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14. ABSTRACT

Pressure ulcers (PU) are the most costly secondary complication following an SCI. In addition to the medical costs, the development of a pressure ulcer adversely impacts activities of daily living, employment and overall quality of life.

Research into pressure ulcer etiology has demonstrated that the damaging effects of pressure are related to both its magnitude and duration. Based upon this and related work, clinical interventions have been based upon the premise that both the magnitude and duration of loading are important. All persons with SCI are taught to relieve pressure on their buttocks regularly. While this is prudent training, it is based upon inference rather than direct evidence.

This project is the first to monitor pressure relief maneuvers and weight-shifting activities during the first year after injury. The project has been designed to fill two significant gaps in the current state of knowledge: 1) accurate measurement of dedicated pressure reliefs and other weight shift activities and 2) the relationship between activities that redistribute weight on the buttocks and the occurrence of pressure ulcers.

15. SUBJECT TERMS
Pressure ulcer; spinal cord injury, wheelchair seating

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Contents

1. Introduction

Pressure ulcers (PU) are the most costly secondary complication following an SCI. In addition to the medical costs, the development of a pressure ulcer adversely impacts activities of daily living, employment and overall quality of life.

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2. Keywords

Wheelchair, wheelchair cushion, spinal cord injury; pressure ulcer; pressure relief, weight shift; data logger

3. Accomplishments

Major goals of the project and accomplishments under these goals

Task 1. Design, configure and test weight shift sensor and weight shift monitors (months 1-8)

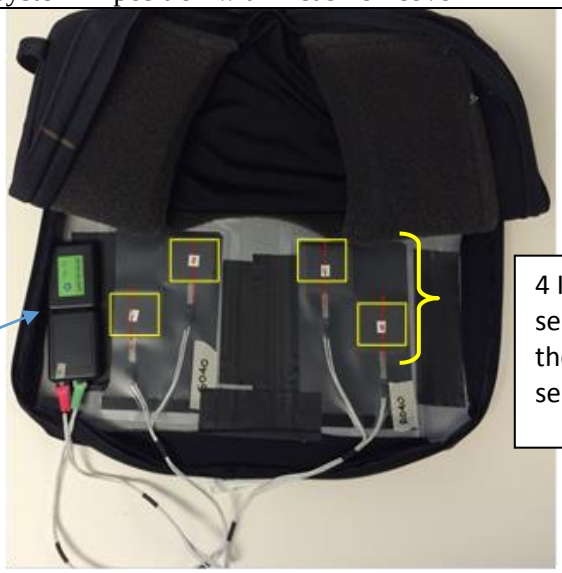
Design of weight-shift monitoring system

The weight-shift monitoring system is comprised of a weight shift sensor and a weight shift monitor. The weight shift sensor is placed underneath the wheelchair cushion to monitor forces on the seat surface. The weight shift monitor is composed of a 4 channel analog voltage input and data logger

After review of design specifications and testing, instrumentation from Gulf Coast Data Concepts (GCDC) was selected for the weight-shift monitor. This US-based company met specifications at a lower cost compared to a European company. Interlink sensors were selected for the weight shift sensor based upon testing and comparison with FlexiForce sensors. GCDC were provided Interlink samples along with response characteristics to facilitate the design, fabrication and testing of the interfacing circuit.

Multiple prototypes were exchanged between study personnel and GCDC; during each iteration, testing was deployed to assess the measurement, analog-to-digital conversion and storage of sensor response to loading. Battery life was also evaluated. Testing included cyclical loading of the system suing a buttock model to simulate weight shift activities. Specifically, a buttock model loaded the sensors for 30 minutes followed by partial unloading for 30 seconds. This partial unloading was designed to mimic a pressure relief performed by a wheelchair user. Therefore, the test was designed to validate the ability of the sensors to detect periodic movement after extended periods of loading. Also, the test characterized sensor creep.

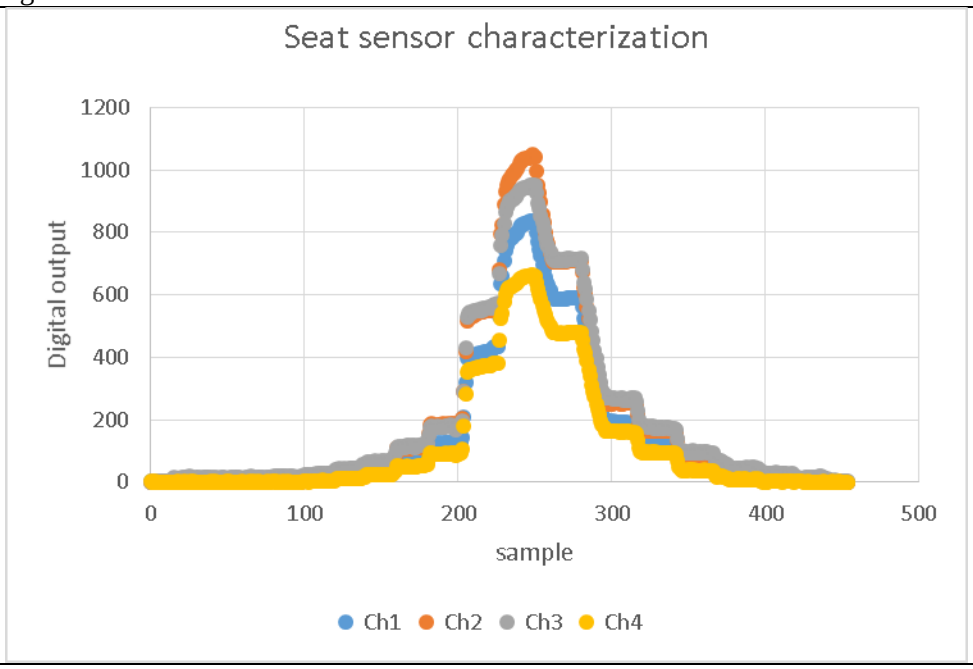
Weight shift monitoring system in position within cushion cover



Fabrication of seat sensors, interfacing with data measurement hardware, and sensor characterization.

Each weight shift sensor is comprised 4 Interlink pressure sensors that must be characterized. A total of 40 complete weight shift sensors were fabricated before characterization. Sensor characterization involved applying known forces in a stepwise manner to document the voltage responses from each individual Interlink sensor. This permitted us to optimize the bridge circuit in the data logger

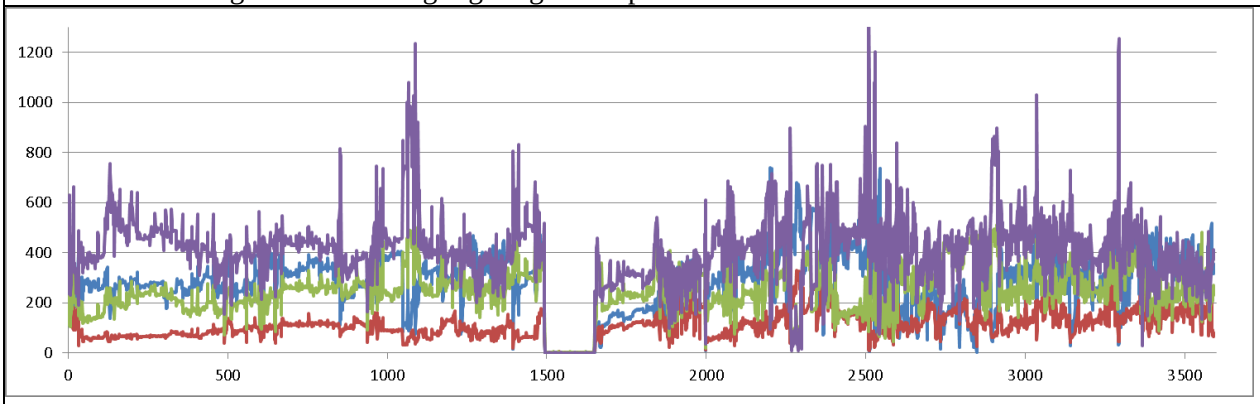
Characterizing the 4 Interlink sensors within each seat sensor



The weight-shift sensor is designed to monitor the loading on a wheelchair cushion. Changes in posture result in changes in load which is measured by the weight shift monitoring system. In order to document the type and frequency of weight shifting behaviors, force data from the sensors must be categorized. This is a difficult challenge and one that is on-going.

Of note is the fact that the protocol collects a 'training data set' for each subject. This individual assessment is needed because forces on the cushion and changes in force due to movement will differ across people. This training data set because the basis upon which classification is based. The table below depicts 60 minutes of data- one response is from each of the sensors that comprise the weight-shift monitor.

60 minutes of weight shift data- highlighting the responses from each of the 4 sensors



Task 2. Finalize methodology and submit for IRB approval (months 2-8)
One human subject research protocol is required to complete the Statement of Work. The protocol was developed, submitted and approved at all three sites. The protocol has received HPRO approval

Protocol [HRPO Assigned Number]: SC120127

Title: Pressure relief behaviors and weight shifting activities in persons with SCI

Submitted to and Approved by:

- Georgia Tech, Shepherd Center, Kessler have each approved the protocol
- HRPO

Status:

- Protocol has been approved

Task 3. Develop research manuals for each facility and train staff (months 6-8)
Research Manual were developed for Kessler and Shepherd Center and were provided to each clinical site after a few rounds of iteration. While the complete Research Manual is extensive, a shorter Reference Manual was also developed for use during subject engagement; this document is appended to this annual report

Both Shepherd Center and Kessler staff have undergone formal training to establish proper technique and subject protocol.

Task 4. Enroll and monitor subjects for 12 months (months 9-33)
Subject screening for possible inclusion began at Shepherd Center in July and Kessler in September

Total patients screened	99
Total met inclusion criteria	72 (55 out of state)
Total Local who declined	2
Total enrolled	2
Total currently being monitored for D/C	13

What opportunities for training and professional development has the project provided?

Nothing to report

How were the results disseminated to communities of interest?

Nothing to report

4. Impact

What was the impact on the development of the principal discipline(s) of the project?

Nothing to report

What was the impact on other disciplines?

Nothing to report

What was the impact on technology transfer?

Nothing to report

What was the impact on society beyond science and technology?

Nothing to report

5. Changes/Problems

Changes in approach and reasons for change

Recruitment is difficult in a study such as this. The actual subject involvement is not rigorous. In fact, the set-up procedure takes less than 60 minutes. The challenge is in gaining interest from persons who are newly injured and have a pending discharge date. We noted this challenge while engaging potential subjects and come to the conclusion that asking someone to commit to a 12 month study before they have even been discharged was overwhelming to them.

To help overcome this situation, we made a slight change in the presentation of the project. Note- there is no change in the objectives or the targeted data set, rather a change in fully explaining the study to insure autonomy.

We have started to present this study in sections instead of as a 12 month commitment. Operationally, this targets recruitment for the initial visit within 1 month of discharge and in concert with another outpatient hospital visit. We also express our intent to schedule the participants for additional testing- if he or she is so interested.

Actual or anticipated problems or delays and actions or plans to resolve them

One potential problem or delay concerns subject recruitment; one problem was identified and has been addressed- as described above. This was not a significant change, rather was a change in sematic presentation.

The project is adequately staffed to perform recruitment, so personnel time is not a problem. Nonetheless, recruitment requires a consistent level of attention and ability to articulate the study clearly and answer questions. We are confident that the principals at Shepherd Center and Kessler will recruit their targeted number

of subjects, but we also recognize that recruitment is always a potential problem, especially for a protocol requiring multiple visits.

PI Sprigle and CoI Sonenblum maintain regular contact with Shepherd Center staff and have even assisted in running subjects. Consistent contact with Kessler has also been maintained and no problems are evident.

Changes that had a significant impact on expenditures

Expenditures were lower than anticipated; this was due to the inertia of ramping up the clinical sites. This is a temporary impact that will not change the Scope of Work of the project

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

None

Significant changes in use or care of human subjects

None

Significant changes in use or care of vertebrate animals.

N/A

Significant changes in use of biohazards and/or select agents

N/A

6. Products

Publications, conference papers, and presentations

Nothing to report

Website(s) or other Internet site(s)

Nothing to report

Technologies or techniques

The activities of this project has led to the development of a simple 4 channel analog data logger. This was developed by study personnel in collaboration with Gulf Coast Data Concepts. This device is not IP, per se, as many analog data loggers exist, but it has some useful features that others might deem beneficial

The activities have also been working on a technique to categorize weight shifting activities and pressure reliefs. This work is a part of the Rehabilitation Engineering Research Center, a project funded by the National Institute on Disability and Rehabilitation Research. This algorithm, uses the voltages from the weight shift sensors to calculate metrics and perform classification. Trying to characterize behavior using sensor data is a complicated task because behaviors can be so varied. A description of the development activity is included in the Appendix

Inventions, patent applications, and/or licenses

Nothing to report

Other Products

Nothing to report

7. Participants & Other Collaborating Organizations

Name:	Stephen Sprigle
Project Role:	Principal Investigator – GIT
Researcher Identifier (ORCID ID):	0000-0003-0462-0138
Nearest person month worked:	1
Contribution to Project:	designed sensor testing protocol, reviewed sensor testing data; processed subagreements with Shepherd Center and Kessler; worked on IRB submission; subject set-up
Funding Support:	State of Georgia

Name:	Sharon Sonenblum
Project Role:	Lead Investigator- GIT
Researcher Identifier :	
Nearest person month worked:	3
Contribution to Project:	established sensor and logger design specs; engaged data logging manufacturer; worked on classification algorithm; reviewed sensor testing data; submitted IRB application to GIT and Shepherd IRB ; Committees; subject set-up
Funding Support:	NIDRR (Dept of Education)
Name:	Nagmesh Kumar
Project Role:	Research Engineer- GIT
Researcher Identifier	
Nearest person month worked:	3
Contribution to Project:	designed and deployed sensor testing methodology; data analysis and synthesis; report writing
Funding Support:	NIDRR (Dept of Education)

Name:	Trevor Dyson-Hudson, M.D.
Project Role:	Kessler PI
Researcher Identifier	
Nearest person month worked:	1
Contribution to Project:	Dr. Dyson-Hudson serves as site-PI at our collaborative clinical site, Kessler Foundation and Kessler Institute.
Funding Support:	NA

Name:	Marina Moldavskiy
Project Role:	Shepherd study Coordinator
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1.2
Contribution to Project:	Screen and enroll participants. Assist with data collection. Schedule participant visits. Input data and maintain all participant logs.
Funding Support:	

Changes in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to report

What other organizations were involved as partners?

Nothing to report

8. Special Reporting Requirements

9. APPENDICES:

DoD Research Manual – Short Version

Equipment Checklist

☐ Consent form	☐ Weight Shift Monitor (WSM) sensors (2)
☐ Subject Payment Forms	☐ Data logger with USB cable
☐ Demographic Questionnaire	☐ Tape & Attachment materials
☐ Pressure Ulcer Knowledge Test	☐ Cable ties
☐ Setup/Takedown Survey	☐ Extension cords
☐ FSA Interface pressure mat, box, cable, incontinence covers	☐ Antibacterial Spray
☐ FSA laptop	☐ Accelerometer
☐ Camera	☐ Tape measure or yard stick

Setup Protocol

EQUIPMENT SET UP - PRIOR TO SUBJECT ARRIVAL

1. Charge data logger and accelerometer for at least 12 hours.
2. Delete old files from the Data Logger and accelerometer.
3. Record the serial numbers of the data logger and accelerometer that you charged and prepared for the study.

DataLogger_SN	Data logger serial number	
Accelerometer_SN	Accelerometer serial number	

4. Calibrate FSA if it has not been calibrated within 2 weeks and record the Calibration Date and the Serial # of the IPM Mat.

IPM_CalibrationDate	Date of IPM calibration	
IPM_MAT_SN	Number - serial number on FSA mat	

5. Confirm that FSA is set to collect data at 1 Hz.

WITH SUBJECT PRESENT

1. Consent
2. Review weights shifts for training set
3. Transfer out
4. Attach WSM and accelerometer
   - ☐ Take photograph of WSM sensors placed on seat or cushion bottom.

SensorMat_SN_Left	string serial number labeled on WSM mat plugged into the LEFT (Red)	
SensorMat_SN_Right	string serial number labeled on WSM mat plugged into the RIGHT (Green)	

5. Attach WSM data logging unit – inside cushion cover OR to wheelchair frame
6. Plug WSM mats into data logging unit – make sure color coded cables are plugged into matching connectors.
7. Turn on the datalogger.

DataLogger_StartDate	Date	
DataLogger_StartTime	Time	

8. Turn on accelerometer.
    - □ Take photograph of wheel with Accelerometer mounted.

WhichWheel	LEFT OR RIGHT (wheel containing Accelerometer)	
wheelDiam	Number (inches)	
Accelerometer_StartDate	Date	
Accelerometer_StartTime	Time	

9. Start FSA recording
10. Wait 20 seconds and Have the subject transfer back to chair.
11. Perform Training protocol.

********** DO TRAINING **********

12. Stop FSA recording and SAVE as "DODKR##_v#.fsa" or "DODSC##_v#"
13. Remove IPM mat
14. Paperwork
    - □ Reimbursement paperwork
    - □ Pressure Ulcer (PU) Knowledge Test (1st visit)
    - □ Demographic questionnaire.
15. Go over equipment and care with subject.
16. Record time and date that setup was completed

mountDate	MM/DD/YY	
mountTime	hh:mm:ss AM/PM	

17. Confirm takedown date and time
    - □ Date and time for take-down: _____ ; _____

AFTER SUBJECT LEAVES

1. File reimbursement paperwork
2. Record all data (including the *Training Protocol Data* in the table) in the individual's METADATA tracking sheet (DODKR##_v#_Metadata.xlsx)
3. Record the PU Knowledge Test results into the Survey Tracking sheet (DODKR##_Survey.xlsx)
4. Record the Demographic questionnaire results into the Subject Info Tracking sheet (DODKR##_SubjectInfo .xlsx)
5. Send data to Georgia Tech (FSA data, Metadata, PU Knowledge test results, Demographic questionnaire)

Training Protocol Data

Record frame numbers from the bottom right corner of the FSA screen when subject begins each activity listed.

NOTE Post-training is optional, occurs at take-down, and is only completed if it is determined that there was a problem with the pre-training data.

Duration (sec)	***Activity***	***Magnitude***	***Pre Training (setup)*** ***Frame #***	***Optional Post Training (take down) Frame #***
N/A	Palpate **Left** IT	Palpate to identify IT's (ischial tuberosity aka sitting bones) on IPM mat – hand under FSA mat to create a high peak pressure at the IT.		
N/A	Palpate **Right** IT	Palpate to identify IT's on IPM mat – hand under FSA mat to create a high peak pressure at the IT.		
120	Upright	Sitting upright in the chair.		
20	Front Lean 1	(can be chest on knees or "full lean" – max they can do)		
20	Front Lean 2	(can be elbows on knees or "medium lean" – 2/3 of max)		
20	Front Lean 3	(can be hands on knees or "small lean" – 1/3 of max)		
20	Upright	Sitting upright in the chair without leaning.		
10	Push-up (tricep dip) / Stand	if possible		
20	Upright	Sitting upright in the chair.		
20	Left Lean 1	(can be 150% or "full lean" defined however you want)		
20	Left Lean 2	(can be 125% or "medium lean" defined however you want)		
20	Left Lean 3	(can be 110% or "small lean" defined however you want)		
20	Upright	Sitting upright in the chair without leaning.		
10	Push-up (tricep dip) / Stand	if possible		
20	Upright	Sitting upright in the chair without leaning.		
20	Right Lean 1	(can be 150% or "full lean" defined however you want)		
20	Right Lean 2	(can be 125% or "medium lean" defined however you want)		
20	Right Lean 3	(can be 110% or "small lean" defined however you want)		

20	Upright	Sitting upright in the chair without leaning.		
10	Push-up (tricep dip) / Stand	if possible		
20	Upright	Sitting upright in the chair without leaning.		
40-160	Other Movements, pressure relief, or Weight Shifts	Any other positions that he sits in (besides upright) - may include cross legged, hooked on push handle, etc. Hold each for 20 sec, separated by 20 seconds upright sitting. Describe each weight shift:		
20	Upright	Sitting upright in the chair without leaning.		
60	Free Movement	Ask the subject to move freely in the (stationary) chair – they can reach, lean, adjust legs, etc. Whatever they want for 60 seconds (Note: they don't have to move constantly, and if they can't get to 60 seconds, that's ok – just be reasonable)		
20	Upright	Sitting upright in the chair without leaning.		
60	Beach ball volleyball	Bounce the beach ball back and forth with the subject in an effort to create a dynamic situation with lots of leaning.		
20	Upright	Sitting upright in the chair without leaning.		
N/A	Palpate **Left** IT	Repeat palpation. Palpate to identify IT's on IPM mat – hand under FSA mat to create a high peak pressure at the IT.		
N/A	Palpate **Right** IT	Repeat palpation. Palpate to identify IT's on IPM mat – hand under FSA mat to create a high peak pressure at the IT.		

Take-Down Protocol

With subject present

1. Carefully remove all equipment from chair, watching to not clip wires.
    - □ Data logger
    - □ 2 WSM sensors
    - □ Accelerometer
2. Complete takedown survey questions.
3. Record date and time of takedown

dismountDate	Date	
dismountTime	Time	

4. Repeat training protocol if it was determined that something did not work at setup.

After subject leaves

1. Clean equipment
2. Update METADATA tracking Sheet
3. Download weight shift data from the Data logger
4. Download wheel data from accelerometer
5. Send data to Geo

Development of Pressure Relief Monitor data-processing algorithm

The data from the PRM (pressure relief monitor) mat consists of eight concurrent pressure-time histories measured on a rectangular grid of sensels (sensor elements) comprised of two square arrays of four sensels each with their epicenters under each buttock. These mats are located between the cushion on which the subject is sitting and the wheelchair seat beneath it. From the measured pressures, an algorithm has been developed to determine whether the subject is executing a pressure relief (PR) maneuver, what type of PR the subject is executing (full or partial), and what the subject's level of activity is as a function of time. The first step in this algorithm is to reduce the eight pressure time histories into four feature histories based on features that were empirically determined to relate to the metrics of interest. These are: 1) the medial/lateral location of the center of pressure (CoP) on the PRM mat, 2) the anterior/posterior location of the CoP, and 3) the maximum pressures measured on the subject's right and 4) left sides. An activity metric is defined as the distance traveled by the subject's CoP during a prescribed time interval centered on the time of interest.

PR status and type determination is a more complicated matter. The preferred standard for the direct measurement of these involves interface pressure monitoring (IPM) between the cushion and buttocks using a more densely populated array of sensels and requiring the subject to be nominally stationary between maneuvers.[1] In order to account for the fundamental difference between the IPM and PRM measurements, a training procedure was used in which the subject executed a prescribed series of maneuvers while simultaneous data was collected on both an IPM mat and a PRM mat. The status determined from the IPM measurements was then associated with the concurrent PRM features to define contiguous regions of PR and non-PR in a three-dimensional feature space corresponding to

[1] S. Soneblum, T. Vonk, T. Janssen, and S. Sprigle, "Effects of wheelchair cushions and pressure relief maneuvers on ischial interface pressure and blood flow in people with spinal cord injury", Archives of Physical Medicine and Rehabilitation, Vol. 95 no.7, pp. 1350-1357, July 2014.

each buttock. This feature/status set was then used as a Euclidean nearest-neighbor classifier for the remaining PRM data. It was necessary to discard elements from this classifier where either the feature values were changing rapidly or the status of nominally identical feature sets was ambiguous because of cushion-induced latency or because of different impulse responses between the sensels in the two mats. For the subsequent PRM data, where periods of stillness could not be prescribed, subject movement not related to PR activity was accounted for using a zero-delay (acausal) low-pass filter to set a baseline for the normalization of each of the features. This filter was applied to the portions of the data where the subject was in the chair and not executing an obvious total PR (times when the measured pressures were unambiguously non-zero). This was then linearly interpolated over times of zero pressure. A similar technique can be iteratively applied to the times over which PRs were subsequently determined to have occurred in order to avoid baseline distortion due to frequent or lengthy PRs. The technique was validated using an extended series of concurrent measures with both PRM and IPM mats with three substantially different intervening cushions and three different subjects. These measurements included both a training sequence and a subsequent period of prescribed and free movements to assess the technique. The technique was generally found to work well, but to be dependent on the true status associated with the training maneuvers, which was not known a priori.