. Hence, the increased falls risk with medication use found in other studies is not solely due to changes in these skills. Further research is needed in order to investigate the effect of attention division and the circumstances in which medication users fall.		
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PUBLICATIONS	Hegeman, J., Van den Bemt, B., Duysens, J. and Van Limbeek, J. NSAIDs and the risk of accidental falls in the elderly: a systematic review. <i>Drug Safety</i> 2009; 32: 6, 489-498.		

Hegeman, J., Weerdesteyn, V., Van den Bemt, B. J., Nienhuis, B., Van Limbeek, J. and Duysens, J. Even low alcohol concentrations affect obstacle avoidance reactions in healthy senior individuals. *BMC Research Notes* 2010; 3: 1, 243.

Hegeman, J., Nienhuis, B., Van den Bemt, B., Weerdesteyn, V., Van Limbeek, J. and Duysens, J. The effect of a non-steroidal anti-inflammatory drug on two important predictors for accidental falls: Postural balance and manual reaction time. A randomized, controlled pilot study. *Human Movement Science* 2010; Epub ahead of print.

THE EFFECTS OF DOXYCYCLINE ON REDUCING SYMPTOMS IN KNEE OSTEOARTHRITIS: RESULTS FROM A TRIPLE BLINDED RANDOMIZED CONTROLLED TRIAL

PERIOD	2008-2010		
PARTICIPANTS	G. Snijders	SMK	Researcher
	C. van den Ende	SMK	Senior Researcher Allied Healthcare
	P. van Riel	RU	Rheumatologist
	F. van den Hoogen	SMK	Rheumatologist
	A. den Broeder	SMK	Rheumatologist
SPONSOR	Sint Maartenskliniek		
PURPOSE	Evidence suggests that doxycycline might have disease modifying properties in osteoarthritis (OA). However, the clinically relevant question whether doxycycline also modifies symptoms in knee OA is unanswered. The objective of this study was to investigate the effectiveness of doxycycline on pain and daily functioning in symptomatic knee OA.		
METHODOLOGY	This was a 24-week, randomized, triple blind, placebo-controlled trial to the symptomatic effectiveness of doxycycline twice a day 100 mg in knee OA patients according to the clinical and radiological American College of Rheumatology (ACR) classification criteria. The primary endpoint was the difference in proportion of participants in both study groups achieving a clinical response defined by the OMERACT-OARSI set of responder criteria. Secondary endpoints included pain, stiffness, daily functioning, patient global assessment, quality of life, OA related medication and side effects.		
PROGRESS	Study has been completed.		
RESULTS	Results will be available mid 2011.		
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INFLIXIMAB TROUGH LEVELS AND DOSE DE-ESCALATION IN RA PATIENTS WITH LOW DAS28

PERIOD	2010-2011		
PARTICIPANTS	A. van der Maas	SMK	Resident Rheumatology
	A. den Broeder	SMK	Rheumatologist
	B. van den Bemt	SMK	Pharmacist
	G. Wolbink	Sanquin	Rheumatologist
	W. Kievit	UMCN	Epidemiologist
	P. van Riel	UMCN	Rheumatologist
	F. van den Hoogen	SMK	Rheumatologist
SPONSOR	Sint Maartenskliniek		
PURPOSE	Assessment of the test characteristics (sensitivity and specificity analyses) of infliximab serum trough levels for prediction of whether or not dose de-escalation of infliximab will be successful in RA patients with stable low disease activity and stable infliximab treatment. Also a cost minimization analysis will be done to approximate the possible pharmaco-economic gains of dose de-escalation.		
METHODOLOGY	In RA patients with stable infliximab treatment and stable low DAS28 infliximab dose will be gradually de-escalated until disease activity deteriorates or infliximab is stopped. During one year DAS28, infliximab serum levels, infliximab antibodies, use of RA medication, outpatient clinic visits and health related absence are assessed every visit and a quality of life questionnaire every 3 months. Afterwards sensitivity and specificity analyses will be done for infliximab trough levels.		
PROGRESS	All patients are included and dose de-escalation of infliximab started in January 2010. Follow-up visits are scheduled until march of 2011.		
RESULTS	No results are available at this time.		
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2.4 PARTICIPATION IN EXTERNAL RESEARCH PROJECTS

PERSISTENT LYME EMPIRIC ANTIBIOTIC STUDY EUROPE (PLEASE)

PERIOD	2010-2012		
PARTICIPANTS	F. Vos	SMK	Internist-infectious diseases Specialist
	A. Berende	UMCN	Resident Internist-infectious diseases Specialist
	H. ter Hofstede	UMCN	Internist-infectious diseases Specialist
	B. Kullberg	UMCN	Internist-infectious diseases Specialist
SPONSOR	ZonMW DoelmatigheidsOnderzoek 2010-2012: sub program cost-effectiveness The study is a collaboration between Radboud University Nijmegen Medical Center and St Maartenskliniek Nijmegen.		
2 PURPOSE	Treatment of persistent Lyme disease (PLD) is highly controversial, and two divergent and contradicting "evidence-based" guidelines are used in the Netherlands, each suggesting evidence for strikingly opposing therapeutic approaches: 2 weeks of antibiotic treatment versus long term treatment for at least 6 months. The primary goal of the study is to directly compare the guidelines, in order to establish whether prolonged antibiotic treatment is efficient and leads to better patient outcome than short-term treatment.		
METHODOLOGY	A 3-armed, randomized, double-blind, placebo-controlled trial comparing both guidelines. Study population: Patients with suspected PLD, defined as specific musculoskeletal pain, arthritis, neuralgia, neuropsychological/cognitive disorders and fatigue that are: (a) temporally related to proven symptomatic Lyme disease, or (b) accompanied by a positive B. burgdorferi IgG or IgM immunoblot (strictly defined by standard criteria). Intervention: Open-label i.v. ceftriaxone (2 wks, all patients) followed by blinded randomized oral follow on treatment for 12 weeks with: I. doxycycline (ILADS variant 1); II. clarithromycin plus hydroxychloroquine (ILADS 2); or III. placebo (resulting in 2 weeks' standard CBO treatment followed by placebo). Outcome measures: Success at 14 weeks (end of treatment), defined as improvements on validated pain and functional impairment scales. The study will evaluate the cost-effectiveness of the 3 strategies from a societal perspective.		
PROGRESS	Patient recruitment is expected to continue until Q4 2011.		
RESULTS	An interim analysis on blinded data will be performed after 70 patients have reached the EOT study visit, which is expected in Q2 2011.		
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PREDICTORS FOR USE OF HEALTHCARE IN EARLY OSTEOARTHRITIS: RESULTS FROM THE CHECK COHORT

PERIOD	2009-2010		
PARTICIPANTS	T. Hoogeboom	SMK	Physiotherapist, Junior Researcher
	G. Snijders	SMK	Researcher
	H. Cats	SMK	Rheumatologist
	R. de Bie	UM	Epidemiologist
	S. Bierma-Zeinstra	EMC	Senior Researcher
	P. van Riel	UMCN	Rheumatologist, Senior Researcher
	A. den Broeder	SMK	Rheumatologist, Senior Researcher
	C. van den Ende	SMK	Senior Researcher Allied Healthcare
SPONSOR	Dutch Arthritis Association Sint Maartenskliniek		
PURPOSE	To describe healthcare utilization (HCU) over time and to predict future healthcare consumption in individuals with early hip and knee osteoarthritis.		
METHODOLOGY	Baseline and two-year data on HCU of 1002 participants with early hip and knee OA were used of the Cohort Hip & Cohort Knee (CHECK) study. Six forms of healthcare services were distinguished: use of analgesics and/or supplements and contact with general practitioner, allied health professional, secondary care or alternative care. By use of median split, high overall users of healthcare were identified. Participants without HCU at baseline and two years were labeled persistent no-users. Multivariate logistic regression was performed to identify predisposing, enabling and disease-related variables that could predict either high-overall healthcare use at two years or persistent no-use of healthcare.		
PROGRESS	The manuscript is being finalized for submission.		
RESULTS	At two years, the majority of patients reported some form of HCU for their OA complaints. No relevant difference in HCU between participants with early hip OA and knee OA were found. Several predictors were identified for future HCU.		
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3

RESEARCH WITHIN THE ORTHOPEDIC DEPARTMENT

Research within the Orthopedic department in the Sint Maartenskliniek is facilitated by the Orthopedic research unit of the department of Research, Development & Education (RD&E). Five scientists, one research nurse and administrative personnel give professional support to the orthopedic surgeons at almost all aspects during all study phases. This ensures the validity and continuity of the data collected.

The orthopedic department is divided into 6 units, each specialized in one single area of orthopedic surgery. The six units are Upper Limb unit, Spine unit, Hip unit, Knee Reconstruction unit, Foot and Ankle Reconstruction unit and Anesthesiology. Currently, sixteen orthopedic surgeons, one sports medicine physician, one fellow, and five nurse practitioners and physician assistants are connected to one or more of the units.

The approach for conducting research at the department is evidence based. Multicenter randomized trials and Cochrane literature reviews are conducted when possible. Examples are the multicenter randomized studies on the comparison of knee prostheses. Also, cohort studies are used in appropriate cases. The observational, international study on three surgical techniques for lumbar fusion for spondylolisthesis is one example. Gait analysis studies are performed in close collaboration with the gait analysis laboratory of the Department of RD&E. Gait studies are currently performed with single and double osteotomy cases within the Knee Reconstruction unit, with foot deformity patients in the Foot and Ankle Reconstruction unit and in patients with idiopathic scoliosis in the Spine unit.

The organization and working procedures of the unit have contributed considerably to the professionalization of the Research department of the Sint Maartenskliniek, resulting in a certified Clinical Research Organization (CRO) within the department in 2009. New research projects will be prepared and organized in according to the working procedures of the clinical research organization.

The projects and the scientific output for 2009 and 2010 will be presented within each specialized unit. In addition to the projects described, baseline epidemiological data is collected for patients undergoing specific types of operations. These databases can be used later in historic cohort studies and form the basis for the increasing demand for quality control. Publications and presentations that are not encompassed in the above mentioned research lines can be found in the list of total output.

3.1 THE UPPER LIMB UNIT

The clinical work performed by the surgeons of the Upper Limb Unit (ULU) is focused on elbow, shoulder, and wrist arthroplasty, posttraumatic deformities as malunion, contractures and instability, joint replacement and sports medicine. All patients undergoing upper limb surgery are preoperatively assessed using joint specific validated functional assessment scoring systems to allow meticulous evaluation of the surgical results.

Joint replacement is performed for patients with primary osteoarthritis, and those with posttraumatic osteoarthritis and rheumatoid arthritis. In the latter group a multidisciplinary approach with colleagues from the department of rheumatology is used. In line with this expertise, a major part of research in the previous years was set up with regard to these patient groups.

The unit has specific interest in early micro motion as can be assessed with Roentgen Stereo photogrammetric Analysis (RSA) as a predictor for late loosening and for identification of early failure in a small sample. Currently, the IBP implant is being evaluated with this method and a new cohort study on the glenoid component of a total shoulder arthroplasty is being prepared.

STABILITY OF THE HUMERAL COMPONENT OF THE IBP ELBOW PROSTHESIS, MEASURED WITH RADIO-STEREOMETRY

PERIOD	2003-2011		
PARTICIPANTS	M. de Vos D. Eygendaal J. Luites P. Anderson	SMK Amphia hospital SMK SMK	Orthopedic Surgeon Orthopedic Surgeon Health Scientist Experimental Psychologist
SPONSOR	Ortomed		
PURPOSE	Since 1990 the Kudo Total Elbow Prosthesis (TEP) is used in the Sint Maartenskliniek. Recently the humeral component was modified, resulting in less removal of humeral bone, a more anatomical shape and a larger porous coated surface. In this prospective cohort study, the stability of the humeral component of this iBP elbow prosthesis is determined, calculating the migration of the humeral component relative to the humeral bone using Rontgen Stereophotogrammic Analysis (RSA).		
METHODOLOGY	In 16 patients an iBP TEP was placed using a posterior approach. Baseline RSA took place 1 week after surgery, postoperative follow-up images were made. Migration was defined as translation of more than 0.4 mm and/or rotation of more than 1° in 1 or more directions. Clinical evaluation consisted of VAS scores for pain, range of motion (ROM), the EFA and Broberg & Morrey scores. Radiolucency was assessed using the Morrey classification on plain.		
PROGRESS	A revised article has been submitted to the Journal of Bone and Joint Surgery.		
RESULTS	After 24 months all patients showed pain reduction and functional improvement of the elbow function; 14 prostheses stabilized during the first year. Two continued migration during the second postoperative year. One of these was malpositioned during surgery. The other migrating prosthesis rotated back in opposite direction during the second year. Both patients had no clinical complaints. Both migrating implants showed radiolucent lines. However, the radiolucency score of all radiographs was not consistent with the RSA micromotion results.		
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LONG TERM EVALUATION OF THE BIAxIAL TOTAL WRIST ARTHROPLASTY IN RHEUMATOID ARTHRITIS

PERIOD	2009-2010		
PARTICIPANTS	D. van Harlingen	SMK	Resident Orthopedic Surgery
	M. de Vos	SMK	Orthopedic Surgeon
	P. Heesterbeek	SMK	Health Scientist
SPONSOR	Sint Maartenskliniek		
PURPOSE	Total wrist arthroplasty (TWA) can serve as a treatment for severe wrist disorders without compromising wrist function. The 3rd generation of TWA has been designed to solve the early loosening problem but little long-term follow-ups are available. The purpose of this study is to present the survival analysis for the biaxial total wrist prosthesis.		
METHODOLOGY	Forty biaxial wrist prostheses were implanted uncemented in 36 patients with rheumatoid arthritis. Thirty-two wrists were followed for radiographic and clinical assessment, including radiographic loosening, range of motion, pain, DASH score, satisfaction, strength and complications. Seven wrists prostheses had been revised at a median of 21 (range 8 - 71) months; 1 patient died of an unrelated cause. Mean follow-up of the remaining 32 wrists was 76 (SD 10.3) months. Kaplan-Meier survival analysis was performed with revision defined as failure.		
PROGRESS	The study has been finished and a paper has been submitted.		
RESULTS	Survival after 88 months was 80.8% (95%CI 63.5 - 90.5). There were 31 complications. Twenty-two wrists showed radiographic loosening. Range of motion improved significantly, except for pronation. The mean DASH score improved and the median postoperative ordinal pain score (0-10) at rest was 0 (range 0 - 6) and in activity 0 (range 0 - 7). The mean cumulative survival for revision after over 7 years was satisfying. The biaxial total wrist arthroplasty gives satisfactory clinical results, but has a high risk of radiographic loosening after 5 years. Therefore a periodic radiographic and clinical follow-up is necessary.		
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PROPIONIBACTERIUM INFECTION IN ORTHOPEDIC SURGERY

PERIOD	2008-2010		
PARTICIPANTS	F. Verhulst J. Meis F. de Man P. Heesterbeek	SMK CWZ SMK SMK	Resident Orthopedic Surgery MD, Microbiologist Orthopedic Surgeon Health Scientist
SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>Propionibacterium acnes (<i>P. acnes</i>) is a skin commensal which is often interpreted as a contaminant when found in cultures of surgical specimens when infection is suspected. However, recent reports suggest that <i>P. acnes</i> can be identified as the causative micro-organism of infection. Furthermore <i>P. acnes</i> infections occur more often after shoulder surgery than after surgery of the lower extremities or spine. The aim of this study was to identify how frequently <i>P. acnes</i> was responsible for infection after orthopedic surgery of the shoulder, lower extremity and spine.</p>		
METHODOLOGY	<p>Inclusion criteria were the occurrence of infection after surgery of the shoulder, lower extremity (hip and knee), or spine as well as all cases where <i>P. acnes</i> was cultured and no infection was present after these same types of surgery in our orthopedic hospital. The inclusion period was between January 2000 and May 2008. Infection was defined when two or more cultures were positive with the same micro-organism in the presence of clinical signs and symptoms. The first goal was to identify the incidence of infection due to <i>P. acnes</i> amongst all infections. The secondary goal was to identify the incidence of infection versus contamination amongst all cases with positive cultures for <i>P. acnes</i>. Both outcomes were compared for surgery of the shoulder, lower extremity and spine.</p>		
PROGRESS	Study has been finished and the paper will be submitted shortly.		
RESULTS	The low virulent <i>P. acnes</i> can cause orthopedic surgical infections and should not be regarded a priori as a contaminant in cultures. This is especially true for shoulder surgery, where <i>P. acnes</i> infections occur frequently and significantly more often than in surgery of other joints.		
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3.2 SPINE UNIT

The spine team has grown in the last years, and now includes the Institute for Spine Surgery and Applied Research. This is a co-operative unit, together with neurosurgeons, neurophysiologists, and anesthesiologists. Clinically there is expertise especially in the field of degenerative cervical and lumbar pathology, and spinal deformities. The unit continues to evaluate the use of alternative treatment options such as bone substitutes and conservative treatments, especially for patients with chronic low back pain. The research lines run parallel to this clinical expertise.

In the field of lumbar spine, the research line on treatment of low-grade spondylolisthesis is continued with the design of an international cohort of three different surgical techniques. The earlier work in cooperation with the University Medical Center of Utrecht, a systematic literature review and a retrospective cohort, has proven invaluable in the setup of the study. Moreover, an anatomical study on the geometry of the lumbar vertebrae is performed in a case-control study of patients with low-grade spondylolisthesis. In the treatment of degenerative lumbar disc disease, several cages were evaluated with or without the combination of ChronOs as bone substitute.

The referral of patients with spinal problems has been optimized in the One-Stop Solution concept. A number of conservative treatments are available at the Sports Medical Center where the results are analyzed, such as the IDD therapy and the RealHealth program for patients with chronic low back pain. In the next year, the RealHealth program will be expanded to patients with failed back surgery and will also be closely monitored and evaluated in a randomized controlled trial.

The upright MRI has given interesting research facilities for studying the anatomy of the spine and spinal deformities such as scoliosis in more detail. A study of the normal geometry of the spine in a loaded position was conducted in collaboration with the University Medical Center of Utrecht.

The VICON motion analysis system in the gait laboratory is used to study the effect of a corrective surgery in patients with idiopathic scoliosis.

The analysis of neuro-monitoring in spinal deformity surgery has been continued after research by H.L. Journée and D.H. Langeloo. Nowadays all monitored patients are being studied to investigate the side effects of the transcranial motor evoked potential monitoring during spinal surgery.

ACCEPTANCE AND COMMITMENT THERAPY, AN ADDITION IN THE TREATMENT FOR CHRONIC MUSCULOSKELETAL PAIN: SYSTEMATIC REVIEW AND ANALYSIS OF EFFECT SIZES

PERIOD	2009-2010		
PARTICIPANTS	S. Bluysen	SMK	Psychologist
	C. Hofstad	SMK	Movement Scientist
	P. Anderson	SMK	Experimental Psychologist
	J. van Limbeek	SMK	Epidemiologist
SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>Although several studies have illustrated the effectiveness of Cognitive Behavioral Therapy (CBT) for chronic pain, a substantial proportion of patients with chronic musculoskeletal pain have not been helped by traditional CBT. CBT focuses on seeking changes in thoughts and beliefs. In contrast, Acceptance and Commitment Therapy (ACT) focuses on accepting thoughts and feelings that previously have triggered unhelpful responses. The efficacy of ACT has been evaluated in patients with a wide range of psychiatric disorders. The aim of this review is to update, summarize and analyze the findings from previous studies concerning the effectiveness of ACT in patients with chronic musculoskeletal pain.</p>		
3 METHODOLOGY	<p>To assess the quality of these studies, a criteria list of 25 items based on the CONSORT Statement 2001 checklist and the STROBE statement checklist was developed. The effect size (Cohen's d) for each selected outcome was determined by subtracting post-treatment from pre-treatment scores and subsequently dividing this difference by the standard deviation (SD) of the pre-treatment scores (Cohen, 1988). Comparisons were made between ACT and another psychological treatment or a waiting list.</p>		
PROGRESS	The review is submitted.		
RESULTS	<p>After screening 147 potentially relevant publications, only seven studies were included. Two studies passed the methodological quality assessment, and fulfilled the criteria for A-level classification. Further analyzes and effect size calculations showed that medium to large effect sizes could be found for most of the outcomes: these were sustained six months later.</p> <p>ACT seems to be an addition to the treatment for chronic musculoskeletal pain. To show the effectiveness of ACT, further research with good quality trials is needed.</p>		
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BALANCE CONTROL AND GAIT ANALYSIS IN IDIOPATHIC SCOLIOSIS BEFORE AND AFTER SURGERY

PERIOD	2009-2012		
PARTICIPANTS	M. de Kleuver J. Duysens N. Keijsers J. Schimmel	SMK SMK/UMCN/KUL SMK SMK	Orthopedic Surgeon Neurophysiologist Movement Scientist Health Scientist
SPONSOR	Sint Maartenskliniek		
PURPOSE	Patients with disturbed trunk symmetry, such as patients with adolescent idiopathic scoliosis (AIS), have problems with stability control during standing and walking. Often these patients require spinal fusion surgery, which reduces the spinal mobility and affects the trunk biomechanics. So far, one lacks appropriate quantitative measures to assess the functional outcome of these interventions. Patients will be tested before and after surgery in demanding tasks such as fast walking and walking uphill to test their functional potential and to highlight compensatory strategies.		
METHODOLOGY	At least fifteen patients with idiopathic scoliosis will participate in this study and will be tested before and after surgery (3 months and 1 year). In the first part, static postural stability will be obtained with two force-plates. Several tasks will be performed, for example eyes open/eyes closed. In the second part, subjects will be tested during level walking and walking on a treadmill. The treadmill is used to perform seven walking trials at different speeds, starting at 2 km/h up to 8 km/h with increments of 1 km/h and two walking trials at 4 km/h with 5 and 10% incline. Special emphasis will be placed on pelvic and thoracic rotation, as well as on asymmetries.		
PROGRESS	All patients have been included. We hope to present the final results in 2012.		
RESULTS	The first preliminary results showed that patients with idiopathic scoliosis were able to perform all walking trails and that extra axial rotation can be achieved by introducing walking at higher velocities. The basic sagittal kinematics of hip, knee and ankle showed an increased range of motion at higher velocities, but not different between the scoliosis patients and healthy females. How the changes with speed affect transverse trunk rotation and/or the (ability to) counter rotate between thorax and pelvis in adolescent idiopathic scoliosis needs further exploration.		
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FUSION FOR LOW GRADE ISTHMIC SPONDYLOLISTHESIS; A STUDY OF THREE DIFFERENT TECHNIQUES

PERIOD	2009-2013		
PARTICIPANTS	P. Horsting	SMK	Orthopedic Surgeon
	M. de Kleuver	SMK	Orthopedic Surgeon
	M. Spruit	SMK	Orthopedic Surgeon
	J. van Loon	SMK	Orthopedic Surgeon
	J. Schimmel	SMK	Health Scientist
	S. Susan	SMK	Research Nurse
	E. Hoebink	Amphia	Orthopedic Surgeon
	D. Schlenzka	Orton	Orthopedic Surgeon

SPONSOR AOSpine

PURPOSE Specific treatment for low-grade isthmic spondylolisthesis is still not completely clarified. A systematic review of the literature could not determine the optimal surgical treatment. In order to clarify the optimal surgical intervention for the treatment for isthmic spondylolisthesis a multi-center cohort study is designed. In this study three different surgical techniques will be compared.

3 METHODOLOGY

Three different surgical techniques. The three participating centers each have their own treatment protocol and will not have to change these for the benefits of this study. No randomization will be used but consecutive patient series will be included. The procedures as performed in the hospitals are as follows:

- Sint Maartenskliniek Nijmegen: Combined posterior and anterior approach with use of instrumentation
- Amphia Hospital Breda: Posterior approach only with pedicle screw instrumentation
- Orton Orthopaedic Hospital Helsinki, Finland: Posterior approach only with fusion in situ, without use of instrumentation

Several clinical, radiological and economical outcomes will be evaluated, of which the VAS pain scores will be the primary outcome measure. Follow-up moments are planned as follows: pre-op and at 3, 6, 12, 18 and 24 months postoperative.

PROGRESS Inclusion is still going on. In each center 45 patients will be included.

RESULTS Not yet available.

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GOOD FUNCTIONAL OUTCOME 10 YEARS AFTER SINGLE LEVEL ANTERIOR LUMBAR FUSION

PERIOD	2009-2010		
PARTICIPANTS	P. Horsting P. Pavlov J. van Limbeek	SMK SMK SMK	Orthopedic Surgeon Orthopedic Surgeon Epidemiologist
SPONSOR	Sint Maartenskliniek		
PURPOSE	The aim of this study was to analyze long term functional outcome after single level anterior lumbar interbody fusion and identify possible influence of adjacent segment disease (ASD).		
METHODOLOGY	Thirty-three patients with chronic low back pain caused by single-level disc degeneration underwent anterior lumbar interbody fusion with SynCage® and additional posterior fixation (translaminar screws, n=30 or pedicle screws, n=3). Radiological and functional results were evaluated (VAS and Oswestry Disability Index, ODI). General health was measured by SF-36. Adjacent segment disease (ASD) was evaluated radiologically using a 0.6 Tesla Fonar Upright™ MRI.		
PROGRESS	Results will be published in 2011.		
RESULTS	25 patients (76%, 18 females, 7 males) were available for follow-up after 129 months (127 - 131). Mean age was 47 years (37-67). Fusion levels were L2-L3: 1, L4-L5: 10, L5-S1: 14. Functional scores showed significant improvement in pain and function up to the 2-year follow-up but at the 4- year follow-up, there was some deterioration. The 10-year follow-up results remained stable (VAS 3 points less and ODI 30 points better than pre-op). We registered degenerative signs in 8/25 (32%) patients. The results seem not related to adjacent segment disease (ASD). Facet joint osteoarthritis did not occur without disc degeneration. The SF-36 score was less compared to the general population, but better than preoperative spinal surgery population scores. Anterior lumbar interbody fusion with SynCage and additional posterior fixation is a safe and effective procedure. An initial improvement in VAS and ODI scores is partly lost at the 4-year follow-up observation, but remains stable afterwards. Scores are still significantly better than the preoperative scores at 10-year follow-up. General health is lower than the general population but better than low-back pain group. Results seem not related to adjacent segment disease.		
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THE DUTCH REALHEALTH PAIN MANAGEMENT PROGRAM FOR PATIENTS WITH CHRONIC LOW BACK PAIN

PERIOD	2008-2010		
PARTICIPANTS	J. O'Dowd	LBH/RealHealth UK	Orthopedic Surgeon
	J. van der Merwe	RealHealth UK	Clinical Psychologist
	M. de Kleuver	SMK	Orthopedic Surgeon
	P. Pavlov	SMK	Orthopedic Surgeon
	M. Spruit	SMK	Orthopedic Surgeon
	J. van Limbeek	SMK	Epidemiologist
	M. van Hooff	SMK	Health Scientist
SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>Chronic low back pain (CLBP) poses a major health and economic problem for society.</p> <p>Daily intensive multidisciplinary programs with a mean duration of 100 hours of Cognitive Behavioral Therapy exposure seem to be effective in the treatment of patients with CLBP. The 2-week residential Dutch RealHealth program is based upon these principles. The main purpose was to evaluate the 1-year results of the Dutch RealHealth program in terms of improvement and maintenance of results on disability and self-management of CLBP.</p>		
METHODOLOGY	<p>Patients are included according to the following criteria: CLBP \geq 6 months, confirmed no indication for medical treatment, no intention to ask for medical treatment during RealHealth program for 1 year, age 20-65 years, motivation to train behavior, and understanding of the Dutch language in reading and writing. Exclusion criteria were severe psychiatric disorders. The first consecutive eleven groups with 107 patients were considered as cohort study group. Outcomes were RMDQ, ODI, PSEQ, and SF36. All parameters were measured at baseline, end of 2-week program, and at 1 and 12 months follow-up. Significance and clinical relevance of study results are calculated.</p>		
PROGRESS	<p>The results have been published. Meanwhile a database exists with data of 450 consecutive patients who have finished the 1-year follow-up assessment. The challenge is to examine the data and evaluate which predictive factors are related to CLBP and are influenced by the RealHealth program. Moreover, which subgroup of patients benefit from this program.</p>		
RESULTS	<p>Participants meeting the inclusion criteria improve fast in daily functioning and learn to be able to manage their CLBP.</p>		
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PUBLICATIONS

Van Hooff, M. L., Van der Merwe, J. D., O'Dowd, J., Pavlov, P. W., Spruit, M., De Kleuver, M. and Van Limbeek, J. Daily functioning and self-management in patients with chronic low back pain after an intensive cognitive behavioral programme for pain management. *European Spine Journal* 2010; 19: 9, 1517-1526.

FUNCTIONING AND THE USE OF HEALTHCARE SERVICES AFTER AN INTENSIVE PAINMANAGEMENT PROGRAM

PERIOD	2008-2010		
PARTICIPANTS	J. O'Dowd M. de Kleuver P. Horsting W. van Lankveld J. van Limbeek M. van Hooff	LBH/RealHealth UK SMK SMK SMK SMK SMK	Orthopedic Surgeon Orthopedic Surgeon Orthopedic Surgeon Psychologist Epidemiologist Health Scientist
SPONSOR	Sint Maartenskliniek		
PURPOSE	Chronic low back pain (CLBP) poses a major health and economic problem for society. The 2-week Dutch RealHealth seems to be effective in the treatment of patients with CLBP. The purpose of this study was to evaluate the 2-year follow-up effects in terms of daily functioning, quality of life, healthcare use, and the use of pain medication.		
METHODOLOGY	The consecutive cohort of 107 patients with CLBP is continued. A fifth assessment, a telephonic post-market survey, is conducted after 2-year follow-up. Primary outcome was the RMDQ. Secondary outcomes included SF36 and indicators of healthcare consumption and the use of pain medication. Tertiary outcomes included VAS pain intensity and VAS pain disturbance during daily activities.		
PROGRESS	Evaluation of the 2-year results including functionality, healthcare consumption and the use of pain medication is recently finished and an article is submitted for publication. A subgroup of patients who had a previous surgery for the back pain problems seem to benefit of this program. A research protocol including an RCT, with the purpose to examine the effectiveness of the RealHealth program in patients with a Failed Back Surgery Syndrome, is set up and submitted for a grant.		
RESULTS	Selected and motivated patients with longstanding CLBP improve in daily functioning and experience improved quality of life. The results gained in the first year are maintained at 2-year follow-up. Above all, most of the participants are at work and the use of both pain medication and healthcare services have decreased substantially.		
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3

THE EFFICACY OF INTERVERTEBRAL DYNAMICS THERAPY IN PATIENTS WITH LOW BACK PAIN

PERIOD	2007-2009		
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	M. de Kleuver	SMK	Orthopedic Surgeon
	P. Horsting	SMK	Orthopedic Surgeon
	M. Spruit	SMK	Orthopedic Surgeon
	J. van Limbeek	SMK	Epidemiologist
	J. Schimmel	SMK	Health Scientist
SPONSOR	Steadfast Corporation Limited		
PURPOSE	<p>Although initial conservative therapy may be beneficial, persisting chronic low back pain (LBP) may frequently lead to surgical intervention. Any non- invasive treatment as an alternative to surgery deserves attention. The Accu-SPINA System is a medical device that delivers a non-invasive dynamic therapy focused on the treatment of the intervertebral disc when it is considered the main source of LBP. The therapy used is called IDD Therapy (Intervertebral Differential Dynamics Therapy®). The purpose of the study is to investigate the additional effect of the Accu-SPINA treatment on the graded activity program for LBP patients with symptomatic lumbar disc degeneration without radicular pain.</p>		
METHODOLOGY	<p>In a single-blinded randomized controlled study the effect of the IDD therapy added to standard conservative -therapeutic care (graded activity) will be compared to a placebo IDD therapy added to graded activity in a series of 60 patients, who did not receive prior surgical treatment with dynamic stabilization, fusion or disc replacement. In total the IDD therapy will be monitored in 20 sessions within 6 weeks. The treatment outcome and therapy effect will be monitored using VAS pain scores for low back pain and leg pain, the Oswestry disability index and the SF 36 questionnaire. These parameters will be measured before treatment, after 2 weeks, 6 weeks and 3 months.</p>		
PROGRESS	Results are published in European Spine Journal.		
RESULTS	<p>Both groups were comparable before the start of the treatment. VAS back pain improved significantly with both the IDD protocol® as well as the SHAM protocol. However, no difference was seen between the SHAM or IDD protocol®. Leg pain decreased, whereas the ODI and SF-36 scores were increased 3 months after start, but the differences between the groups were not statistically significant. The additional effect of the IDD therapy® to a standard graded activity program on LBP could not be proven after three months.</p>		

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PUBLICATIONS Schimmel, J. J., De Kleuver, M., Horsting, P. P., Spruit, M., Jacobs, W. C. and Van Limbeek, J. No effect of traction in patients with low back pain: a single centre, single blind, randomized controlled trial of Intervertebral Differential Dynamics Therapy((R)). *European Spine Journal* 2009; 18: 12, 1843-1850.

SIDE EFFECTS OF INTRA-OPERATIVE TRANSCRANIAL ELECTRICAL STIMULATION

PERIOD	2009-2011		
PARTICIPANTS	I. Racz	SMK	Neuro-Monitoring Assistant, Anesthesia Assistant
	H. Berends	SMK	Neuro-Monitoring Assistant, Human Movement Scientist
	M. de Kleuver	SMK	Orthopedic Surgeon
	P. Heesterbeek	SMK	Health Scientist
	H. Journee	RUG	Clinical Neurophysiologist
SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>Intra-operative TCE-MEP (transcranial electrical motor evoked potential) is being used routinely in the Sint Maartenskliniek during corrective spinal surgery. During TCE-MEP, motor areas in the brain are stimulated, and the muscle response is controlled for significant changes. This is an established method to control the functioning of the spinal cord and the nerves. Although this method is safe, some adverse effects can exist, that are less visible, but important for the patient. It can be expected that the muscular contractions cause effects like muscular pain, stiffness, or headache. In the literature, the existence and frequency of these effects is unknown. The goal of this study was to identify these after effects.</p>		
METHODOLOGY	<p>For this prospective study, 150-200 subsequent patients will be interviewed after their surgery with the use of TCE-MEP. During the neuromonitoring, stimulation parameters will be noted. On the second day after surgery, a questionnaire will be filled out together with the patient. Patients were asked about the presence of headache, muscle pains, pressure wounds, wounds in the mouth and visual disturbances. In the analysis relationships between stimulation parameters and the frequency of complaints will be investigated.</p>		
PROGRESS	So far, 34 patients have been included in the study.		
RESULTS	No results available yet.		
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SYNFIX-LR® CAGE IN DEGENERATIVE DISC DISEASE: SHORT TERM RADIOLOGICAL AND FUNCTIONAL OUTCOME

PERIOD	2007-2010		
PARTICIPANTS	M. Poeschmann	SMK	Resident Orthopedic Surgery
	P. Horsting	SMK	Orthopedic Surgeon
	D. Schönfeld	SMK	Radiologist
	J. van Limbeek	SMK	Epidemiologist
	P. Pavlov	SMK	Orthopedic Surgeon
	J. Schimmel	SMK	Health Scientist
SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>Chronic low back pain is associated with high rates of absence from work and a long and uncertain rehabilitation. When conservative treatment fails anterior lumbar interbody fusion (ALIF) is a good alternative. Though titanium alloy cages give good fusion rates, a disadvantage is problematic radiological evaluation of fusion. Polyetheretherketone cages (PEEK), such as the Synfix-LR® cage should overcome this. The purpose of this study was to evaluate the early clinical and radiological outcome of the Synfix-LR® cage.</p>		
3 METHODOLOGY	<p>From December 2004 until August 2007 a total of 95 patients (21 double level, 74 single level) with degenerative disc disease from L3 to S1 were operated by a single surgeon. Primary outcome measure was re-operation. Secondary outcome measures were bony bridging within the cage based on CT-scan and clinical improvement measured by the ODI score. The median duration of follow-up was 47.7 months (range 29.9 - 61.6 months).</p>		
PROGRESS	All results have been analyzed and the manuscript will be published in 2011.		
RESULTS	<p>In total 24 patients (25.3%) were re-operated after a mean of 21.9 months (range 6.7-46.9) of the initial surgery. 23 Patients (18 single-level, 5 double-level) were re-operated for symptomatic pseudarthrosis, one patient for a deep wound infection. In one double-level patient both levels were pseudarthrotic. A CT-scan was performed in 89 patients (109 out of 116 levels; 94%). According to our radiological scoring system 43 levels (39.4%) in 41 patients were pseudarthrotic. The mean ODI score improved from 28.1 (SD 6.4) to 16.0 (SD 9.3). No relation has been found between the ODI score and radiological outcome in our population.</p>		
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ANATOMICAL VERTEBRAL PARAMETERS IN LUMBAR SPONDYLOLISTHESIS

PERIOD	2009-2010		
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SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>Spondylolisthesis indicates a forward slippage of the vertebra, whereas spondylolysis is a unilateral or bilateral defect in the pars interarticularis. Despite the fact that several (geometric) risk factors for the development of spondylolisthesis have been studied, it is unknown to what extent a combination of these factors are associated with a higher grade of slip. Therefore, the purpose of our study was to determine to what extent several geometric factors could be associated with a higher grade of slip.</p>		
METHODOLOGY	<p>With the use of a new measurement technique we are able to measure the geometry in a more accurate way, in particular the deformity of the vertebra (wedging), the sacral slope and the anteroposterior diameter (hypoplasia). Standing lateral X-rays of the lumbar spine were collected and several landmarks were identified manually. With the help of Matlab-software, the main outcome parameters could be calculated.</p>		
PROGRESS	<p>Two-tailed independent t-tests, Chi-square tests or appropriate non-parametric alternatives were used to identify differences between the cohort and the control group. Thereafter, a multivariate logistic regression was performed to identify independent risk factors for spondylolisthesis.</p>		
RESULTS	<p>The sacral slope, wedging and hypoplasia (ratio diameter L5:S1) were all independently associated with the degree of slip. An increasing wedge of L5 and increasing sacral slope and a decreasing ratio L5:S1 increased the risk for a spondylolisthesis. However, the ratio L5:S1, wedge L5 and sacral slope were not different between the grade I and grade II slips, indicating that these factors probably are not influencing the grade of slip.</p>		
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SCOLIOSIS IN THE UPRIGHT MRI

PERIOD	2010		
PARTICIPANTS	M. de Kleuver S. Bokhoven A. van Aalten J. Schimmel	SMK SMK SMK SMK	Orthopedic Surgeon Radiologist Laborant Radiology Health Scientist
SPONSOR	Sint Maartenskliniek		
PURPOSE	Patients diagnosed with (idiopathic) scoliosis are mainly young girls. During the clinical follow-up period almost every year a X-ray will be taken in order to determine the progression of the scoliosis. The upright MRI offers excellent opportunities to decrease the amount of radiation. However, it is not known if the measurement of the Cobb-angle could be performed reliably and if this will be comparable to the 'golden standard' X-ray. The purpose of this study was to asses if the upright MRI will be a valuable tool in the clinical evaluation of (idiopathic) scoliosis.		
METHODOLOGY	Scoliosis patients visiting the Radiology department for a conventional X-ray were asked to undergo an upright MRI. The measurements of the Cobb angle on MRI and X-ray were performed by two independent radiologists. The inter- and intraobserver agreement was calculated and the measurements of the MRI and X-ray were compared.		
PROGRESS	Only 10 patients could be included in the study period. Therefore, the results should be interpret with caution.		
RESULTS	The results showed that the upright MRI is not yet suitable for replacement of the conventional X-ray with the present software. The measurements of the Cobb angle differed quite a lot between the X-ray and MRI. Furthermore, patients experienced some problems with the upright MRI, as they had to stand quite still for a relatively long period, whereas an X-ray takes several seconds.		
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PRE-EXISTING ROTATION IN THE SPINE OF HEALTHY VOLUNTEERS MEASURED IN THE UPRIGHT MRI

PERIOD	2009-2010		
PARTICIPANTS	L. Bartels	UMCU	Research Associate
	R. Castelein	UMCU	Orthopedic Surgeon
	W. Dhert	UMCU	Director Orthopedic Research
	M. Janssen	UMCU	PhD-student Orthopedic Surgery
	M. de Kleuver	SMK	Orthopedic Surgeon
	M. Obradov-Rajic	SMK	Radiologist
	M. Viergever	UMCU	Director of Image Sciences Institute
	K. Vincken	UMCU	Research Associate
SPONSOR	University Medical Center Utrecht (UMCU)		
PURPOSE	<p>Rotational instability and vertebral rotation plays an important role in the onset and progression of AIS. However, rotational stability of the spine is diminished under dorsal shear loads, as has been shown in a recent biomechanical cadaveric study. Dorsal shear loads only occurs in the upright human spine, not in the spines of other vertebrates, quadrupedal or bipedal alike. Moreover, it has been shown that the normal nonscoliotic spine has a preexistent rotation corresponding to the most prevalent types of thoracic idiopathic scoliosis. However, this was measured in a supine position. By subjecting the spine to either more axial load, dorsally- or ventrally directed shear load by altering the position of the body, the effect of these forces on preexistent vertebral rotation can be studied in vivo. To investigate the effect of different spinal loading conditions on (preexistent) vertebral rotation in the normal nonscoliotic human spine in vivo.</p>		
METHODOLOGY	<p>Four MR-scans of the spine (T2-S1) will be made in an upright weight-bearing MR apparatus, all four in a different body position. One standing in an upright position, one in a supine, one in a seated-upright position and one in a 'quadruped' position (on hands and knees). Vertebral rotation in the transversal plane will be measured by a semiautomatic computerized method. Ten healthy adults aged 18-40 will participate.</p>		
PROGRESS	Results have been published in European Spine Journal.		
RESULTS	<p>It was shown that in all three positions the mid- and lower thoracic vertebrae were predominantly rotated to the right. However, vertebral rotation was significantly less in the quadrupedal position than in both the standing upright and supine positions.</p>		
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RISK FACTORS FOR DEEP SURGICAL SITE INFECTIONS AFTER LUMBAR SPINAL FUSION

PERIOD	2009		
PARTICIPANTS	G. Wonders P. Horsting M. de Kleuver J. van Limbeek J. Schimmel	SMK SMK SMK SMK SMK	Hygienist Orthopedic Surgeon Orthopedic Surgeon Epidemiologist Health Scientist
SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>Surgical site infections (SSI) are undesired and troublesome complications after spinal surgery. The reported infection rates range from 0.7 to 11.9%, depending on the diagnosis and the complexity of the procedure. Besides operative factors, patient characteristics could also account for increased infection rates. Because the medical, economic and social costs of SSI are enormous, any significant reduction in risks will pay dividends. The purpose of this study is to compare patients who developed deep SSI following lumbar or thoracolumbar spinal fusion with a randomly selected group of patients who did not develop this complication in order to identify changeable risk factors.</p>		
METHODOLOGY	<p>With a case-control analysis nested in a historical cohort of patients who had had a spinal fusion between January 1999 and December 2008, we identified 36 cases with deep SSI (CDC criteria). Information regarding patient-level and surgical-level risk factors was derived from standardized but routinely recorded data and compared with those acquired in a random selection of 135 uninfected patients. Univariate analyses and a multivariate logistic regression were performed.</p>		
PROGRESS	<p>The overall rate of infection in 1,615 procedures (1,568 patients) was 2.2%. A positive history of spinal surgery was associated with an almost four times higher infection rate (OR = 3.7, 95% BI = 1.6-8.6). The risk of SSI increased with the number of levels fused, patients with diabetes had an almost six times higher risk and smokers had more than a two times higher risk for deep SSI. The most common organism cultured was Staphylococcus aureus. All infected patients underwent at least one reoperation, including an open debridement and received appropriate antibiotics to treat the organism.</p>		
RESULTS	<p>Patients who had had a previous spinal surgery are a high-risk group for infection compared with those that never had surgery. Total costs associated with preventive measures are substantial and should be compensated by healthcare insurance companies by means of separate clinical pathways. High-risk patients should be informed about the increased risk of complications. The results are published in European Spine Journal.</p>		

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PUBLICATIONS Schimmel, J.J., Horsting, P.P., De Kleuver, M., Wonders, G. and Van Limbeek, J. Risk factors for deep surgical site infections after spinal fusion. *European Spine Journal* 2010; 19: 10, 1711-1719.

3.3 HIP UNIT

The hip unit of the Department of Orthopedics of the Sint Maartenskliniek has a long tradition of hip surgery: clinical expertise exists in the field of pediatric hip deformities, hip osteotomies, reconstructive surgery for degenerative hip disease, and arthroplasty and revision arthroplasty surgery. The hip research line concentrates on total hip arthroplasty.

There have been several cohort studies in the past years, analyzing different hip arthroplasty aspects, and currently the uncemented RM-cup fifteen years survival is being calculated. Earlier work on the RM-cup is continued, evaluating different aspects of the iso-elastic properties of the cup through literature studies, stress shielding analysis by means of finite element analysis as well as by DEXA and CT assessments of bony areas around the cup, and fixation of press-fit cups by RSA-measurements.

For aftercare of total hip replacement surgery, the hip unit evaluates efficacy of post clinical physiotherapy in a randomized trial.

ISO ELASTICITY OF THE PRESS-FIT RM CUP

PERIOD	2006-2011		
PARTICIPANTS	G. van Hellemond D. Pakvis W. Jacobs N. Verdonschot B. Scheurs J. van Susante	SMK SMK SMK UMCN UMCN Alysis	Orthopedic Surgeon Resident Orthopedic Surgery Health Scientist Engineer Orthopedic Surgeon Orthopedic Surgeon
SPONSOR	Mathys ltd., Bettlach, Switzerland		
PURPOSE	<p>The new RM press-fit all polyethylene titanium coated mono-bloc acetabular component is a modification of the classical RM cup, which had pegs for screw stabilization against rotational forces. It benefits the modulus of elasticity of the polyethylene which is comparable to bone, minimizing stress shielding behind the cup and therefore preventing aseptic loosening of the cup. However the pegs increased mal positioning and therefore the risk at loosening, and are left out. This improves positioning of the cup and increases the osseointegration surface.</p> <ol style="list-style-type: none">1. The survival of the RM classic is the subject of the first study.2. With Dual-Energy X-Ray Absorptiometry (DEXA), stress shielding behind a metal backed hip resurfacing acetabular component is analyzed.3. The theoretical advantage of isoelastic acetabular components on the retroacetabular bone will be investigated with Final Element Method (FEM) analysis.4. In this last part evidence in literature has been reviewed for superiority of a fixation type, cemented vs. uncemented.		
METHODOLOGY	<ol style="list-style-type: none">1. RM FU 10 -17 years post operative retrospective cohort investigation. Survival analysis, clinical evaluation and radiographic migration analysis.2. DEXA scan will be used to measure the Bone Mass Density (BMD) behind a rigid acetabular component in a hip resurfacing. Prospective clinical, blood and radiological analysis is being performed in both a cohort as well in a RCT trail. The RCT trial entails comparison between a large metal backed resurfacing acetabular component and an uncemented screw cup.3. Using a computer simulation model a Finite element analysis of acetabular bone will be performed on different types of acetabular components. Metal backed, cemented, uncemented isoelastic and MOM isoelastic acetabular components.4. Review cement vs. uncement RCT: a systematic literature review has been performed for articles concerning articles using RCT which compare cemented and uncemented acetabular components.		

PROGRESS

1. An article is in progress.
2. The inclusion has completed.
3. The FEM model has been tested and adjusted to mimic real life. We are now running the tests (walking cycles) with which we can compare the different types of acetabular components.
4. An article is in progress.

RESULTS

There were no differences in clinical outcomes and stability as measured with RSA, between the RM press-fit cup fixated with additional screws and the RM cups without extra fixation. All cups were stable in the second year. In all patients pain was decreased and functionality was increased.

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THE STABILITY OF THE PRESS-FIT RM CUP WITH AND WITHOUT SCREWS USING RADIOSTEREOMETRIC ANALYSIS

PERIOD	2007-2011		
PARTICIPANTS	G. van Hellemond	SMK	Orthopedic Surgeon
	M. Spruit	SMK	Orthopedic Surgeon
	E. de Visser	SMK/Rijnstate	Orthopedic Surgeon
	B. Swierstra	SMK	Orthopedic Surgeon
	D. Pakvis	SMK	Resident Orthopedic Surgery
	J. Luites	SMK	Health Scientist
	H. de Gouw	SMK	Research Nurse
	S. Susan	SMK	Research Nurse
	E. Garling	LUMC	Engineer
SPONSOR	Mathys ltd., Bettlach, Switzerland		
PURPOSE	The new RM press-fit all polyethylene titanium coated mono-bloc acetabular component is a modification of the classical RM cup. It benefits the modulus of elasticity of the polyethylene which is comparable to bone, minimizing stress shielding behind the cup and therefore preventing aseptic loosening of the cup. To investigate the stability of the press-fit RM cup, the migration will be analyzed, in 2 groups, with and without screw fixation, using radiostereometric analysis (RSA).		
METHODOLOGY	A prospective Randomized Clinical Trial (RCT), with 40 patients (power=0.9), who will receive a total hip arthroplasty (THA) with an RM press-fit cup. Half of the patients receive no screws, the other half receive screw fixation. Special radiographs according to the RSA-protocol will be made at several follow-up moments (2, 6, 12 and 24 months) to calculate stability of the RM cup. Besides that osteolysis, pain and functional outcome will be scored.		
PROGRESS	The 2 years follow-up is completed, data-analyses have been performed and an article is written.		
RESULTS	There were no differences in clinical outcomes and stability as measured with RSA, between the RM press-fit cup fixated with additional screws and the RM cups without extra fixation. All cups were stable in the second year. In all patients pain was decreased and functionality was increased.		
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STRESS SHIELDING BEHIND THE ELASTIC RM PRESS-FIT CUP

PERIOD	2008-2012		
PARTICIPANTS	G. van Hellemond	SMK	Orthopedic Surgeon
	M. Nijhof	SMK	Orthopedic Surgeon
	E. de Visser	SMK/Rijnstate	Orthopedic Surgeon
	B. Swierstra	SMK	Orthopedic Surgeon
	P. Pavlov	SMK	Orthopedic Surgeon
	D. Pakvis	SMK	Resident Orthopedic Surgery
	J. Luites	SMK	Health Scientist
	H. de Gouw	SMK	Research Nurse
	S. Susan	SMK	Research Nurse
SPONSOR	Mathys ltd., Bettlach, Switzerland		
PURPOSE	<p>The new RM press-fit all polyethylene titanium coated mono-bloc acetabular component is a modification of the classical RM cup. It benefits the modulus of elasticity of the polyethylene which is comparable to bone, minimizing stress shielding behind the cup and therefore preventing aseptic loosening of the cup. Computed Tomography (CT) is used to evaluate retro-acetabular stress shielding behind this iso-elastic acetabular component.</p>		
METHODOLOGY	<p>The retro-acetabular bone mineral density will be measured with a 3D qCT in 25 patients who will receive an isoelastic RM press fit acetabular component. The BMD will be measured prospectively at 1 week, 6 months and 24 months after surgery. Comparison between the heterolateral side and literature will be performed. Pain and functional outcome will be scored using VAS, Harris Hip Score and Oxford Hip score.</p>		
PROGRESS	<p>The inclusion for the CT study has been completed, the 2 years follow-up will be completed in 2011.</p>		
RESULTS	<p>In all patients' pain decreased and functional outcome increased. Within the first follow-up year in three patients adverse events occurred, however not device-related. Results about stress shielding are not available yet.</p>		
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EFFICACY OF POST-CLINICAL PHYSICAL THERAPY ON FUNCTIONAL RECOVERY AFTER TOTAL HIP ARTHROPLASTY

PERIOD	2007-2012		
PARTICIPANTS	J. de Jong	SMK	Physical Therapist, Movement Scientist
	T. Janssen	SMK	Physical Therapist
	W. Rutten	SMK	Physical Therapist
	P. Goudriaan	SMK	Physical Therapist
	S. Susan	SMK	Research Nurse
	P. Heesterbeek	SMK	Health Scientist
SPONSOR	Sint Maartenskliniek		
PURPOSE	Physical therapy after Total Hip Arthroplasty (THA) is not standard at the Sint Maartenskliniek. However, it may have an additional attribution to better and faster clinical recovery. To gain insight in the effect of physical therapy after THA, this study has been set up. The main question to be answered, is if patients who receive an individualized physical therapy treatment after THA, have a better functional status then those who don't.		
METHODOLOGY	In a prospective randomised clinical trial, 60 patients receiving an THA, will be randomized to the group receiving 8 weeks of physical therapy treatment at the Sint Maartenskliniek or at home, or to the group without therapy. The treatment (2 times a week) will be tailored to the needs of the patient through the Patient Specific Symptom Scale. Clinical improvement will be determined, measuring hip function pre-operative and after 8 weeks through the Patient Specific Symptom Scale, Harris Hip Score, Oxford Hip Scale and functional tests. After 6 months, the functional scores will be measured to analyze if the additional effect remains for a longer period after surgery.		
PROGRESS	The study has been started, patients are being included from November 2008.		
RESULTS	The study is ongoing, there are no results available yet.		
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HEALTH SERVICE UTILIZATION OF PATIENTS WITH END-STAGE OA OF THE HIP OR KNEE

PERIOD	2009-2011		
PARTICIPANTS	T. Hoogeboom	SMK	Physiotherapist, Junior Researcher
	C. van den Ende	SMK	Senior Researcher Allied Healthcare
	R. de Bie	UM	Epidemiologist
	A. den Broeder	SMK	Rheumatologist, Senior Researcher
	B. Swierstra	SMK	Orthopedic Surgeon, Senior Researcher
SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>In the Netherlands, multidisciplinary consensus is achieved on the step-wise treatment strategy for patients with hip or knee osteoarthritis. We expect that current practice does not comply to a large extent to these recommendations. It is more likely that the amount of health service utilization (HSU) is associated with patient characteristics. To gain more insight in HSU, we decided to study HSU, determinants on HSU and to assess the appropriateness of HSU in patients with osteoarthritis referred to secondary care.</p>		
METHODOLOGY	<p>The study utilized a cross-sectional postal survey. Patients older than 18 who visit secondary care due to a new episode of complaints because of hip or knee osteoarthritis are eligible for inclusion. HSU will be measured by straightforward questions. Additionally measured variables are pain, functioning, attitudinal-belief variables and fatigue. Data analysis is performed with descriptive analyses, logistic regression analysis and t-tests.</p>		
PROGRESS	Data collection is finished. Data analysis and manuscript finalization are scheduled for 2011.		
RESULTS	403 of the 500 patients returned the questionnaire (>80%). Further analyses follow.		
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RISK ON CANCER AFTER FIRST KNEE OR HIP ARTHROPLASTY: A POPULATION BASED COHORT STUDY IN THE NETHERLANDS

PERIOD	2009-2011		
PARTICIPANTS	B. van den Bemt	SMK	PharmD, Scientist
	M. Nijhof	SMK	Orthopedic Surgeon
	J. Afink	SMK	Movement Scientist
	J. van Limbeek	SMK	Epidemiologist
	M. van Hooff	SMK	Health Scientist
SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>The number of hip and knee replacements in patients diagnosed with osteoarthritis increases with years. Although patients obviously benefit from these joint replacements in terms of mobility and quality of life, implant specific local and systemic adverse effects due to corrosion and wear are still a matter of concern. Epidemiologic data proving causal relationships between joint replacement and cancer are rare. Early population based studies in New Zealand and in Finland suggested an increased risk of remote cancer during the first decade following the hip or knee arthroplasty. Increased risks can largely be explained by biases of various sorts. Therefore, concern remains and further research consisting of well designed large cohorts are still needed. The purpose of this study was to study time trends in risks on cancer after a first hip or knee arthroplasty, and to compare the incidences of cancer per year with the incidences of cancer found in earlier published cohorts.</p>		
METHODOLOGY	<p>The study is set up as a population based closed cohort in the Netherlands. We used data from the national registry of hospital admissions. Records of all first hip or knee arthroplasty cases were obtained in the period from 1996 up to 2006. In order to assess the impact of possible risk of cancer due to implantation of chrome and cobalt containing endoprotheses, we studied the trend of risks after first hip or knee implants in two cohorts with 7 and 9 years follow up. Standardized, age and death- adjusted cumulative incidence rates for the two defined cohorts were determined.</p> <p>Age-adjusted Rate Ratios were calculated to compare the observed standardized cumulative incidences in the different cohort to the expected cumulative incidence, based on the incidences found in earlier published research. The corresponding 95% CI was calculated, assuming the number of cases observed followed a Poisson distribution.</p>		
PROGRESS	Final analyses are accomplished. Results will be interpreted and a paper prepared.		

RESULTS Preliminary results show no increased incidence of cancer in the elderly who received a first knee or hip arthroplasty. A first hip or knee arthroplasty does not elevate the risk on cancer compared to results found in literature.

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3.4 KNEE RECONSTRUCTION UNIT

The main focus of research performed by the Knee Reconstruction Unit (KRU) is on clinical and functional performance of patients following joint replacement for degenerative diseases.

Open wedge high tibial osteotomy has now been proven a safe treatment. The addition of early weight bearing is being evaluated in a new group of patients. The effect of tibial, femoral and combined osteotomies on gait patterns is analyzed in the gait laboratory with the VICON motion analysis system.

Prosthetic treatment evaluation focuses on ligament surgery and the factors that influence the degrees of freedom for the position of the prosthesis. Techniques to assess ligament balancing have been developed and analyzed and are now in clinical use. Currently, design aspects of different prostheses types are evaluated in randomized controlled trials.

In revision knee arthroplasty, dr. G. van Hellemond supervises the project on clinical outcome after revision surgery in close cooperation with the University Hospital Pellenberg in Leuven, Belgium. Stability of the cemented and uncemented stem component in revision surgery is closely monitored in a randomized controlled trial with RSA as measurement device.

The unit continues to evaluate the treatment of several knee surgeries, such as ligament reconstructions and meniscus replacement, in order to monitor these specific patient groups and further improve treatment.

The unit also participates in two PhD projects, namely the "reconstruction of the anterior cruciate ligament bundle using computer assisted surgery" of J. Luites and "clinical and technical aspects of PCL-retaining total knee replacement with the balanced gap technique" of P. Heesterbeek, the latter being finished in January 2011.

ANATOMIC DOUBLE BUNDLE ACL RECONSTRUCTION

PERIOD 1999-2010

PARTICIPANTS	J. Luites	SMK	Health Scientist
	A. Wymenga	SMK	Orthopedic Surgeon
	L. Blankevoort	ORCA	Biomedical Engineer
	J. Kooloos	RU	Biologist
	N. Verdonschot	UMCN	Engineer

SPONSOR Grant 99-W14, AO-Research Foundation, Davos, Switzerland.

PURPOSE A torn anterior cruciate ligament (ACL) of the knee, which consists of the anteromedial (AMB) and posterolateral bundle (PLB), can be reconstructed using single bundle or double bundle grafts. In both methods, accurate tunnel positioning is important for clinical success. The aim of this project is to develop methods to improve anatomical positioning. In the first part (1, 2) the centers of the insertion sites of both bundles have been mapped with different methods. In the second part (3, 4) two tools will be developed to support anatomical placement of the tunnels. Finally, the developed tools will be applied in two studies (5, 6) comparing the single bundle reconstruction technique with the anatomic double bundle technique.

3

METHODOLOGY From 35 dissected specimens, the AMB and PLB insertion sites were marked. Through lateral radiographs the geometry was 2D mapped (1), with Fastrak the attachment sites were measured 3D (2). With these data, a femoral aiming device was developed (3) and a computer template of the femoral insertion data was made for a Computer-Assisted Surgery System (4). Both methods were validated on 12 femora and tested for intra- and inter-observer reproducibility. In an in-vitro experiment, the anterior-posterior laxity of 10 cadaveric knee specimens were tested in a special frame with intact ACL, with the ACL cut, with an isometric single-bundle reconstruction (5) reconstruction and with a computer-assisted anatomical placed, double-bundle ACL (6).

PROGRESS All studies have been performed, data analyses have been done, and articles are written.
One article (2) has been published in 2007, one article has been accepted (4).

RESULTS

1. The radiologic position of the femoral ACL insertion, as well as the AMB and PLB.
2. Description of the 3D attachment geometry of the anteromedial and posterolateral bundles of the ACL from arthroscopic perspective.
3. Development and validation of a femoral tunnel placement device.

4. Development and validation of a femoral computer template.
5. In vitro analysis of an isometric single bundle ACL reconstruction.
6. In vitro analysis of computer-assisted anatomic double bundle ACL reconstruction.

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TUBEROSITY TRANSFER

PERIOD	2000-2012		
PARTICIPANTS	A. Wymenga	SMK	Orthopedic Surgeon
	P. Anderson	SMK	Experimental Psychologist
	J. Schimmel	SMK	Health Scientist
SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>Patellofemoral disorders are a common orthopedic problem. One treatment advocated since the 1940s is a tibial tubercular transfer to achieve a distal realignment. However, this correction did not always produce the desired results of reduced pain and patella stability. The conclusions based on studies in the literature are difficult to interpret as the patellofemoral pain syndrome is poorly defined. Therefore, a prospective cohort study was obtained in which patients less than 40 years of age presenting with patellofemoral complaints were carefully selected based on the diagnosis. Patients in both the objective patella instability group as well as the lateral tracking patella group had a marked improvement in pain and functional scores at follow up. A 7.5-year follow-up study has been started to see whether the improvement found at the 2-year follow up has been maintained.</p>		
METHODOLOGY	<p>In the prospective cohort, 30 patients were included in each group. The patient was included in the objective patella instability group if there was a history of luxations and pain, a positive patella apprehension and mediolateral patella mobility greater than one half the patella width. The patient was included in the lateral tracking patella group if there was chronic pain without a history of luxations, the physical examination showed no patella apprehension and the mediolateral patella mobility was less than one half the patella width. The Kujala and the Lysholm scoring lists will be completed to assess the patient's knee function.</p>		
PROGRESS	Patients will be seen for the long term follow-up in the next year.		
RESULTS	Not yet available.		
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STABILITY OF OPEN VS CLOSED WEDGE HTO WITH RSA

PERIOD	2001-2009		
SPONSOR	Arbeitsgemeinschaft für Osteosynthese-fragen (AO), Switzerland		
PARTICIPANTS	R. van Heerwaarden	SMK	Orthopedic Surgeon
	A. Wymenga	SMK	Orthopedic Surgeon
	J. Brinkman	SMK	Resident Orthopedic Surgery
	J. Luites	SMK	Health Scientist
PURPOSE	Corrective osteotomy of the proximal tibia is an accepted method for the treatment of early stage medial osteoarthritis in varus knee joints with reliable mid- and long-term results. Goal is to restore the normal load alignment in the knee through valgus correction of the tibia. In this study the stability of two techniques, closed wedge (CW) - and opening wedge (OW) High Tibial Osteotomy (HTO) are compared, calculating the migration of the proximal tibial part relative to the distal part using Rontgen Stereophotogrammic Analysis (RSA).		
METHODOLOGY	Forty-two patients received randomly the opening or closed wedge technique. In both methods a TomoFix plate and screws (Mathys Medical Ltd) were used to stabilize the correction. In the opening wedge technique a ChronOS-Tri-Calcium Phosphate wedge was inserted in order to stimulate bone growth. Baseline stereo radiographs, according to the RSA-method, were made after surgery. Postoperative follow-up images were made. The X-rays were analyzed with the digital RSA-CMS program (MEDIS medical imaging, Leiden, The Netherlands) to calculate the 3-dimensional migration.		
PROGRESS	An article has been published in the Journal of Bone and Joint Surgery.		
RESULTS	The operations were performed without major complications. There were no differences between the OW-HTO and CW-HTO patients in time to regain knee function and full weight bearing. All osteotomies showed consolidation of the bone within the first year. The mean micromotion results were small, with translations less than 0.4 mm and rotations within 1.1°. No differences were seen between both groups (P>0.05) and the results seemed to be clinically irrelevant. After 1 year all osteotomies were stabilized. In conclusion, opening wedge and closing wedge HTO's fixated with angle stable implants showed excellent stability. No clinically relevant differences were found between both groups comparing micromotions on RSA-radiographs and bone consolidation on regular radiographs in a 24 months follow-up.		
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PUBLICATIONS

Luites, J.W.H., Brinkman, J.M., Wymenga, A.B. and Van Heerwaarden, R.J.
Fixation stability of opening-versus closing wedge high tibial osteotomy.
A randomized clinical trial using radiostereometry. *Journal of Bone and
Joint Surgery (British)* 2009; 91-B: 1459-1465.

Brinkman, J.M., Luites, J.W., Wymenga, A.B. and Van Heerwaarden, R.J.
Early full weight bearing is safe in open-wedge high tibial osteotomy. *Acta
Orthopaedica* 2010; 81: 2, 193-198.

STABILITY OF AN OPEN WEDGE HIGH TIBIAL OSTEOTOMY IN EARLY FULL WEIGHT BEARING CONDITIONS THROUGH RADIOSTEREOMETRY

PERIOD	2005-2010		
PARTICIPANTS	R. van Heerwaarden	SMK	Orthopedic Surgeon
	A. Wymenga	SMK	Orthopedic Surgeon
	J. Brinkman	SMK	Resident Orthopedic Surgery
	J. Luites	SMK	Health Scientist
SPONSOR	Synthes Inc, Oberdorf Switzerland Stichting OrthoResearch Maartenskliniek		
PURPOSE	High Tibial Osteotomy (HTO) is performed to stop or inhibit progression of osteoarthritis and to avoid or postpone placement of a knee prosthesis in patients with arthritis of the knee. In this study the stability of opening wedge HTO (OW-HTO) followed by a new postoperative early full weight bearing protocol was compared to the standard protocol of partial weight bearing for 6 weeks, calculating the migration of the proximal tibial part relative to the distal part using Rontgen Stereophotogrammic Analysis (RSA).		
METHODOLOGY	In a prospective cohort study, 14 patients with OW-HTO fixated with a Tomofix LCP plate, revalidated according a full early weight bearing (EWB) protocol after wound healing. After surgery, baseline RSA-stereographs were made, as well as follow-up images. The migration results have been compared to a group of 23 similar patients that underwent the same operation, but had used standard weight bearing (SBW) protocol (10-15 kilograms) for 6 weeks. The knee function was measured using WOMAC, Lysholm and KOOS; pain was scored on a Visual Analogue Scale.		
PROGRESS	An article has been published in the Acta Orthopaedica.		
RESULTS	In the EWB group all osteotomies had completely healed at 12 months, there were no re-interventions and all osteotomies were stable, without loss of correction. There were no significant differences in clinical outcome or migration between the EWB and SWB groups at any of the RSA measurement moments or time intervals. Significant improvements in the EWB group were found in WOMAC, Lysholm and KOOS scores at 12 months post-operatively. Pain had decreased significantly at 12 months.		
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PUBLICATIONS	Brinkman, J.M., Luites, J.W., Wymenga, A.B. and Van Heerwaarden, R.J. Early full weight bearing is safe in open-wedge high tibial osteotomy. <i>Acta Orthopaedica</i> 2010; 81: 2, 193-198.		

GAIT AND VALGUS CORRECTION OSTEOTOMY

PERIOD	2007-2011		
PARTICIPANTS	R. van Heerwaarden	SMK	Orthopedic Surgeon
	F. Wagenaar	SMK	Orthopedic Residence
	N. Keijsers	SMK	Movement Scientist
	N. Stolwijk	SMK	Movement Scientist
SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>Symptomatic lateral compartment osteoarthritis with a valgus malalignment can be treated by a femoral supracondylar osteotomy (SCO) or a high tibial osteotomy (HTO). In contrast to the large amount of available literature regarding valgus osteotomy for varus osteoarthritis, the reports addressing the results of varus osteotomy for knees with a valgus osteoarthritis are scarce and unclear. This is partially related to the difference in prevalence of the deformity, i.e. varus osteoarthritis being much more common than valgus osteoarthritis. The biomechanics of varus and valgus deformity are different. Aim: To study the preoperative and postoperative characteristics of gait in patients with valgus malalignment.</p>		
3 METHODOLOGY	<p>11 patients and ten healthy control subjects are included in this study. All underwent gait analysis (VICON motion analysis system) at self-selected speed, simultaneously collecting kinematic, kinetic and digital video data. Preoperative gait analysis was performed approximately 3 months prior to surgery, postoperative gait analysis approximately 1 year after the correction osteotomy. The investigated mechanisms were toe-angle, Trendelburg gait, lateral trunk lean, walking speed and stride length. Furthermore, Pain and function is assessed using clinical evaluation forms HSS and Kujala, testing the range of motion and ligament laxity.</p>		
PROGRESS	<p>All measurements have been completed. Postoperative data have to be analyzed in detail. A manuscript will be written.</p>		
RESULTS	<p>We found that patients walked with a significantly lower walking speed, stride length and maximum knee flexion during stance phase. The valgus patients had a significantly smaller valgus moment or a valgus moment than the control group. There was a strong correlation between tibiofemoral alignment and the varus/valgus moment at the knee. Compensatory mechanisms did not seem to influence the varus/valgus moment at the knee in this study.</p>		
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GAIT AND DOUBLE OSTEOTOMY

PERIOD	2007-2011		
PARTICIPANTS	R. van Heerwaarden	SMK	Orthopedic Surgeon
	F. Wagenaar	SMK	Orthopedic Residence
	N. Keijsers	SMK	Movement Scientist
	N. Stolwijk	SMK	Movement Scientist
SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>This study investigates the effect of a double osteotomy on gait in patients with severe varus or valgus deformity. In contrast to the large amount of available literature regarding valgus osteotomy for varus osteoarthritis, the reports addressing the results of double osteotomy for knees with a valgus osteoarthritis are scarce.</p> <p>Aim: To study the preoperative and postoperative characteristics of gait in patients with severe valgus or varus malalignment. Furthermore, pain and function is assessed using clinical evaluation forms (HSS and Kujala).</p>		
METHODOLOGY	<p>9 patients and ten healthy control subjects are included in this study. All underwent gait analysis (VICON motion analysis system) at self-selected speed, simultaneously collecting kinematic, kinetic and digital video data. Preoperative gait analysis was performed approximately 3 months prior to surgery, postoperative gait analysis approximately 1 year after the correction osteotomy. The investigated mechanisms were toe-angle, Trendelburg gait, lateral trunk lean, walking speed and stride length.</p>		
PROGRESS	<p>All measurements have been completed. So far, preoperative data are analyzed. Postoperative gait analysis has to be performed. A manuscript will be written.</p>		
RESULTS	<p>We found that patients walked with a significantly lower walking speed, stride length and maximum knee flexion during stance phase. The varus patients had a significantly higher varus/valgus moment than the control group. There was a strong correlation between tibiofemoral alignment and the varus/valgus moment at the knee. There was no correlation between foot progression angle and either tibiofemoral alignment or varus/valgus moment. Compensatory mechanisms did not seem to influence the varus/valgus moment at the knee in this study.</p>		
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FLEXION AND EXTENSION LAXITY OF KNEES WITH A BALANSYS MEDIAL UNICONDYLAR KNEE PROSTHESIS COMPARED TO THE OXFORD KNEE PROSTHESIS

PERIOD	2003-2013		
PARTICIPANTS	A. Wymenga	SMK	Orthopedic Surgeon
	D. van der Schaaf	SMK	Orthopedic Surgeon
	A. ten Ham	SMK	Orthopedic Surgeon
	W. Jacobs	SMK	Health Scientist
	P. Heesterbeek	SMK	Health Scientist
SPONSOR	Mathys Ltd, Bettlach, Switzerland		
PURPOSE	The purpose of this study is to assess the postoperative flexion laxity of the medial BalanSys unicompartmental knee prosthesis, a tension guided system, and compare this to the flexion laxity of the Oxford unicompartmental implant, spacer guided system.		
METHODOLOGY	A tension guided unicondylar knee prostheses (BalanSys™, Bettlach, Switzerland) was compared with a retrospective group of a spacer guided system (Oxford, Biomet Ltd, Bridgend, UK). 25 tension-guided prostheses were placed compared to 28 spacer-guided prostheses. The laxity in both groups was measured at least 6 months postoperatively. The stress x-rays were made fluoroscopically aided in 70 degrees of flexion. Laxity measurements in extension were made with the Telos device. Knee Society Scores (KSS) were performed when these x-rays were made.		
PROGRESS	All patients have been included for the study. The analysis is being performed and the paper will be submitted shortly.		
RESULTS	Laxity in flexion was statistically significantly higher for the tension guided group, whereas laxity in extension was higher for the spacer guided group. There was no significant difference between the two groups in the KSS. A unicondylar knee prosthesis placed with a spacer guided system approximates the values we found in healthy individuals in flexion and in extension.		
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COMPUTER-ASSISTED IMPLANTATION OF BALANSYS TOTAL KNEE ARTHROPLASTY

PERIOD	2004-2010		
PARTICIPANTS	A. Wymenga	SMK	Orthopedic Surgeon
	P. Heesterbeek	SMK	Health Scientist
	W. Jacobs	SMK	Health Scientist
	N. Keijsers	SMK	Movement Scientist
	N. Verdonschot	UMCN	Biomedical Engineer
SPONSOR	Mathys Medical Ltd., Bettlach, Switzerland		
PURPOSE	<p>An important aspect of total knee arthroplasty is the accuracy of placing the prosthesis components relative to the bones. A computer navigation system uses a camera system to determine the location of the bones in space during surgery. When preoperative and peroperative characteristics of the knee are entered into the computer, an algorithm can be used to help to decide the orientation of the saw planes and ligament releases. This computer-assisted technique also provides the opportunity to obtain more insight into several parameters. We are interested in the varus-valgus stability during and after surgery, the position of the patella and the influence of ligament releases on rotation of the femoral component.</p>		
METHODOLOGY	<p>For this prospective cohort study 50 consecutive patients were included. These patients were evaluated preoperatively, and postoperatively at 3, 6, 12, and 24 months. During surgery, kinematics of the knee were measured using the computer navigation system. Peroperative and 6 months postoperative, functional tests were performed in addition to the normal follow-up protocol. At 6 months postoperative, stress radiographs in flexion and extension were taken to determine varus-valgus laxity.</p>		
PROGRESS	<p>All 50 patients are included in the study and the 2 years follow-up has been completed. The results have been published in 8 papers and a thesis.</p>		
RESULTS	<p>Varus-valgus laxity was not increased by ligament releases and compares well tot that of healthy elderly. The balanced gap technique leads to a relatively high range of femoral component rotation. Releases themselves do not change rotation of the femoral component, however, knees with major medial ligament releases do have more endorotated femoral component compared to knees with lateral releases. This variable femoral component rotation does not predict postoperative patellar malposition.</p>		
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PUBLICATIONS

- Heesterbeek, P. J., Jacobs, W. C. and Wymenga, A. B. Effects of the Balanced Gap Technique on Femoral Component Rotation in TKA. *Clinical Orthopaedics and Related Research* 2009; 467: 4, 1015-1022.
- Heesterbeek, P., Keijsers, N., Jacobs, W., Verdonschot, N. and Wymenga, A. Posterior cruciate ligament recruitment affects antero-posterior translation during flexion gap distraction in total knee replacement. An intra-operative study involving 50 patients. *Acta Orthopaedica* 2010; 81: 4, 471-477.
- Heesterbeek, P. J., Keijsers, N. L. and Wymenga, A. B. Ligament releases do not lead to increased postoperative varus-valgus laxity in flexion and extension: a prospective clinical study in 49 TKR patients. *Knee Surgery, Sports Traumatology, Arthroscopy* 2010; 18: 2, 187-193.

MOBILE VERSUS FIXED BEARING TOTAL KNEE ARTHROPLASTY, A RANDOMIZED CONTROLLED TRIAL

PERIOD	2002-2010		
PARTICIPANTS	G. van Hellemond	SMK	Orthopedic Surgeon
	A. Wymenga	SMK	Orthopedic Surgeon
	W. Jacobs	SMK	Health Scientist
SPONSOR	Mathys Medical Ltd, Bettlach, Switzerland		
PURPOSE	To evaluate the difference in functional performance as measured using the active range of motion between patients with a fixed bearing total knee arthroplasty (TKA) and a mobile bearing total knee arthroplasty at one year. Long term follow-up is monitored until ten years postoperatively.		
METHODOLOGY	The study was designed as a randomized controlled trial. Participants were assigned to interventions by using block-stratified, random allocation to receive a TKA with either a polyethylene insert fixed to the tibial component or a polyethylene insert which has some gliding and rotation possibilities. Outcome parameters were active flexion, passive flexion, and Knee Society Score. Outcome parameters were assessed preoperatively and at 3, 6 and 12 months postoperatively by an independent nurse.		
PROGRESS	The study has been finished and a paper has been published.		
RESULTS	Ninety-two patients were included, 46 in each group. Active flexion was comparable for the two groups, 99.9° for the mobile bearing group and 101° for the fixed bearing group. Post-hoc power analysis confirmed that the sample size was adequate for a definite answer to the primary question. The Knee Society Score was comparable between the two bearing groups, except for the stairclimbing subscore, where the fixed bearing type performed better. In our study there was no difference between fixed bearing and mobile bearing total knee arthroplasty.		
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JOURNEY VERSUS GENESIS II PRIMARY TOTAL KNEE ARTHROPLASTY FOR ACTIVE KNEE FLEXION

PERIOD	2004-2012		
PARTICIPANTS	G. van Hellemond	SMK	Orthopedic Surgeon
	A. Wymenga	SMK	Orthopedic Surgeon
	K. Defoort	SMK	Orthopedic Surgeon
	J. Schimmel	SMK	Health Scientist
	S. Susan	SMK	Research Nurse
SPONSOR	Smith & Nephew		
PURPOSE	This is a randomized controlled trial to evaluate the difference between the Journey and the Genesis II implants. The only design feature is a more natural tibial plateau alignment, which is believed to yield more maximal flexion.		
METHODOLOGY	Patients are randomized into two groups receiving either the Journey or the Genesis II prosthesis. Preoperatively and postoperatively, clinical scores as well as functional assessment are obtained. Clinical scores are Knee Society Clinical Rating System and maximal flexion possibilities. Functional scores are the functional score of the Knee Society Clinical Rating System, the patellar score, and the UCLA score. Furthermore VAS pain scores were obtained as well as the postoperative KOOS scores.		
PROGRESS	All 124 patients were included and all surgeries are performed.		
RESULTS	The first results are planned in the second half of 2011.		
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PROSPECTIVE COHORT STUDY OF THE GENESIS REVISION TOTAL KNEE PROSTHESIS

PERIOD	2004-2020		
PARTICIPANTS	A. Wymenga	SMK	Orthopedic Surgeon
	G. van Hellemond	SMK	Orthopedic Surgeon
	K. Defoort	SMK	Orthopedic Surgeon
	R. van Kempen	SMK	Arthroplasty Fellow
	J. Schimmel	SMK	Health Scientist
SPONSOR	Smith & Nephew		
PURPOSE	Revision total knee arthroplasty is a complicated procedure due to difficult exposure and bone loss during removal of the failed primary prosthesis. In the Genesis system, bone deficiencies can be filled with spacers and the problem of exposure is tackled with a tibial tubercle osteotomy, when necessary. The purpose of this study is to evaluate the short and long term results of the Genesis revision knee prosthesis.		
METHODOLOGY	Consecutive patients scheduled for a total revision of their primary total knee arthroplasty are evaluated with the Knee Society Clinical Rating System. Preoperatively as well as fixed moments postoperatively, Knee Society Score, VAS-pain and VAS satisfaction and complications are reported. Preoperatively, the components and operative procedures used are recorded as well as the bone defects.		
PROGRESS	So far, 400 patients have been included in the study. The 12 and 24 months follow-up visits are well under way and the first patients are visiting the clinic for the 60 months follow-up.		
RESULTS	From this cohort the first 150 consecutive patients with a minimum follow-up of 24 months were analyzed. At 24 months postoperative the average KSS clinical and functional scores showed an improvement, VAS pain score was reduced from 61 to 35. Overall we found the largest improvement to occur in the first 3 months after surgery. Divided into the different indication groups; the arthrofibrosis group performed significantly worse on all outcome measures, while the aseptic loosening group showed the best results. The relation between indication and clinical outcome after revision TKA gives the surgeon the opportunity to better estimate the outcome in a certain diagnosis group, thereby providing better information and counseling for the patient.		
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PRIMARY STABILITY OF CEMENTED VS UNCEMENTED STEMS IN REVISION TOTAL KNEE ARTHROPLASTY MEASURED WITH RSA

PERIOD	2007-2012		
PARTICIPANTS	G. van Hellemond A. Wymenga P. Heesterbeek S. Susan	SMK SMK SMK SMK	Orthopedic surgeon Orthopedic surgeon Health scientist Research nurse
SPONSOR	Smith & Nephew		
PURPOSE	The number of revision total knee arthroplasties continues to increase annually. In revision total knee arthroplasties stems are mounted on the prosthesis to offload and reduce interface stresses of damaged bone in the distal femur or proximal tibia. Stems are often used to bypass bone defects or provide additional prosthetic surface for implant fixation. Until now, it is not clear whether stems should be cemented or press-fit. The purpose of this study will be to compare the stability of cemented versus uncemented stems in revision total knee prosthesis.		
METHODOLOGY	This study is set up as a prospective randomized clinical trial. The cementing or press-fit stem treatment will be randomly allocated at surgery (16 patients in each group). Movement of the prosthesis will be measured using roentgen stereophotogrammetric analysis (RSA). At five follow-up moments, RSA radiographs will be performed: post-operative within a few days, 6 weeks, 3 months, 6 months, 1 year and 2 years post-operative. On the second follow-up moment (6 weeks), double RSA radiographs will be performed in order to measure the accuracy of this method in this type of prosthesis. Translation and rotation of the prosthesis will be measured using model-based RSA software.		
PROGRESS	Inclusion has been finished and by March 2011 the 1 year follow-up will be completed for all patients.		
RESULTS	No results yet.		
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FLEXION INSTABILITY AFTER PRIMARY TOTAL KNEE ARTHROPLASTY: DOES REVISION LEAD TO IMPROVEMENT?

PERIOD	2009-2010		
PARTICIPANTS	T. van Tienen	SMK	Orthopedic Surgeon
	G. van Hellemond	SMK	Orthopedic Surgeon
	A. Wymenga	SMK	Orthopedic Surgeon
	R. van Kempen	SMK	Arthroplasty Fellow
	J. Schimmel	SMK	Health Scientist
SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>A recent study by Romero et al. established the existence of midflexion laxity after total knee arthroplasty (TKA). Goal of our study was to justify flexion instability after TKA as a reason for revision. We hypothesized that the revision procedure would lead to a significantly more stable knee joint in 70 degrees of flexion, better functional and clinical results, less pain and good patient satisfaction.</p>		
METHODOLOGY	<p>We report a one year follow - up prospective analysis of results of revision TKA in a consecutive series of patients with proven midflexion instability of $>10^\circ$ on varus/valgus stress flexion fluoroscopy after primary TKA. Cases treated with a hinge prosthesis were left out this group. Preoperatively, three months and one year after the revision procedure different questionnaires were completed by physician and patient, i.e. Knee Society Score (KSS) clinical and functional scores, a 100-mm visual analogue scale (VAS) for pain and patient satisfaction. Stability of the joint was evaluated with the use of varus/valgus stress fluoroscopy in 70 degrees of flexion. Student's paired t-tests were used to compare pre- and postoperative values. A total of 16 patients were included between 2004 and 2008, fifteen with $>10^\circ$ lateral laxity and one with a medial laxity of $>10^\circ$.</p>		
PROGRESS	All results have been analyzed and will be published in 2011.		
RESULTS	<p>The mean age of the patient group was 64.6 ± 9.4 years. In one patient the insert was exchanged, in one patient the femoral component was revised and in fourteen patients the prosthesis was fully revised. One year after surgery the mean lateral laxity of the injured knee improved significantly on flexion stress radiographs to $6.7 \pm 2.8^\circ$ ($p < 0.05$). Medial laxity did also improve, however not significantly ($p = 0.08$). The KSS clinical and functional scores increased significantly one year postoperative (clinical from 49.2 ± 18.8 to 76.9 ± 16.4 and functional from 39.7 ± 17.7 to 62.5 ± 27.1, respectively). The patients did not report a significant decreased VAS pain score (62.5 ± 17.9 to 48.6 ± 27.0 after one year, $p = 0.25$), however they were fairly satisfied (59.6 ± 20.1). Three patients received a thicker insert due to rest-instability, one patient underwent</p>		

manipulation under anesthesia and one patient presented with an infrapatellar neurinoma.

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MEDIAL AND LATERAL COLLATERAL LIGAMENT RECONSTRUCTION

PERIOD	2004-		
PARTICIPANTS	T. van Tienen	SMK	Orthopedic Surgeon
	A.Wymenga	SMK	Orthopedic Surgeon
	P. Heesterbeek	SMK	Health Scientist
	S. Susan	SMK	Research Nurse
SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>The appearance of severe injury of collateral ligaments is rare. Occurrence is mostly due to severe valgus or varus knee trauma. Because of the low incidence rate the knowledge and expertise on treatment is limited. Reconstruction of the injured ligament in the SMK is performed with a tendon allograft. The presumption is that reconstruction with allograft gives more positive outcomes than tissue repair or tissue reefing. The purpose of this quality study is to compare our clinical results with literature.</p>		
METHODOLOGY	<p>This study has been set up as a prospective cohort study of 30 consecutive patients. Patients are included when indicated for reconstruction surgery. Inclusion criteria were medial or lateral instability of the knee (grade 2-3), and laxity of a collateral ligament as shown on stress radiographs in extension. Outcomes include VAS, Tegner and IKDCscore. The patients are evaluated, pre-, and post-operatively at 3, 6, 12, 24, and 60 months follow-up. The stress-extension radiograph is repeated after 12, 24, and 60 months.</p>		
PROGRESS	All patients are included and follow-up has not been completed yet.		
RESULTS	No results yet.		
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TROCHLEAPLASTY IN PATIENTS WITH SEVERE TROCHLEA DYSPLASIA AND OBJECTIVE PATELLAR INSTABILITY

PERIOD	2004-2012		
PARTICIPANTS	A. Wymenga	SMK	Orthopedic Surgeon
	B. Mollen	SMK	Resident Orthopedic Surgery
	P. Heesterbeek	SMK	Health Scientist
	S. Susan	SMK	Research Nurse
SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>In this study short and long term results are described in terms of stability in patients who had a trochleaplasty of the knee after patellar instability and trochlea dysplasia type III. Trochlea dysplasia is the most important susceptible factor for patellar instability. It occurs in 85% of patients with recurrent luxations of the patella. In literature different surgical techniques are described for the correction of trochlear dysplasia including the technique according to Bereiter. The purpose of this study is to examine whether instability and pain are reduced, and whether anatomic recovery is radiographically shown.</p>		
METHODOLOGY	<p>This study is set up as a prospective cohort study of 20 consecutive patients. Patients are included when indicated for reconstruction surgery. Inclusion criteria were: objective instability of the patella, trochlea dysplasia grade (III; according to H. Dujour), J-sign, trochlea bump ≥ 3 mm, and trochlea depth ≤ 4mm. Gonarthrosis of the knee was an exclusion criterion. Outcomes include Kujala score, IKDCscore, SF36, VAS pain, and VAS stability. Radiologically outcomes include crossing sign, trochlea bump, trochlea depth, and sulcus angle. The patients are evaluated, pre-, and post-operatively at 3, 6, 12, and at 24 months follow-up.</p>		
PROGRESS	All patients are included and follow-up has not been completed yet.		
RESULTS	No results yet.		
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MENISCAL TRANSPLANTATION

PERIOD	2009-		
PARTICIPANTS	T. van Tienen	SMK	Orthopedic Surgeon
	K. Defoort	SMK	Orthopedic Surgeon
	P. Heesterbeek	SMK	Health Scientist
	S. Susan	SMK	Research Nurse
SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>The meniscus is the cartilage in the knee which separates the thigh bone (femur) from the lower leg bone (tibia). A meniscal transplantation is performed in patients who still experience pain after the removal of (a part) of the meniscus in the lateral or medial compartment of the knee joint and only small damage of the cartilage. Theoretically, with this procedure the intra-articular pressure of the knee joint will be restored like in the original meniscus. The procedure will reduce knee pain and probably prevent further cartilage destruction (osteoarthritis). The purpose of this study is to evaluate the short and long term results of the meniscal transplantation. Furthermore, we would like to investigate radiologically if a narrowing of the joint space will be visible, which indicates progression of the osteoarthritis.</p>		
METHODOLOGY	<p>Consecutive patients scheduled for a meniscal transplantation are selected from the waiting list. Patients included are <50 years with cartilage destruction of grade 2 or less (Kellgren-Lawrence scale), with a stable knee and neutral alignment. The patients are evaluated with the Knee Society Score, the KOOS questionnaire and VAS scores for pain and satisfaction. Preoperatively and at fixed moments postoperatively (3, 6, 12, 24, 48 months) all clinical scores and complications are reported. Radiological results will be evaluated at 12, 24 and 48 months after surgery. Furthermore, 24 months after the transplantation an MRI will be obtained.</p>		
PROGRESS	So far, 6 patients underwent meniscal transplantation. The follow-up visits are well under way.		
RESULTS	Yearly, in three to five patients a meniscal transplantation is performed. The first results will be expected in 2012.		
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THE TIBIOFEMORAL CONTACT POINT IN KNEES WITH TKR AND IN NORMAL KNEES: NORMAL VALUES AND REPRODUCIBILITY

PERIOD	2006-2009		
PARTICIPANTS	R. de Jong	SMK	Resident Orthopedic Surgery
	P. Heesterbeek	SMK	Health Scientist
	A. Wymenga	SMK	Orthopedic Surgeon
SPONSOR	Sint Maartenskliniek		
PURPOSE	Flexion gap instability after cruciate retaining TKR allows paradoxical anterior movement of the femur during flexion. The tibiofemoral contact point (CP) moves anteriorly and produces a decrease in the lever arm of the extensor apparatus. This can provoke patellofemoral, tibiofemoral joint pain and instability. Standardized measurement of the CP could be a way to objectively document these phenomena. So far, no appropriate measurement methods or normal values are known. Therefore we developed a CP measurement technique for lateral radiographs that can be applied to natural knees and knees with a TKR, and determined the normal value for the CP in healthy knees.		
METHODOLOGY	Conventional lateral radiographs were chosen to measure the CP in 90° flexion. To compare pre- and post TKR radiographs the posterior tibial cortex was chosen as fixed reference point and an artificial tibial cut of 7 mm for natural knees was introduced. The intra- and interobserver reproducibility of this measurement method was assessed by calculating the intraclass correlation coefficient (ICC) and by using the Bland and Altman method. The normal range of the CP in natural knees from 30 radiographs of healthy knees was determined.		
PROGRESS	A paper has been published.		
RESULTS	The contact point for a normal knee was determined at approximately 1/3 from the PA tibia distance at 90 degrees of flexion, measured 7 mm below the medial joint line. The contact point measurement technique as presented is reproducible on lateral radiographs of knees with or without a TKR. This CP measurement method can be used clinically to evaluate the CP after TKR as well as in patients with suspected (posterior cruciate) ligament lesions. The normal values can be used in TKR to aim for restoration of the natural contact point.		
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PUBLICATIONS

De Jong, R.J., Heesterbeek, P.J. and Wymenga, A.B. A new measurement technique for the tibiofemoral contact point in normal knees and knees with TKR. *Knee Surgery, Sports Traumatology, Arthroscopy* 2010; 18: 388-393.

SELF ALIGNING (SAL) KNEE PROSTHESIS: PROSPECTIVE EVALUATION 5 AND 10 YEAR

PERIOD	1995-2011		
PARTICIPANTS	M. Diks	MKW	Orthopedic Surgeon
	A. Wymenga	SMK	Orthopedic Surgeon
	P. Anderson	SMK	Experimental Psychologist
	H. Radenborg	SMK	Orthopedic Nurse Practitioner
	R. van Stralen	SMK	Resident Orthopedic Surgery
SPONSOR	Zimmer Centerpulse		
PURPOSE	The Self Aligning (SAL) total knee prosthesis (Sulzer Medica, Switzerland) is a mobile bearing knee system allowing rotation and translation with a slot on post principle. This study is to evaluate the clinical and radiological results and survival analysis of the SAL II mobile bearing knee prosthesis after 5 and 10 years of follow up.		
METHODOLOGY	All patients operated between February 1995 and March 1998 were included. The Knee Society clinical and functional rating scores were determined for each knee preoperatively and at 5 and 10 years postoperatively. Radiologic assessment was done with (standing) anteroposterior, lateral and Merchant view radiographs.		
PROGRESS	All patients who were physically able to come to the out-patient department have been seen. Others have been contacted by telephone. The preliminary data analysis has been completed.		
RESULTS	246 SAL II total knee arthroplasties in 232 patients were analyzed. At 5 years, ten revisions (4%) had taken place. At the 5-year assessment no knees showed signs of component loosening by the criteria of complete radiolucent lines or implant migration, and no signs of wear for the polyethylene insert, defined as more than 2 mm decrease in height, were found. Between the 5 and the 10 year follow ups no revisions had been performed and there were still no signs of loosening based on radiolucency. The mean age of the patients at the last follow up varied between 39 and 95. 112 patients were able to visit the hospital; their clinical data is being analyzed. The survival rate based on all patients will be calculated.		
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EVALUATION OF A NEW SURGICAL IMPLANTATION TECHNIQUE FOR THE JOURNEY CR TOTAL KNEE ARTHROPLASTY

PERIOD	2009-2012		
PARTICIPANTS	A. Wymenga	SMK	Orthopedic Surgeon
	P. Heesterbeek	SMK	Health Scientist
	L. Labey	ECKR	Engineer
	B. Innocenti	ECKR	Lead Project Manager, Numerical Kinematics
SPONSOR	Smith & Nephew		
PURPOSE	<p>A newly developed spacer technique and implant (Journey cruciate retaining (CR) total knee arthroplasty) needs to be evaluated in the cadaver lab before this technique will be applied to patients. This new technique will help to balance the posterior cruciate ligament. Together with this technique, a new anatomical insert has been developed. The goal was to investigate whether the surgical technique with the new spacer has a desired postoperative result and whether the biomechanical performance of the insert is optimal.</p>		
METHODOLOGY	<p>The study is designed as a laboratory experiment. A total of 10 Journey CR prostheses will be implanted in 10 legs. The surgeries and measurements are performed in the European Centre for Knee Research in Leuven. With a VICON system and pressure films, kinematica and contact points between the femur and tibia were measured. Series of measurements were performed before surgery, and with the new anatomical insert and with the old insert.</p>		
PROGRESS	Measurements have been performed. Analyses and papers are being prepared.		
RESULTS	Preliminary results show that the kinematica of the new anatomical insert is similar to that of the native knee. The spacer technique seems to result in a stable knee replacement.		
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3.5 FOOT AND ANKLE RECONSTRUCTION UNIT

The Foot and Ankle Reconstruction Unit (FARU) of the Department of Orthopedics has become a distinct clinical entity within this department. Three orthopedic surgeons J.W.K. Louwerens, B.A. Swierstra and A.G. Witteveen and one physician assistant M. Tuinhout work within this unit.

The main emphasis of the research performed in the FARU concerns the evaluation of the outcome of foot and ankle surgical procedures and assessment of foot build and function. Studies have been performed concerning the results of various operative treatment modalities and diagnostics and long term follow-ups are available.

In the past period studies have been performed and started using pressure measurements and gait analysis. Studies are performed concerning inlays and forefoot problems, during normal daily activities and during exercise. These research modalities will also be applied to establish the outcome of treatment of foot deformities resulting from Charcot-Marie Tooth disease and rheumatoid arthritis.

Two randomized controlled trials are performed in collaboration with the Isala Clinic in Zwolle. One is concerning the treatment modalities for correction of MTP-deformities in the rheumatic forefoot and the other concerning the surgical techniques for the PIP-joint in the correction of rigid symptomatic claw toes.

MID-TERM RESULTS AFTER TRIPLE ARTHRODESIS OF THE HINDFOOT

PERIOD	2000-2012		
PARTICIPANTS	P. Jaspers	SMK	Resident Orthopedic Surgery
	J. Louwerens	SMK	Orthopedic Surgeon
	J. Schimmel	SMK	Health Scientist
SPONSOR	Sint Maartenskliniek		
PURPOSE	Cohort study in order to determine the results of the triple arthrodesis of the hindfoot 5-8 years postoperatively. Furthermore the relation of malalignment and the development of degenerative changes of the ankle joint are investigated.		
METHODOLOGY	Physical examination and digital photographs were made to determine the alignment of the hindfoot. X-ray's of the hindfoot are taken in order to quantify the amount of arthrosis. Moreover, several questionnaires are completed (VAS satisfaction, FFI, AOFAS score) to establish functioning of the foot and patient's satisfaction.		
PROGRESS	All patients are included.		
RESULTS	Study is running, until now no results available.		
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CAVOVARUS FEET IN CHARCOT-MARIE-TOOTH DISEASE TREATED WITH TRIPLE ARTHRODESIS

PERIOD	2007-2009		
PARTICIPANTS	A. Leeuwesteijn	SMK	Resident Orthopedic Surgery
	F. Verhulst	SMK	Resident Orthopedic Surgery
	J. Louwerens	SMK	Orthopedic Surgeon
SPONSOR	Sint Maartenskliniek		
PURPOSE	Purpose of this study is to evaluate short and midterm results of triple arthrodesis in treatment of rigid cavovarus foot deformity due to Charcot-Marie-Tooth disease (CMT).		
METHODOLOGY	Between 1997 and 2007, triple arthrodesis was performed on 31 patients. The validated Foot Function Index (FFI) (range 100-0, best score 0) was used to measure pain and impairment prospectively. Evaluation consisted of physical examination with assessment of early and late complications. The AOFAS-score, VAS-score for patients' satisfaction and a QUOTE (Quality Of care Through the patients' Eyes) questionnaire were used retrospectively.		
3 PROGRESS	Presentation has been held at the NOV congress 2009.		
RESULTS	Mean follow-up time was 4.4 years. The FFI-score for pain improved from a mean 30.4% to a mean 16.7% (p=0.001). The lower the score the better. The mean score for disability did not improve; 20 patients significantly improved in function, however 11 patients significantly worsened. Mean postoperative AOFAS score was 74 points (range 48-94, best score 94 points). According to the QUOTE questionnaire, 77% of the patients was satisfied about the correction of the deformity, 63% could walk barefoot again and pressure callosities diminished in 84%. Mean patients' overall satisfaction (VAS-scale) was 80%. Triple arthrodesis offers pain reduction with high patients' satisfaction in these patients. Correction of foot deformity seems to have no certain effect with regard to improvement of function. Function is probably more related to the severity of the CMT.		
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PLANTAIR PRESSURE DISTRIBUTION AND 3D FOOT GEOMETRY IN PATIENTS WITH CLAW TOES BEFORE AND AFTER SURGICAL CLAW TOE CORRECTION

PERIOD	2007-2011		
PARTICIPANTS	J. Louwerens N. Keijsers N. Stolwijk	SMK SMK SMK	Orthopedic Surgeon Movement Scientist Movement Scientist
SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>Metatarsalgia refers to plantar pain in the region of the metatarsal heads and is often associated with claw toes. Claw toe deformity causes forward positioning of the plantar fascia, which consequently causes forward positioning of the plantar pads. As the function of the plantar pads is to distribute load equal over the forefoot, claw toes cause high pressures on the metatarsal heads, which causes severe pain. Surgical claw toe correction repositions the toes and is aimed at normalizing plantar pressure distribution. Therefore, this study is aimed at investigating the effect of surgical claw toe correction on plantar pressure distribution and 3D foot geometry during walking.</p>		
METHODOLOGY	<p>Twenty patients, who are listed for surgical claw toe correction, are asked to attend this study. Three months prior to surgery and 12 months after surgery, plantar pressure and foot kinematics are assessed. In addition, physical examination, AOFAS score, and VAS score are assessed. Foot lengthening, shortening and mean, peak plantar pressure of patients with claw toes before and after surgery is compared to normal data. In addition, the effect of walking velocity on plantar pressure and foot kinematics is studied</p>		
PROGRESS	<p>In total, 18 patients and 19 controls have been measured. In addition, an extra of 35 control subjects at various walking velocities have been measured. The post surgery tests will be analyzed in 2011. A manuscript on the effect of walking speed on foot kinematics in healthy feet is almost finished and other manuscripts will be written.</p>		
RESULTS	<p>The foot length increases after toe strike and after heel-off, the foot shortens with a rapid shortening just before toe-off. On average, total foot length range is 12mm. Preoperative analysis show that the lengthening and shortening of the foot during stance phase in patients with claw toes is significantly different from the control group. Walking velocity does minimally effect foot lengthening and shortening during stance.</p>		
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PROSPECTIVE EVALUATION OF THE SCANDINAVIAN TOTAL ANKLE REPLACEMENT (STAR)

PERIOD	2005-2020		
PARTICIPANTS	J. Louwerens	SMK	Orthopedic Surgeon
	J. Schimmel	SMK	Health Scientist
	P. Anderson	SMK	Experimental Psychologist
SPONSOR	Sint Maartenskliniek		
PURPOSE	Purpose of this study is to get insight in the mid- and long-term clinical and radiological results of the STAR total ankle prosthesis, for different indications. Specific interest will be evaluation of the learning curve, if present.		
METHODOLOGY	All patients who are indicated for an ankle arthroplasty will be included in the study. X-ray's, Kofoed and FFI score will be taken preoperatively and at 1, 2, 3, 5, 7½, 10, 12½ and 15 years postoperatively. Extra X-ray's will be taken at 3 and 6 months postoperatively. After 5 and 10 years Kofoed score and FFI score will be analyzed. A Kaplan Meier survival curve will be made. Also clinical and radiological findings of the failed prosthesis will be reviewed.		
3 PROGRESS	Results of the first 49 patients will be compared to the last 50, in order to determine if a learning curve exists. For statistical analysis Student's t-test, Chi-square test and Kaplan-Meier survival curve were used.		
RESULTS	Results regarding the first group were already published (2008). A significant improvement of the FFI score was observed and the mean postoperative Kofoed ankle score was good. First analyses of the second group reveal comparable clinical results. Radiological the prosthesis was somewhat better aligned and less complications were observed. A learning curve was observed for alignment and occurrence of complications but was not observed for clinical scores. Results regarding the second group will be published in the first half of 2011. The first results about the mid-term clinical and radiological parameters of the total group will be analyzed in 2012.		
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IS THERE A DIFFERENCE IN OUTCOME BETWEEN PIP RESECTION ARTHROPLASTY AND PIP ARTHRODESIS IN CORRECTION SYMPTOMATIC CLAW TOES?

PERIOD	2008-2011		
PARTICIPANTS	J. Schrier	Isala Klinieken	Orthopedic resident
	C. Verheyen	Isala Klinieken	Orthopedic Surgeon
	J. Louwerens	SMK	Orthopedic Surgeon
	B. Swierstra	SMK	Orthopedic Surgeon
	A. Zeegers	Medisch Spectrum Twente	Orthopedic Surgeon
	G. Matricali	KUL	Orthopedic Surgeon
	N. Keijsers	SMK	Movement Scientist
	N. Stolwijk	SMK	Movement Scientist
SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>There are several surgical procedures to correct claw toes. In the treatment of rigid claw toes a PIP resection arthroplasty or a PIP arthrodesis can be performed. Although both treatments are accepted worldwide, there is no international consensus about the treatment of choice. So far, there are no prospective randomized studies which compare the outcome of both techniques in patients with rigid claw toes. Therefore, the aim of this study is to compare the postoperative results of the PIP arthroplasty and PIP arthrodesis in patients with symptomatic rigid claw toes.</p>		
METHODOLOGY	<p>A multicenter randomized controlled trial. Orthopedic departments of 5 hospitals participate in this study. In each center, twenty patients, who are listed for surgical claw toe correction, are asked to attend this study. Patients are allocated to either the PIP arthroplasty or the PIP arthrodesis group in a random manner. Three months prior to surgery and 3, 6 and 12 months after surgery the following scores are assessed:</p> <ol style="list-style-type: none"> 1. Physical examination: alignment, range of motion, stability of the MTP and PIP joint, complications 2. SF-36, AOFAS score, VAS score, VAS satisfaction. Cosmetics scale, Nijmegen classification 3. X-ray foot 		
PROGRESS	10 patients have been included at the Sint Maartenskliniek. 4 patients have finished the study. Detailed analyses have to be done.		
RESULTS	The first results are expected in 2011.		
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DIFFERENCE BETWEEN THE HOFFMAN AND THE MTP RELEASE PROCEDURE IN THE CORRECTION OF MTP DEFORMITY IN PATIENTS WITH RHEUMATOID ARTHRITIS

PERIOD	2008-2011		
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	J. Louwerens	SMK	Orthopedic Surgeon
	B. Swierstra	SMK	Orthopedic Surgeon
	A. Zeegers	Medisch Spectrum Twente	Orthopedic Surgeon
	G. Matricali	KUL	Orthopedic Surgeon
	N. Keijsers	SMK	Movement Scientist
	N. Stolwijk	SMK	Movement Scientist

SPONSOR Sint Maartenskliniek

PURPOSE Approximately 90% of all patients with rheumatoid arthritis (RA) report foot complaints of which 75% with claw toes. There are 2 common used surgical procedures to correct claw toe deformity: The Hoffman procedure (excision of the MPT heads) and the MTP release method, in which the MTP heads are repositioned only. With the MTP release method the normal foot shape and function can be saved. The MTP release method is less invasive and destructive compared to the Hoffman procedure. However, both surgical interventions have good results. So far, there are no prospective randomized studies which compare the outcome of both techniques in patients with RA. Therefore the aim of this study is to compare the postoperative results of the Hoffman procedure with the MTP release method.

METHODOLOGY A multicenter randomized controlled trial. Orthopedic departments of 5 hospitals in the Netherlands participate in this study. Twenty patients with RA, who are listed for surgical claw toe correction, are asked to attend this study. Patients are allocated to either the Hoffman group or the MTP release method in a random manner. Three months prior to surgery and 3, 6 and 12 months after surgery the following scores are assessed:

1. physical examination: alignment, range of motion, stability of the MTP and PIP joint, complications
2. SF-36, AOFAS score, VAS score, VAS satisfaction. Cosmetics scale, Nijmegen classification
3. X-ray foot

Furthermore, movement analysis using the VICON motion analysis system and plantar pressure measurement is performed 3 months prior to surgery and 1 year after surgery.



PROGRESS 6 patients have been included of which 2 have finished the 1 year follow-up.

RESULTS The first results are expected in 2011.

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FEET4FEET; PREVENTION OF FOOT COMPLAINTS DURING THE INTERNATIONAL 4 DAY MARCHES

PERIOD	2007-2012		
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	N. Keijsers	SMK	Movement Scientist
	J. Duysens	SMK/UMCN/KUL	Neurophysiologist
	K. Koenraad	SMK	Movement Scientist
	A. Delsman	SMK	Marketing Communications Specialist
SPONSOR	Oost NV Health Valley Nijmegen Gemeente Nijmegen POM POM VZC		
PURPOSE	<p>The International Four Day Marches (IFDM) is the largest annual walk event of the world with over 45000 participants. Many walkers develop injuries of the locomotor apparatus. To a large extent these injuries are located at the foot. There are 3 aims in this research project. First, investigate the influence of walking 160 tot 200 km in four days on foot shape and plantar pressure distribution. Second, can we predict which participant has a higher risk to develop foot complaints during the IFDM? Third, can foot complaints be prevented by using proper insoles?</p>		
METHODOLOGY	<p>Prior to the IFDM Nijmegen (Sunday or Monday), the first measurement took place at the Sint Maartenskliniek located in Nijmegen. Plantar pressure distribution was measured when walking barefoot over a pressure plate and a questionnaire about foot complaints was administered. In 2008, all measurements were repeated during the four days of the International Marches, directly after finishing. In 2010, plantar pressure measurements prior to the IFDM and the questionnaire were completed on each day.</p>		
PROGRESS	<p>In 2008, 62 walkers participated. In 2010, a total of 120 walkers participated. Data of both studies have been analyzed. A new study to evaluate the effects of insoles on development of foot complaints during the IFDM will be started. A first article has been published and more articles will be written.</p>		
RESULTS	<p>Comparison of the plantar pressure distribution between the first measurement and after 4 days of walking showed that the participants walked more on the lateral side of the foot. The mean plantar pressure was significantly higher under the heel and lateral site of the forefoot, whereas it was significantly decreased under the toes and the 1st metatarsal head after walking 4 days. A neural network using plantar pressure parameters as input could correctly classify if participants develop forefoot pain in 80% of the feet.</p>		

3

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PUBLICATIONS Stolwijk, N.M., Duysens, J., Louwerens, J.W. and Keijsers, N.L. Plantar Pressure Changes after Long Distance Walking. *Medicine and science in sports and exercise* 2010; Epub ahead of print.

INTELLIGENT INSOLE

PERIOD	2006-2012		
PARTICIPANTS	N. Keijsers	SMK	Movement Scientist
	N. Stolwijk	SMK	Movement Scientist
	K. Koenraad	SMK	Movement Scientist
	J. Duysens	SMK/UMCN/KUL	Neurophysiologist
	J. van Limbeek	SMK	Epidemiologist
	B. Nienhuis	SMK	Biomedical Engineer
	A. Delsman	SMK	Marketing Communications Specialist
	D. Ruitenbeek	POM	Orthopedic Shoe Technician
	D. van den Wildenberg	POM	Podiatrist
SPONSOR	Prothese en Orthese Makerij Nijmegen Ontwikkelingsmaatschappij Oost NV		
PURPOSE	<p>Non-traumatic musculoskeletal foot complaints are common and are mostly caused by problems such as metatarsalgia, hallux valgus, hallux rigidus, plantaris fasciitis. Insoles appear to be sufficient in the treatment of foot complaints. However, there are no general guidelines for the construction of insoles. The design choice of an insole by podiatrists and pedorthists is often based on their experience. The main purpose of this project is to create an expert system that will help foot experts with the design choice of an insole using objective and quantitative data. Subsequently, insoles from the expert system will be compared to the insoles designed by the podiatrist or pedorthist. This project will also provide a better understanding of the mechanisms underlying the effectiveness of insoles.</p>		
METHODOLOGY	<p>Subjects using insoles for the treatment of foot complaints participate in this research. Individual characteristics of the foot such as plantar pressure distribution barefoot, plantar pressure distribution in the shoe (with and without insole), and 3D foot shape are measured. In addition, questionnaires are used to evaluate the effect of insoles on foot complaints and the 3D insole shape will be measured. The relationship between individual foot characteristics and complaints of the foot and the optimal insole will be used by the expert system to predict the optimal insole for new subjects. The success of the expert system in designing the optimal insole will be evaluated by comparing the convenience and pressure redistribution resulting from that insole with these parameters after walking with insoles designed by a podiatrist or pedorthist.</p>		
PROGRESS	<p>The expert system has been developed based on data of 223 subjects. The success of the expert system has been tested by 12 subjects. Articles have been published and will be written.</p>		

RESULTS A new method was developed to normalize the plantar pressure distribution pattern for foot size and foot angle. Analysis of the data from the 223 subjects revealed decreases in pressure at the metatarsal heads and increases of pressure at the mid foot for walking with insole. The insole shape was specific for the kind of foot complaint and arch height, the differences in shape were very small and the plantar pressure redistribution was similar for all groups. The evaluation of the expertsystem revealed that on average, the 12 subjects gave the best score for the expert system insole.

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PUBLICATIONS Keijsers, N., Stolwijk, N.M., Nienhuis, B. and Duysens, J. A new method to normalize plantar pressure measurements for foot size and foot progression angle. *Journal of Biomechanics* 2009; 42: 1, 87-90.
Pataky, T.C., Keijsers, N.L., Goulermas, J.Y. and Crompton, R.H. Nonlinear spatial warping for between-subjects pedobarographic image registration. *Gait & Posture* 2009; 29: 3, 477-482.
Keijsers, N.L., Stolwijk, N.M. and Pataky, T.C. Linear dependence of peak, mean, and pressure-time integral values in plantar pressure images. *Gait & Posture* 2010; 31: 1, 140-142.

PATIENT COMPLAINTS AND FOOT OUTCOMESCORES CONCERNING THE CONSERVATIVE TREATMENT OF ANKLE OSTEOARTHRITIS

PERIOD	2010		
PARTICIPANTS	M. Breslau A. Witteveen C. Hofstad	SMK SMK SMK	MD Orthopedic Surgeon Health Scientist
SPONSOR	Sint Maartenskliniek		
PURPOSE	To gain information in order to develop a new Foot and ankle score for the evaluation of conservative treatment of Ankle Osteoarthritis.		
METHODOLOGY	A Pubmed search for Foot and Ankle outcome scores has been performed. Patients were interviewed (Focus groups) and orthopedic surgeons were interviewed. Developing of statement.		
PROGRESS	12 patients were interviewed; patients were asked about their most important complaints, function, daily live, treatment goals and positive and negative effects of past treatment modalities. 5 orthopedic Foot and Ankle surgeons were interviewed about outcome scores, ankle osteoarthritis complaints, treatment modalities and their importance and what is needed for a new outcome score.		
RESULTS	Interviewing patients and orthopedic surgeons led to the formation of 32 statements which were sent to all the participating patients and surgeons. 11 patients and 5 surgeons returned their answers. These answers will be used for the formation of a new outcome score.		
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MIDTERM RESULTS OF DOUBLE OSTEOTOMY IN HALLUX VALGUS

PERIOD	2010-2011		
PARTICIPANTS	I. Takács	SMK	Resident Orthopedic Surgery
	P. Heesterbeek	SMK	Health Scientist
	B. Swierstra	SMK	Orthopedic Surgeon
SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>Surgical hallux valgus correction can be performed by several techniques. The hallux valgus angle (HVA) and the intermetatarsal angle (IMA) are good parameters to quantitatively assess the radiological result of the surgery. The double osteotomy gives a radiological satisfactory result. From the literature it is known that these parameters may change in time. This need to be correlated to the clinical result. Goal of this study was to assess whether the HVA, IMA and Foot Function Index change during midterm follow-up in patients with a double osteotomy for hallux valgus.</p>		
METHODOLOGY	<p>29 patients with a moderate to severe hallux valgus deformity were operated between 2004 and 2006. The double osteotomy is performed by a proximal open metatarsal wedge osteotomy with plate fixation combined a Chevron osteotomy with screw fixation. Patients were followed until 3-5 years post-operative and were examined incl X-ray of their foot. The HVA and IMA were measured on this X-ray, Foot Function Index (FFI) was assessed and patients were asked about their satisfaction.</p>		
PROGRESS	Follow-up has not been completed yet.		
RESULTS	No results yet.		
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COMPARISON OF MALAWIAN FEET WITH DUTCH FEET: ARE BAREFOOTERS, FLATFOOTERS?

PERIOD	2007-2011		
PARTICIPANTS	N. Stolwijk	SMK	Movement Scientist
	J. Louwerens	SMK	Orthopedic Surgeon
	N. Keijsers	SMK	Movement Scientist
SPONSOR	RsScan Sint Maartenskliniek		
PURPOSE	There are only a few studies which investigate differences in foot shape and function between races. Most of these studies are not very reliable and used only static measurements to quantify these differences. Therefore, the aim of this study was to compare the dynamic foot shape, plantar pressure distribution and roll off of the foot of an African population to a Caucasian population.		
METHODOLOGY	The plantar pressure and foot geometry of 77 Malawian and 77 Dutch subjects were measured. The subjects walked over a pressure plate and the mean pressure, peak pressure and pressure-time integral were calculated for both groups. The Arch Index was calculated using the method described by Cavanagh and Rodgers. Also the center of pressure trajectory was measured. Standardized pictures were taken from the feet and the medial arch angle and ratio navicular height/foot length were calculated.		
PROGRESS	Data have been analyzed and a manuscript will be written.		
RESULTS	Plantar pressure was significantly larger under the midfoot and smaller under the heel and the metatarsal head II and III for the Malawian group compared to the Dutch group. The Malawian subjects rolled off more laterally during most part of the stance phase. Malawian subjects landed more anteriorly on the heel and the proximal part of the toes was loaded more during the push off. The Malawian group had a significant lower medial arch angle and ratio navicular height/foot length. Based on the results of the static and dynamic measurements, it can be concluded that the African population has a flatter feet compared to a Caucasian population.		
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GAIT AND VALGUS CORRECTION OSTEOTOMY

PERIOD	2010-2011		
PARTICIPANTS	J. Louwerens N. Keijsers	SMK SMK	Orthopedic Surgeon Movement Scientist
SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>Anterior open wedge calcaneal osteotomy (ACO) is one of the most used surgical treatment options for stage II acquired flatfoot deformity (AFFD). However, the best surgical procedure for stage II AFFD remains controversial. In the Sint Maartenskliniek, the ACO procedure is used for patients with stage II AFFD for many years. Therefore, the purpose was to report the outcome of 31 feet treated by ACO in patients with stage II AFFD after a follow-up ranging from 19 to 123 months.</p>		
METHODOLOGY	<p>Clinical outcome at follow-up was assessed by questionnaires and physical examination (FFI-score, CRI-index, VAS pain-score, complications, and osteoarthritis). Foot posture was evaluated by standardized pre- and postoperative weight-bearing radiographs. Finally, postoperative foot function was assessed by plantar pressure and dynamic foot geometry, and compared with controls. To evaluate the long-term effects, clinical outcome scores were analyzed for less (short-term group) and more (long-term group) than 36 months of follow-up.</p>		
PROGRESS	<p>All 31 subjects have been tested and the data have been analyzed. A manuscript will be written.</p>		
RESULTS	<p>At follow-up, a median CRI-index of 83 and a median FFI-score of 15.6 was found and FFI-score improved significantly. All radiographic measurement improved significantly towards a normal foot posture. Although not statistically significant, there was a trend of better clinical outcome scores for the long-term group. In contrast, 1 non-union and 2 relapses, and 1 severe and 3 moderate osteoarthritis occurred in the long-term group, compared to 1 moderate osteoarthritis in the short-term group. Plantar pressure was larger at the medial heel and the midfoot, and change in foot length during roll-off was lower compared with controls, indicating a slightly rigid foot and a suboptimal correction after ACO. In conclusion, despite the high incidence of complications and osteoarthritis and a slightly decreased foot function, ACO resulted in good long-term clinical outcome in patients with stage II AFFD.</p>		
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WHICH TYPE OF WALKING CAST PROVIDES THE BEST ANKLE IMMOBILIZATION

PERIOD	2009-2011		
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	A. Witteveen	SMK	Orthopedic Surgeon
	D. Tangele	SMK	Cast
SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>Lower leg walking casts (LLWC's) are often used to post-operatively immobilize bone structures in the lower leg. After ankle arthrodesis for example, LLWC's come with a cast shoe or a cast heel, however, which of these cast types provides better ankle immobilization is unknown. Therefore, the first purpose of this study was to determine if the heel or shoe cast would provide better ankle immobilization. Patients often do not comply with the walking instructions that come with the LLWC, and switch to an alternative gait pattern to be able to walk more swiftly. Therefore, the second purpose was to determine if non-compliance to the walking instructions would change which type of LLWC had the better ankle immobilization.</p>		
3 METHODOLOGY	<p>A Vicon motion capturing system was used to assess ankle immobilization which was defined as range of motion of the ankle. Pressure insoles were used to assess the pressure distribution under the foot. Six healthy subjects received a cast with heel cast as well as with shoe cast. The ankle angle of the cast foot was estimated using markers on the tuberositas tibiae, on the head of the second metatarsal and on the heel (attached through a hole in the cast) during three different walking conditions: compliant walking; walking with hip-exo-rotation and walking with roll-off.</p>		
PROGRESS	<p>Data capturing has been finished and motion data has been analyzed. Detailed analysis of the pressure insoles have to be done. Results have been presented at a conference of the Verenigde Gipsverbandmeesters Nederland. An article will be written.</p>		
RESULTS	<p>During compliant walking, the range of motion of the ankle angle of the heel cast was larger than the shoe cast. Averaged over all walking conditions the heel cast showed superior ankle immobilization compared to the shoe cast, during the first half of the stance phase. We found no evidence that the heel or shoe cast modified the effect of non-compliant walking differently.</p>		
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TREATMENT OF ADULT, ACQUIRED, FLEXIBLE FLATFOOT DEFORMITY THROUGH LATERAL COLUMN LENGTHENING OF THE CALCANEUS

PERIOD	2010-2011		
PARTICIPANTS	N. Keijsers J. Louwerens	SMK SMK	Movement Scientist Orthopedic Surgeon
SPONSOR	Sint Maartenskliniek		
PURPOSE	Anterior open wedge calcaneal osteotomy is one of the most used surgical treatment options for stage II acquired flatfoot deformity. We report the outcome of 31 feet treated by ACO in patients with stage II AFFD after a follow-up ranging from 19 to 123 months.		
METHODOLOGY	Clinical outcome at follow-up was assessed by questionnaires and physical examination (FFI-score, CRI-index, VAS pain-score, complications, and osteoarthritis). Foot posture was evaluated by standardized pre- and postoperative weight-bearing radiographs. Finally, postoperative foot function was assessed by plantar pressure and dynamic foot geometry, and compared with controls. To evaluate the long-term effects, clinical outcome scores were analyzed for less (short-term group) and more (long-term group) than 36 months of follow-up.		
PROGRESS	Data have been analyzed and reported. A manuscript will be written.		
RESULTS	At follow-up, a median CRI-index of 83 and a median FFI-score of 15.6 was found and FFI-score improved significantly. All radiographic measurement improved significantly towards a normal foot posture. Although not statistically significant, there was a trend of better clinical outcome scores for the long-term group. In contrast, 1 non-union and 2 relapses, and 1 severe and 3 moderate osteoarthritis occurred in the long-term group, compared to 1 moderate osteoarthritis in the short-term group. Plantar pressure was larger at the medial heel and the midfoot, and change in foot length during roll-off was lower compared with controls, indicating a slightly rigid foot and a suboptimal correction after ACO. Despite the high incidence of complications and osteoarthritis and a slightly decreased foot function, ACO resulted in good long-term clinical outcome in patients with stage II AFFD.		
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PSEUDOARTHROSIS REPAIR WITH TURNAROUND INLAY GRAFT AFTER FAILED METATARSOPHALANGEAL 1 ARTHRODESIS

PERIOD	2010		
PARTICIPANTS	I. Takács B. Swierstra	SMK SMK	Resident Orthopedic Surgery Orthopedic Surgeon
SPONSOR	Sint Maartenskliniek		
PURPOSE	In this study the results of a new surgical technique for repairing a failed metatarsophalangeal 1 arthrodesis will be evaluated. This inlay bone grafting technique where the bone block has been turned around before fixation has never been described before.		
METHODOLOGY	Between 2001 and 2009, 26 patients (26 feet) with pseudoarthrosis of a MTP-1 arthrodesis were operated with this technique. The average time from the last arthrodesis attempt until revision arthrodesis was 12 (4-31) months. Average time to follow-up was 4.5 (0.5-9) years. At follow-up all patients were sent a Foot Function Index (FFI) form and a questionnaire containing a VAS score for pain, a question about satisfaction, and a question about orthopedic footwear.		
3 PROGRESS	A paper will be published in 2011.		
RESULTS	2 patients had a non-union. In the other 24 patients, there was no sign of non-union at discharge from routine follow-up, but union is sometimes difficult to judge due to the hardware. 21 patients were satisfied with the postoperative result. 10 patients used prescription shoes and. Despite satisfaction, the FFI scores were not as good as after a primary MTP-1 fusion. However, this new technique seems usable and has the advantage that there is no donor site morbidity since there is no graft needed.		
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POSTOPERATIVE FUNCTION AFTER ARTHRODESIS OF THE FIRST METATARSOPHALANGEAL JOINT

PERIOD	2007-2010		
PARTICIPANTS	D. van Doeselaar	SMK	Resident Orthopedic Surgery
	P. Heesterbeek	SMK	Health Scientist
	J. Louwerens	SMK	Orthopedic Surgeon
	B. Swierstra	SMK	Orthopedic Surgeon
SPONSOR	Sint Maartenskliniek		
PURPOSE	The first aim of the present study was to measure the operative outcome using a validated score in patients that underwent fusion of the first metatarsophalangeal (MTP) joint for hallux rigidus (HR) and hallux valgus (HV) without interference by concomitant foot surgery. Secondly we wanted to examine whether a correlation between foot function and hallux position could be established in order to formulate optimum fusion angles.		
METHODOLOGY	Between 2002 and 2005, a consecutive serie of 62 patients underwent crossed screw MTP I fusion (27 HR and 35 HV) without concomitant foot surgery, previous or bilateral foot surgery. To measure foot function all patients completed the Dutch Foot Function Index (FFI) pre- and postoperatively. Hallux valgus and dorsiflexion angles were measured on standing radiographs before operation and at followup.		
PROGRESS	The study has been finished and a paper has been published.		
RESULTS	Fusion of the first MTP joint in HR and HV results in improved function according to the validated FFI. The FFI score was not different between the HV and HR groups. There was no significant correlation between foot function and hallux position. This could be due to the fact that the desired position of the hallux was most often achieved.		
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PUBLICATIONS	Van Doeselaar, D.J., Heesterbeek, P.J., Louwerens, J.W. and Swierstra, B.A. Foot function after fusion of the first metatarsophalangeal joint. <i>Foot & Ankle International</i> 2010; 31: 8, 670-675.		

SUBTALAR ARTHROEREISIS FOR PEDIATRIC FLEXIBLE PES PLANOVALGUS

PERIOD	2007-2009		
PARTICIPANTS	P. Koning P. Heesterbeek E. de Visser	SMK SMK SMK/Rijnstate	Resident Orthopedic Surgery Health Scientist Orthopedic Surgeon
SPONSOR	Sint Maartenskliniek		
PURPOSE	<p>Flexible pes planovalgus (PPV) is a common condition with flattening of the medial longitudinal arch accompanied by hind foot valgus. Severe cases of PPV may need surgery and a technique that has gained popularity over the last decades is subtalar arthroereisis. A variously shaped implant (endo-orthosis) is inserted in the sinus tarsus limiting the excessive eversion of the subtalar joint present in flexible PPV. None of these implants, however, allow for easy control of the extent of talocalcaneal and talonavicular correction. The primary aim of this study was to describe our technique with the custom build cone-shaped implant. Our secondary aim was to evaluate patient satisfaction, clinical and radiological results as well as the complications with a minimal followup of 5 years.</p>		
METHODOLOGY	<p>Between January 1992 and June 2002, 80 feet of 40 patients were operated on for flexible PPV using subtalar arthroereisis. After temporary sinus tarsi tenderness (12 feet), implant dislocation (two feet) was the most common complication. Questionnaires from 27 patients (54 feet) were analysed and 44 feet were also clinically and radiographically evaluated.</p>		
PROGRESS	The study has been finished and the results were published in a paper.		
RESULTS	<p>Thirteen patients were lost to followup. Mean followup was 12.6 years (± 3.1; range 5.9- 16.1). Eighty-one percent of the patients were satisfied about the result. Clinically, normal alignment was present in 14 feet and mild remaining deformities in 26 feet. Radiographically, the average foot angle measurements were normal. We conclude that subtalar arthroereisis is a simple, minimally invasive operative option with satisfactory subjective and clinical results after mid to long term follow-up.</p>		
CONTACT PERSON	P. Heesterbeek (p.heesterbeek@maartenskliniek.nl)		
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PUBLICATIONS	<p>Koning, P.M., Heesterbeek, P.J. and De Visser, E. Subtalar arthroereisis for pediatric flexible pes planovalgus: fifteen years experience with the cone-shaped implant. <i>Journal of the American Podiatric Medical Association</i> 2009; 99: 5, 447-453.</p>		

3.6 ANESTHESIOLOGY

The department of Anesthesiology has grown extensively in the last year and currently consists of 13 anesthesiologists with Dr. R. Stienstra as head of the department since 2009.

The anesthesiologists perform over 7,000 peripheral nerve blocks per year and therewith the most of all hospitals in the Netherlands and maybe also in Europe.

Anesthesiology research has only been integrated within OrthoResearch since 2009.

The emphasis is optimizing patient care, with lines of research focusing mainly on peripheral nerve blocks, blood management and chronic pain treatment. Different aspects of peripheral nerve blocks are subject of research at the moment. For example the use of a stimulating catheter for continuous nerve blocks after shoulder surgery, the pharmacokinetics of a long acting local anesthetic for anterior cruciate ligament reconstruction and the influence of volume on the duration of axillary brachial plexus block using ultrasound guidance. These studies are part of a PhD project by K.P.W. Schoenmakers.

THE RELATION BETWEEN ELECTRICAL CURRENT AND EFFICACY OF STIMULATING CATHETERS FOR BRACHIAL PLEXUS BLOCK

PERIOD	2009-2011		
PARTICIPANTS	K. Schoenmakers	SMK	MD, Anesthesiology Researcher
	P. Heesterbeek	SMK	Health Scientist
	N. Jack	SMK	Anesthesiologist
	R. Stienstra	SMK	Anesthesiologist
SPONSOR	Sint Maartenskliniek		
PURPOSE	The purpose of the present study is to investigate whether there is a relation between the minimal current at the tip of the stimulating catheter necessary to elicit an appropriate motor response, and the efficacy of the PNB catheter.		
METHODOLOGY	<p>Using Ultrasound guidance and Nerve Stimulation, a brachial plexus catheter will be inserted five cm past the needle tip using an in-plane technique in the interscalene area by an experienced anesthesiologist. After the brachial plexus catheter has been inserted five cm past the needle tip, the minimal current necessary to evoke an appropriate motor response (deltoid, biceps or triceps muscle) will be determined and registered. The observer of motor response is blinded for the current. Brachial plexus block will be established by injecting a total volume of 20 ml ropivacaine 0.75 % in fractionated doses. Time is designated T = 0 upon conclusion of the loading dose.</p> <p>One hour after administration of the brachial plexus loading dose, a continuous infusion of ropivacaine 0.2 % 8 ml/h will be connected to the brachial plexus catheter and maintained until T = 24 h. Upon arrival in the recovery, a PCA morphine device will be connected to an intravenous cannula. Patients will be instructed in the use of the PCA device preoperatively and to maintain postoperative pain scores (NRS 0-10) at or below 3. At T = 24h, the catheter will be removed and the PCA device will be disconnected by the investigator. The total amount of asked and received boluses of morphine will be registered.</p>		
PROGRESS	The study has been started, patients are being included since August 2009.		
RESULTS	No results available yet.		
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PHARMACOKINETICS OF HIGH DOSE ROPIVACAINE FOR COMBINED FEMORAL AND SCIATIC NERVE BLOCK. A PILOT STUDY

PERIOD	2009-2011		
PARTICIPANTS	B. van den Bemt	SMK	PharmD, Scientist
	N. Jack	SMK	Anesthesiologist
	K. Schoenmakers	SMK	MD, Anesthesiology Researcher
	T. Vree		Retired Chemist, Pharmacologist
	R. Stienstra	SMK	Anesthesiologist
SPONSOR	Sint Maartenskliniek		
PURPOSE	The purpose of the present study is to obtain a pharmacokinetic profile of ropivacaine in serum, when injected with or without epinephrine for combined femoral and sciatic nerve block in lower extremity orthopedic surgery. Results of this pilot study will be used in a follow-up study to determine block specific maximum doses using the determined width of C_{max} found in this study.		
METHODOLOGY	Using a sealed envelope technique, patients will be randomly allocated to receive combined femoral sciatic nerve block with 60 ml of either ropivacaine 0.75% alone or ropivacaine 0.75% plus 5 mcg/ml (1:200.000) epinephrine. 18 venous blood samples of 5-10 ml will be taken by the investigator during the 48h study period. Before the first injection, to determine the epinephrine effect, at the end of block and to determine elimination until there is no ropivacaine left traceable in the blood. Samples will centrifuged and plasma samples will be stored at -40 degrees Celsius until assay, using high performance liquid chromatography. Total bound plasma ropivacaine levels will be determined. Later on total unbound plasma ropivacaine levels will be determined in the samples with the highest total bound concentration per patient. The duration of sensory block is considered as the time interval between the administration of the local anesthetic and the first request for postoperative pain treatment. The efficacy of the block will be assessed as successful (no additional intra-operative medication), partial (intra-operative sedation) or unsuccessful (general anesthesia).		
PROGRESS	The study has been started, patients are being included since March 2010.		
RESULTS	No results available yet.		
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QUALITY ASSESSMENT OF PERIPHERAL NERVE BLOCKS AT THE SINT MAARTENSKLINIEK

PERIOD	2009-2010		
PARTICIPANTS	C. Gort K. Schoenmakers R. Stienstra	SMK SMK SMK	Anesthesiologist MD, Anesthesiology Researcher Anesthesiologist
SPONSOR	Sint Maartenskliniek		
PURPOSE	The aim of this study is to develop a quality assessment program for peripheral nerve blocks to determine the frequency of (neurological) complications following orthopedic extremity surgery conducted under PNB. The association of block or surgical characteristics potentially important in the development of these complications is also tested.		
METHODOLOGY	To develop a decent quality assessment program, we started a pilot with paper questionnaires. Eventually the questions will be integrated in our current documentation system. For every patient who received a peripheral nerve block in November 2009, the anesthesiologist, orthopedic surgeon and the investigator filled out a form with data concerning block and operation specific details. After the block had receded, before discharge, the patient was asked to fill out a form as well concerning his experience with, and possible complaints about the peripheral nerve block. One month after surgery, a questionnaire was sent to the patient with a reply envelope, again asking for experience with and possible complaints about / after the peripheral nerve block. If the patient had block related complaints, they were followed up. After this pilot study, the questionnaires were evaluated and will be implemented in everyday practice in the Sint Maartenskliniek.		
PROGRESS	Study is completed.		
RESULTS	Paper questionnaires are not suitable to assess all peripheral nerve blocks conducted at the Sint Maartenskliniek. In November 2009, 511 patients were operated. A peripheral nerve block was performed before surgery in 286 patients. A very small percentage had complaints that were possibly caused by the PNB one month after surgery. After four months, almost all of these complaints had resolved. Only 3 patients suffered from a complication of the PNB. The numbers we found are well within the ranges stated in the literature.		
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QUALITY OF FILTERED SHED BLOOD WITH OR WITHOUT LEUKOCYTE REDUCTION FILTER AFTER TKA

PERIOD	2009-2010		
PARTICIPANTS	A. Rohrbach	SMK	Anesthesiologist
	F. van Schaijk	SMK	Head of the SMK laboratory
	H. van Hauwe	Sarstedt	Consultant
	K. Schoenmakers	SMK	MD, Anesthesiology Researcher
	R. Stienstra	SMK	Anesthesiologist
SPONSOR	Sint Maartenskliniek		
PURPOSE	The purpose of this study was to compare the quality of filtered shed blood collected with or without a leukocyte reduction filter in patients undergoing total knee arthroplasty (TKA).		
METHODOLOGY	Fifty patients received either the Haem-o-Trans device (Sarstedt, Nümbrecht, Germany) with, or the Bellovac-ABT device (Astra Tech AB, Mölndal, Sweden) without a leukocyte reduction filter. Two blood samples were taken from each retransfusion device; one before (PRE), the second after (POST) passage of the filter cascade. Samples were analyzed for white blood cell count (WBCC), free hemoglobin level (free Hb), hemoglobin level (Hb), red blood cell count (RBCC), and platelet count (PLTC).		
PROGRESS	Study is completed, an article is submitted for publication.		
RESULTS	The Haem-o-Trans filter cascade reduced the mean WBCC by 9.3%, but the difference in leukocyte reduction between the two devices was not significant. Free Hb levels PRE were slightly higher in the Bellovac-ABT group, free Hb levels POST did not differ significantly. There were no differences between the two devices with regard to Hb levels, RBCC and PLTC.		
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THE EFFECT OF LOCAL ANESTHETIC VOLUME ON THE DURATION OF SINGLE SHOT AXILLARY BRACHIAL PLEXUS BLOCK

PERIOD	2010-2012		
PARTICIPANTS	J. Wegener K. Schoenmakers R. Stienstra	AMC/SMK SMK SMK	Anesthesiologist MD, Anesthesiology Researcher Anesthesiologist
SPONSOR	Sint Maartenskliniek		
PURPOSE	The purpose of the present study is to compare the duration of sensory and motor block with 15 and 40 milliliters mepivacaine 1.5% for axillary brachial plexus block using ultrasound guidance. Our hypothesis is that there is no difference (less than 60 min) in duration of AXB using the different amounts of local anesthetic under ultrasound guidance.		
METHODOLOGY	<p>The design of this study is parallel, prospective, randomized and single blind. Axillary block will be performed with a combination of nerve stimulation and ultrasound. The musculocutaneous, median, ulnar and radial nerve will be identified separately. Each nerve will be blocked by either 10 ml (40 ml group) or 3-4 ml (15 ml group).</p> <p>Time is designated T = 0 upon conclusion of the axillary nerve block.</p> <p>In the first 30 minutes after injection of local anesthetic solution, a blinded observer will assess the onset of sensory and motor block every 5 minutes until axillary block is complete. If necessary, supplemental blocks will be placed if sensory block is incomplete at 30 min.</p> <p>Upon arrival at the post-anesthetic care unit, offset of sensory and motor block will be assessed every 15 minutes until full recovery in the same manner as preoperatively. In addition, the time to first demand for analgesia will be recorded.</p>		
PROGRESS	The study has been started, patients are being included since June 2010.		
RESULTS	No results available yet.		
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EFFICACY OF THE PAIN PILL ORGANIZER FOR PATIENTS IN DAY CARE

PERIOD	September-October 2010		
PARTICIPANTS	N. Maandag	SMK	Anesthesiologist
	P. Toonen	SMK	Nurse
	J. Kersten	SMK	Student Nurse
SPONSOR	Sint Maartenskliniek		
PURPOSE	The aim of this study is to gain insight in the efficacy of the provided post-operative pain medication in the pain pill organizer for patients in day care after different orthopedic procedures.		
METHODOLOGY	This is a prospective qualitative study. All patients treated in day care in September and October 2010 were contacted by phone at home the day after surgery. They were, amongst other things, asked about postoperative pain, the use of pain medication and satisfaction of pain treatment.		
PROGRESS	Data collection is completed and data are being analyzed at the moment.		
RESULTS	No results available yet.		
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THE INFLUENCE OF SPINAL CORD STIMULATION ON BALANCE AND LOCOMOTION

PERIOD	2010-2011		
PARTICIPANTS	N. Keijsers	SMK	Movement Scientist
	L. Vonhogen	SMK	Anesthesiologist
	N. Rijken	SMK	Movement Scientist
	J. Duysens	SMK/UMCN/KUL	Neurophysiologist
SPONSOR	Sint Maartenskliniek		
PURPOSE	Chronic neuropathic pain is caused by a primary lesion or dysfunction in the nervous system. Treatment interventions have been developed in the past decennia, and especially spinal cord stimulation resulted in significant pain relief. However, patients seemed to become more prone to falls, indicated by the observed highly increased incidence of falls. The research question was: What is the influence of spinal cord stimulation on balance and locomotion in patients with chronic neuropathic pain?		
METHODOLOGY	Fourteen subjects selected for treatment with spinal cord stimulation were included. Static balance was assessed by force plate measurements under four different conditions to challenge balance control. Comfortable walking speed was determined for treadmill walking and joint angles during step cycles were compared between stimulation on and off. The obstacle avoidance task was used to obtain information about dynamic balance. Reaction times and failure rates were used to compare stimulation conditions. The center of mass was used to quantify the ability to maintain normal gait after disturbance. Patients were tested pre and at 2 and 8 weeks post surgery.		
PROGRESS	Data of pre and 2 week post surgery have been analyzed. With the results of the present study we provide useful information for future research to investigate the effects of spinal cord stimulation on balance. A first manuscript is almost finished and will be submitted in 2011.		
RESULTS	For static balance and treadmill walking, no significant differences were found between stimulation on and off. Center of mass pattern of the first post crossing step showed a higher correlation with normal gait for stimulation off compared to stimulation on ($p=0.03$). Since we found differences for the center of mass correlation of the first post crossing step, and various trends for other outcome variables, we do expect that balance is slightly affected by spinal cord stimulation.		
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RESEARCH AT MAARTENSKLINIEK WOERDEN

Since 2009, the Maartenskliniek Woerden is conducting research as part of the concern Sint Maartenskliniek. This research follows the guidelines of Good Clinical Practice and is facilitated by a research coordinator and a research nurse. They give support to the orthopedic surgeons and rheumatologists during all aspects of the research process. The Orthopedic department and the department of Rheumatology are working closely together and hold the same research policy.

The departments Rheumatology and Orthopedics of the Maartenskliniek Woerden both collaborate with the departments Rheumatology and Orthopedics of the Sint Maartenskliniek Nijmegen and with the University Medical Center Utrecht in research. The aim is to improve the treatment of inflammatory conditions of the musculoskeletal system and degenerative and traumatic impairments of the musculoskeletal system.

4.1 ORTHOPEDIC STUDIES

The Orthopedic department is divided into 4 units, each specialized in one single area of orthopedic surgery. Currently, nine orthopedic surgeons are connected to one or more of the units. The four units are Upper Limb unit, Hip and Spine unit, Knee Reconstruction unit and Foot and Ankle Reconstruction unit. Other areas of attention are sports and arthritis surgery. Currently, research at the Orthopedic department of the Maartenskliniek Woerden is mainly conducted within the Hip and Spine unit, Knee Reconstruction unit and Foot and Ankle Reconstruction unit.

A MULTI-CENTER PROSPECTIVE RANDOMIZED PHASE II CLINICAL TRIAL TO EVALUATE SAFETY AND EFFICACY OF HYALOSPINE® IN LUMBER LAMINECTOMY OR LAMINOTOMY

PERIOD	2009-2012		
PARTICIPANTS	P. Pavlov	MKW	Orthopedic Surgeon
	S. Stavridis	BGU Frankfurt	Orthopedic Surgeon
	M. Altena	MKW	Orthopedic Surgeon
	B. van Ginneken	MKW	Research Coordinator
	A. Kramer	MKW	Research Nurse
SPONSOR	Fidia Advanced Biopolymers, s.r.l		
PURPOSE	The aim of this Phase II trial is to evaluate safety and efficacy of Hyalospine® (a gel to decrease epidural scar formation) in patients undergoing lumbar laminectomy or laminotomy for degenerative spinal stenosis or disk herniation. The secondary aim is to evaluate differences in pain, neurological status, neurological symptoms, function, quality of life, patient satisfaction as well as immunologic and clinical laboratory results between patients receiving Hyalospine® and control patients.		
METHODOLOGY	This study is a prospective randomized double (patient and evaluator) blinded controlled trial monitored by a CRO (AOCID, Switzerland). 50 patients will be randomized to one of the treatment arms in a ratio of 1:1. Outcomes will be evaluated at 3 weeks ± 1 weeks, 6 weeks ± 2 weeks, 6 months ± 1 month, 12 months ± 2 months, and at all unplanned visits.		
PROGRESS	Woerden included the first patient in March 2010. Due to strict inclusion/exclusion criteria the number of participants is not sufficient yet. In Woerden, we are aiming at 16 participants. At this moment there are 4 patients included in the study.		
RESULTS	No results available yet.		
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QUOTE STUDY: QUALITY OF CARE OF ARTHRODESIS OF THE FOOT AND ANKLE FROM THE PERSPECTIVE OF THE PATIENT

PERIOD	2010-2012		
PARTICIPANTS	M. Stegeman	MKW	Orthopedic Surgeon
	B. de Wit	MKW	Resident Orthopedics
	B. van Ginneken	MKW	Research Coordinator
	A. Kramer	MKW	Research Nurse
SPONSOR	Maartenskliniek Woerden		
PURPOSE	<p>QUOTE (QQuality Of care Through the patients Eyes) questionnaires are used to study experience, expectations and satisfaction in healthcare from the perspective of patients. Aim of this study is to evaluate the quality of care of arthrodesis of the foot and ankle from the perspective of the patient who will have fusion surgery of the foot and ankle because of arthrosis.</p>		
METHODOLOGY	<p>It is a prospective cohort study. In a former stage we developed a questionnaire by two focus group meetings, interviewing people who experienced fusion surgery of the foot or ankle for arthrosis. This questionnaire consists of important aspects of care concerning a fusion surgery of the foot and ankle. Patient who will have fusion surgery of the foot and ankle because of arthrosis, are asked to fill in the questionnaire twice: pre and post surgery. Pre-surgery, the patient rates the items on importancy. 1-year post surgery, the patient rates the same items on satisfaction. Using these results one can calculate quality for all items by the formula $Q(\text{quality}) = I(\text{importance}) \times P(\text{performance/satisfaction})$.</p>		
PROGRESS	<p>Inclusion phase started at November 2010. In Woerden, we are aiming at 100 participants. At this moment there are 6 patients included in the study.</p>		
RESULTS	<p>No results available yet.</p>		
CONTACT PERSON	<p>M. Stegeman (m.stegeman@maartenskliniek.nl), A. Kramer (a.kramer@maartenskliniek.nl)</p>		
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4.2 RHEUMATIC STUDIES

The department of Rheumatology participates in research lines of the Sint Maartenskliniek Nijmegen, particularly the evaluation of the effectiveness of multidisciplinary treatment programs. Also, the department participates in studies conducted by the Early Utrecht Rheumatoid Arthritis Cohort study group (EURAC; formerly called SRU, Stichting Reumaonderzoek Utrecht), whose task it is to perform treatment strategy studies. Currently, five rheumatologists are working at the department and are involved in all research projects.

UACT EARLY: A MULTI-CENTER RCT TO EVALUATE OPTIMAL “TIGHT CONTROL” TREATMENT IN EARLY RHEUMATOID ARTHRITIS (RA)

PERIOD 2010-2014

PARTICIPANTS	J. Bijlsma	UMCU	Rheumatologist
	M. Custers	MKW	Rheumatologist
	S. Kadir	MKW	Rheumatologist
	W. Noort-van der Laan	MKW	Rheumatologist
	N. van der Laan-Baalbergen	MKW	Rheumatologist
	C. van Vliet	MKW	Rheumatologist

EURAC

The Early Utrecht Rheumatoid Arthritis Cohort (EURAC): a consortium of rheumatologists in the region of Utrecht, The Netherlands: Meander Medical Center Amersfoort and Baarn, Tergooi Hospital Hilversum and Naarden, St. Antonius Hospital Nieuwegein, St. Jansdal Harderwijk, Flevo Hospital Almere, Diaconessen Hospital Utrecht, Maartenskliniek Woerden and the University Medical Center Utrecht.

SPONSOR EURAC
F. Hoffmann La Roche

PURPOSE To evaluate the efficacy and safety of a new treatment protocol in rheumatoid arthritis patients, early in the disease aiming at remission. This protocol consists of Tocilizumab combined with tightly controlled methotrexate treatment (MTX). The efficacy and safety of this protocol will be compared to two other treatments: Tocilizumab or tightly controlled methotrexate as monotherapy.

METHODOLOGY This is a multicenter, prospective, randomized double blinded, placebo-controlled clinical trial. 300 patients will be randomized to one of the three treatment arms:

1. Tocilizumab + MTX
2. Tocilizumab + Placebo MTX
3. Placebo-Tocilizumab + MTX

Outcomes (vital functions and questionnaires) will be evaluated every 4 weeks during a 24 months follow-up period. At each visit a decision is made based on efficacy parameters (DAS-score) and possible occurrence of adverse events. In case remission (DAS28 score < 2.6) is not (yet) reached, treatment is increased in predefined steps. In case of adverse events predefined decision steps are indicated.

PROGRESS Woerden included the first patient in August 2010. In Woerden, we are aiming at 15 participants. At this moment there are 4 patients included in the study.

RESULTS No results available yet.

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BIOLOGICALS STUDY: CLINICAL AND IMMUNOLOGICAL MONITORING OF PATIENTS WITH RHEUMATOID ARTHRITIS TREATED WITH BIOLOGICALS AGENTS

PERIOD 2009-2019

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	M. Custers	MKW	Rheumatologist
	S. Kadir	MKW	Rheumatologist
	W. Noort-van der Laan	MKW	Rheumatologist
	N. van der Laan-Baalbergen	MKW	Rheumatologist
	C. van Vliet	MKW	Rheumatologist
	EURAC		

The Early Utrecht Rheumatoid Arthritis Cohort (EURAC): a consortium of rheumatologists in the region of Utrecht, The Netherlands: Meander Medical Center Amersfoort and Baarn, Tergooi Hospital Hilversum and Naarden, St. Antonius Hospital Nieuwegein, St. Jansdal Harderwijk, Flevo Hospital Almere, Diakonessen Hospital Utrecht, Maartenskliniek Woerden and the University Medical Center Utrecht.

SPONSOR EURAC
F. Hoffmann La Roche
Schering-Plough

PURPOSE Biological agents are used to treat rheumatoid arthritis. Like the variability in the process of the disease, there is a significant variability in the response to different 'biologicals'. To develop a prediction rule for response to biological treatment in rheumatoid arthritis (i.e. effectiveness and adverse events) by identifying immunological and clinical characteristics that are prediction of the effectiveness of different biological agents on the market for rheumatoid arthritis and the characteristics that are predictive of side effects.

METHODOLOGY A total of 880 rheumatoid arthritis patients who start treatment with biologicals are asked to participate in this multicenter, prospective, observational trial. The clinician decides which biological agent will be used. Outcomes such as clinical parameters, radiographs of hands/feet, questionnaires, urine and blood are gathered at baseline (before start with treatment of a new biological), at 3 and 6 months, subsequently yearly and if treatment is stopped due to inefficacy or side effects.

PROGRESS Woerden included the first patient in August 2010. In Woerden, we are aiming at 110 participants. At this moment there are 4 patients included in the study.

RESULTS No results available yet.

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LIST OF ABBREVIATIONS

ACHN	Ambulant Centrum Hersenletsel Nijmegen
AMC	Academisch Medisch Centrum Amsterdam
AOCID	AO Clinical Investigation and Documentation
BGU	Berufsgenossenschaftliche Unfallklinik
CRO	Clinical Research Organisation
CWZ	Canisius Wilhelmina Ziekenhuis
DCC	Donders Centre for Cognition
ECKR	European Center for knee Research
EMC	Erasmus universitair Medisch Centrum Rotterdam
EURAC	Early Utrecht Rheumatoid Arthritis Cohort study group
IOP	Innovatiegerichte onderzoeksprogramma's
KNGF	Koninklijk Nederlands Genootschap Fysiotherapie
KUL	Katholieke Universiteit Leuven
LBH	London Bridge Hospital
LUMC	Leids Universitair Medisch Centrum
MKW	Maartenskliniek Woerden
MODEM	MODEM Communicatie- en Computercentrum
OA	Osteo Arthritis
Oost NV	Ontwikkelingsmaatschappij Oost Nederland
ORCA	Orthopedic Research Center Amsterdam
POM	Prothese en Orthese Makerij Nijmegen
RCT	Randomized Controlled Trial
RD&E	Research, Development & Education
RPB	Reuma Patiënten Bond (Dutch Rheumatic Patient Society Amersfoort)
RU	Radboud Universiteit
RUG	Rijks Universiteit Groningen
RsScan	Runners service Scan
SMC	Sport Medisch Centrum
SMK	Sint Maartenskliniek
SRU	Stichting Reuma onderzoek Utrecht
TKR	Total Knee Replacement
TNO	Toegepast Natuurwetenschappelijk Onderzoek
UMC	Universitair Medisch Centrum
UM	Universiteit Maastricht
UMCN	Universitair Medisch Centrum St Radboud Nijmegen
UMCU	Universitair Medisch Centrum Utrecht/University Medical Centre Utrecht
UT	Universiteit Twente
UU	Utrecht University
UVT	Universiteit van Tilburg
VUMC	Vrije Universiteit Medisch Centrum Amsterdam
VWS	Ministerie voor Volksgezondheid, Welzijn en Sport
VZC	Voet zorg centrum
ZonMw	Zorg Onderzoek Nederland Medische Wetenschappen

