

Wearable device for monitoring disability associated with Low Back Pain

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Abstract—Low Back Pain (LBP) is a leading cause of disability, prevalent in all countries and cultures with economic costs, severe psychological and sociological consequences. Difficulties in the management of LBP include: credibility of self-reported health and function surveys, accurate patient evaluation, identifying reassessment time and classification of patient groups. The most critical issue is the severity assessment during clinic visits instead of continuous monitoring at home or in the workplace. We foresee long-term monitoring of non-specific chronic LBP in natural environments through a wearable, unobtrusive device that monitors and assesses LBP related disability and correlates it to the reported level of pain experienced. The project In-House Monitoring of Low-Back-Pain related Disability (IMPAIRED) aims to design and develop a multi-sensor wearable prototype to monitor disability in movement of the lumbar spine and pelvis, sleep (circadian rhythm) as well as muscle fatigue and activity pattern. We have identified relevant movements correlating with disability associated with LBP, evaluated the suitability of inertial sensors to monitor the expected range of movement and proposed a sensor placement map. Next, we will conduct a pilot study to validate sensor location and selection which will facilitate the design of an initial prototype.

I. INTRODUCTION

The healthcare industry is experiencing a growing emphasis on healthcare management instead of conventional disease management. This change is spurred by the ageing population of the world, growing health concerns and increasing demands of personalised healthcare. High pressure on current medical systems and a shift in focus towards preventive medicine and long-term, continuous health monitoring is anticipated. Current healthcare information systems, designed for managing acute illness (infections, injury) are unsuitable for extensive long-term monitoring [1]. New developments are required. Wearable sensing technology offers a novel solution with the added advantage of multiple user group applicability.

Chronic Low Back Pain (CLBP) is a leading cause of disability prevalent in similar proportions across countries and cultures [2]. One in five adults suffers from LBP annually [3]. In industrialized societies, chronic pain is fast becoming the greatest health problem which includes low back pain costs of US\$100-\$200 billion annually [4]. 75% to 85% of workers' absenteeism can be attributed to recurrent and chronic back pain [5]. Disabling CLBP has severe psychological and social costs. 50% to 67% chronic pain patients are unable to live independently and carry out regular activities such as exercise,

sleep normally, household chores and have healthy relationships.

CLBP, a single attack of back pain lasting over 3 months, usually presents in the lumbosacral region (Figure 1.) and can occur in the buttocks and thighs [6]. The pain tends to be mechanical in that it varies with physical activity. It is non-specific and there are no diagnostic features indicating the source of pain. Patients not only experience the pain but also experience varying degrees of impairment, disability (like in mobility) and chronicity.

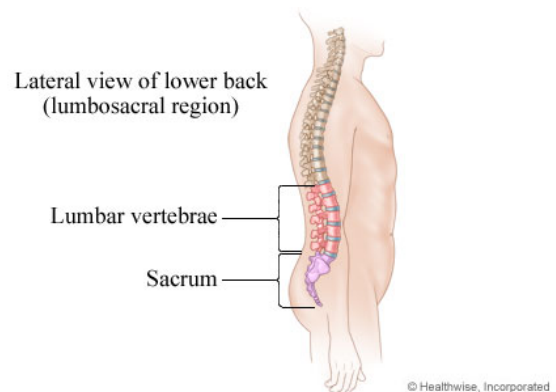


Fig. 1. Lumbosacral region of the spine.

Principal issues in the management of LBP are the credibility of self-reported health and function surveys [7], accurate evaluation of patients [3], identifying time of reassessment, classification and identification of patient groups and compliance with interventions and advice. The paramount issue is that severity of LBP and its impact on physiological and social functioning is determined at a particular single point of time in the artificial environment of a clinic visit instead of monitoring over a period (1 week to 6 months) [8].

The underlying hypothesis of the initiative In-House Monitoring of Low-Back-Pain Related Disability (IMPAIRED) is that the impact of pain and disability experienced by CLBP patients can be properly measured only in the home and work environments over extended periods of time (1 week to 6 months). On this basis, IMPAIRED aims to develop a prototype wearable monitoring device for CLBP patients.

Wearable sensing technology based on Body Sensor Network (BSN) architecture and comprised of a network of wireless wearable sensors monitoring the human body offers

novel and feasible means of non-invasive monitoring in natural environments of the home and workplace [9]. Recent advances in the areas of sensor technology, low power electronics, power delivery, data transmission, security measures and information processing techniques have fostered diverse wearable body monitoring applications all over the world [10-13].

Through the IMPAIRED project, an initial prototype will be designed, built and tested to monitor onsite CLBP related disability in movement, sleep (circadian rhythm), muscle fatigue and activity pattern. A number of companies and research groups have monitored and assessed some aspects related to the present project, but an integrated approach that allows for the monitoring of the various relevant parameters simultaneously and subsequent multivariate analysis is yet to be adopted.

This paper presents the design concept for IMPAIRED, results of initial sensor evaluation and future work planned.

II. RESEARCH ISSUES

To develop the prototype, IMPAIRED has to address central multi-disciplinary issues. These disability assessment and pervasive sensing issues are:

- 1) Identification of physiological reactions and behavioural responses that can determine the degree of pain related disability when correlated with the reported level of low back pain
- 2) Adequate sensor selection to comply with the application requirements including monitoring in the home environment
- 3) Optimal sensor locations
- 4) Necessary sensor placement accuracy
- 5) Sensor wearing strategies
- 6) Simultaneous capturing and subsequent analysis and utilization of multi-sensorial data
- 7) Suitable strategy and protocol for data storage and transmission
- 8) Personalized monitoring of a real life condition to make inferences about the degree of disability caused by it
- 9) Developing a robust, wearable, compact, self-contained prototype for long term monitoring and assessment
- 10) Validation of the developed system and its effectiveness through tests and evaluation studies

III. METHODOLOGY

A. Disability Identification and Parameter Selection

The common effects of CLBP on patients are a change in the movement of the back, tendency to keep pelvis rigid, difficulty in getting restful sleep and experience of fatigue. These effects can be severe and can alter the ability of CLBP patients to perform simple daily activities and lead an independent life. The complexity increases as the disabilities may inter-link. Figure 2. depicts an example of how the onset of one may trigger another, resulting in deteriorating health.

Therefore, the wearable prototype will be developed with the functionality to monitor Movement of the Lumbar Spine

and Pelvis, Sleep disturbance, Muscle Fatigue and Activity Pattern.

The key parameters that must be monitored for assessing movement disability in CLBP patients are velocity and orientation of the spine and pelvis. Sleep disturbance can be monitored by observing the circadian rhythm (the body's natural sleep and wake cycle) in CLBP patients. To determine circadian rhythm, the parameters to be monitored are rest and activity cycles, environmental time and light exposure levels followed by comparison of their phase relationships [14].

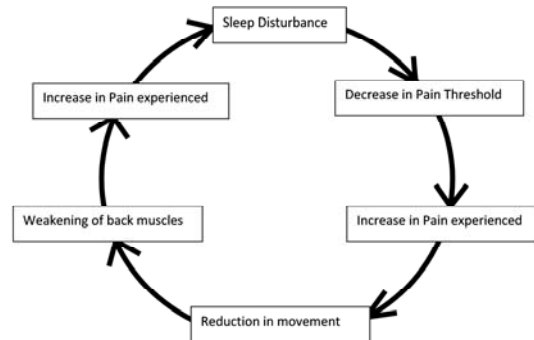


Fig. 2. Example of disability cycle in LBP patients

B. Selection of Sensors

Inertial sensors (3D accelerometer and 3D gyroscope) will monitor movement (velocity and orientation) of the lumbar spine and pelvis along the three planes of movement. Goniometers and bend sensors are unsuitable since they must be fixed securely at two points and they monitor movement along one plane only. Using multiple goniometers or bend sensors simultaneously to monitor movement of the spine and pelvis accurately along the three axes is not feasible.

Inertial sensors also have the advantage that the accelerometers can be used to gather data on rest and activity cycles which when combined with ambient light data from a light sensor will determine circadian rhythm. Commercially available devices for monitoring sleep are unsuitable because of their large size, unnecessary complexity and possible detraction of patients from natural sleeping habits. Bed pressure sensors are unsuitable too as data collection times are limited to bed usage.

Electromyography (EMG) is the primary technique applied for monitoring muscle fatigue and activity patterns. Commercially available wireless EMG systems with surface EMG (sEMG) sensors worn by patients are inconvenient owing to the large size and weight of the wireless base station, wired links to the sEMG sensors and requirement of direct skin contact. Wireless and skin contact free EMG sensors are currently unavailable but research is ongoing [15]. In the initial stages of prototype development, a wireless EMG system with sEMG sensors will be employed [16].

Key sensor characteristics required are small size, low weight and low power consumption which will minimize prototype size and weight as well as reduce user discomfort.

C. Wireless Sensor Platform

IMPAIRED requires a miniature, low power, wireless sensor mote that can be easily programmed and integrated with multiple sensors. Preference is also for motes with sensor boards comprised of any of the selected sensors. The BSN node [17], the Tyndall Mote [18] and SHIMMER [19] were considered. Though SHIMMER has a 3D accelerometer, it is largest in size. The Tyndall and BSN nodes are similar in size but, while the Tyndall Mote provides connections for sensors, the BSN node has a sensor board with a 2D accelerometer, temperature sensor and extension slot (to form 3D accelerometer). The Tyndall Wireless Inertial Measurement Unit is also unsuitable as other sensors cannot be connected to it. Therefore, the hardware platform selected was the BSN node.

The BSN hardware is supported by TinyOS, an open source, embedded operating system. Designed specifically for managing hardware and wireless sensor networks, TinyOS also enables power management (energy efficiency) and code minimization (small sized files).

D. Sensor Placement

An initial Sensor Location Map is proposed (Figure 3.).

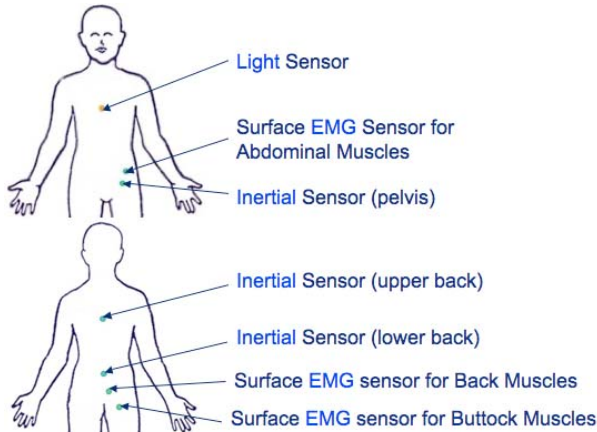


Fig. 3. Initial Sensor Location Map

Inertial sensors will be placed on the lower back and pelvis. Initially, the behaviour of the upper back will also be investigated with an inertial sensor on the upper back (thoracic spine). The light sensor will be placed on the chest. For Muscle Fatigue and Activity Pattern, sEMG sensors will be placed on back muscles (Erector Spinae and Multifidus), abdominal muscles (Transversus Abdominals, Internal and External Oblique) and buttock muscles (Gluteus maximus and minimus). These muscles have been chosen as the back muscles and oblique muscles are involved in functional performance movements while the abdominals help maintain core stability. Pain in the buttock muscles is a confounding syndrome and is thought to be referred pain.

All the selected sensor locations can be identified by bony landmarks which will help maintain symmetry and ease of sensor placement across different subjects. The sensor location map will be revised following a pilot study to

determine optimal sensor locations.

In the early stages of the project, the sensors are to be placed locally on the area using PALStickies™ [20] gel-stickers as local placement is simple and relatively inexpensive for design, onsite testing and system feature development. At a later stage, a more robust and wearable approach will be adopted (like sensors mounted on a lumbar belt) as local placement increases susceptibility to damage outside a controlled environment and allows limited onsite patient monitoring. The suitability of smart textile technology to develop a wearable sensing garment will also be investigated.

E. Inertial Sensor Feasibility Study

To assess the feasibility of inertial sensors monitoring movement of the lumbar spine, we conducted experiments using an inertial demo sensor, Xsens Technologies' MTi Attitude and Heading Referencing System (AHRS) [21]. The MTi sensor orientation output is in the form of quaternions, Euler angles or rotation matrices. Movement tests included back extension, a key functional performance test applied while assessing LBP associated disability.

The back extension movement test was conducted on two healthy volunteers. The inertial sensor was secured firmly to the clothing of the subject above the L1 vertebrae of the lumbar spine using Tegaderm™ dressing. The subject performed four back extensions (bending backwards) at a natural pace to a comfortable limit. For validation purposes, the slope of lumbar back (where the sensor was placed) at the start and maximum extension points for every back extension were manually drawn on a chart. Next, the angle between the two slopes was measured with a protractor. The orientation data was collected in rotation matrix format and examined.

IV. RESULTS OF FEASIBILITY STUDY

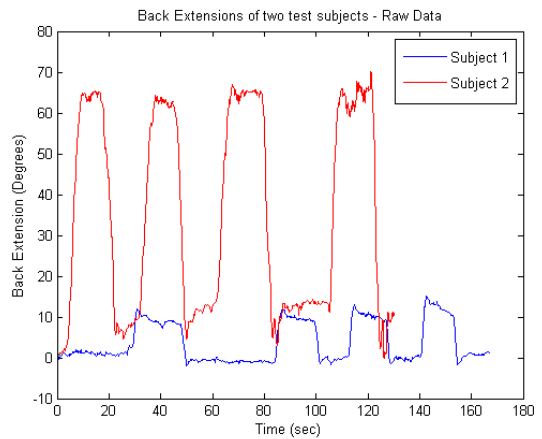


Fig. 4. Sensor output for Back Extensions of two test subjects.

TABLE 1
ANGLES OF BACK EXTENSION IN
SUBJECT 1

Back extension	Angle (°)	Sensor Output	Manual record	Absolute Difference
1	θ_1	7.54	7	0.54
2	θ_2	10.77	11	0.23
3	θ_3	13.82	15	1.18
4	θ_4	12.58	18	5.42

SUBJECT 2

1	θ_1	64.62	70	5.8
2	θ_2	56.00	70	14
3	θ_3	54.39	63	8.61
4	θ_4	51.95	60	8.05

V. DISCUSSION

The sensor output (Figure 4.) indicates that the back extension ability of the two subjects is different. Average degree of back extension for Subject 1 was 11.18° and 56.74° for Subject 2. Table 1 indicates that the sensor output for Subject 1 is relatively consistent with the manual recordings made. The marginal differences for back extensions 1-3 are attributed to human error. However, the difference of 5.42° for the fourth back extension is attributed to error in marking the slope of the back at maximum extension due to greater oscillation of the subject's back at that point. For subject 2, the differences between sensor output and manual record are considerably larger. These are attributed to combined error of imprecise manual markings of slopes of the lumbar back and the greater natural oscillation of the subject's back around the rest and maximum extension positions. Furthermore the signals have not been filtered. Nevertheless, this preliminary experiment confirmed that the gyroscope (in the inertial sensor) is sensitive to changes in orientation of the spine and is suitable for use in a wearable device for movement monitoring purposes. The results also suggest that the range of movement could differ greatly from person to person.

The inertial sensor technology needs to be further investigated in detail for a range of movements, with sensors in multiple locations, and with more participants. Filtering techniques to eliminate noise should also be applied. Validation techniques with greater precision such as opto-electronic tracking should be implemented.

VI. PILOT STUDY PLANNED

As the results and observations of the feasibility study suggested that inertial sensors may be used for monitoring orientation of the spine but required a detailed investigation, a pilot study has been planned to investigate the use of wearable sensor technology to characterise movement of the lumbar spine and pelvis.

A. Study Objectives

The objectives of the pilot study are:

- 1) To conduct an assessment of commercially available sensors on study participants, studying the correlation

between multi-sensorial data and range of movements for various daily activities.

- 2) To define the sensor specification required that must be met by the customised sensors for monitoring orientation and speed of movement of the lumbar spine and pelvis during daily activities
- 3) To identify the locations on the back for sensor placement such that various back movements can be effectively monitored
- 4) To determine the accuracy of sensor placement that is essential for effective monitoring
- 5) To investigate various sensor wearing strategies
- 6) To determine the best possible way of collecting and analysing data from the multiple sensors

B. Study Methodology

The study of 1 year duration will involve 20 healthy volunteers and will be instrumented using commercially available MicroStrain[®] Inertia-Link[®] wireless inertial sensors [22]. At every study session, the sensors will be placed on the skin of the participant using PALStickies[™] at areas identified by bony landmarks. The participant will be asked to perform a series of tasks that test functional performance and daily activity in each plane of movement. These tasks include basic range of movement tasks such as forward and lateral flexion, rotating to the left and to the right to the comfortable limits of range. A series of functional tests will be done including walking, moving from sitting to standing position (and vice versa), lifting, walking up and down stairs.

To assess the test-retest reliability of the system, a cohort of the participants will be asked to return for more sessions. A cohort may also be measured with other equipment including electromagnetic and opto-electronic tracking devices for validation purposes.

Questionnaires will also be applied such as the International Physical Activity Questionnaire (IPAQ) and a general questionnaire on demographic data and participant feedback. These will help establish whether patterns exist between the movement characteristics and activity levels or demographic characteristics.

C. Study Outcome

At the end of the pilot study, a report will be prepared that details the understanding of the movement of the lumbar spine and pelvis for various daily activities in healthy subjects, observations of movements over different sessions and assessment of commercial sensors, sensor specification of the application, sensor location map, establishes sensor placement accuracy required, defines the strategy for making the sensors wearable and establishes a protocol for multi-sensorial data collection and analysis. The outcome of this study will affect critical decisions in the design and development of the initial prototype.

VII. CONCLUSIONS

The IMPAIRED project adopts a novel integrated approach for a comprehensive assessment of the degree of disability associated with LBP. The initial prototype that IMPAIRED aims to build is a first step in the direction of the development of an integrated, unobtrusive, long-term monitoring device for chronic Low Back Pain patients in their home and work environments. We have identified relevant movements correlating to disability associated with LBP, evaluated the suitability of inertial sensors to monitor the expected range of movement and proposed a sensor placement map.

The next stage of our project will involve a pilot study to further evaluate the chosen sensor technology, determining the required sensor specification, optimal sensor placement locations, necessary placement accuracy and sensor wearing strategies. We will then customize the chosen sensors as necessary and incorporate them into the BSN platform, implement selected sensor wearing strategies and all necessary support software for data acquisition, storage and analysis. The final stage will involve further evaluation studies and a possible clinical trial.

A commercial product based on the IMPAIRED concept will enable accurate assessment of chronic LBP patients, monitoring treatment effects on patients, checks on whether patients follow treatment plans and objective assessment of the clinical effectiveness of existing and novel therapies. Key competitive advantages the product will have are an integrated approach towards disability assessment and applicability to multiple patient groups through relatively minor modifications.

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