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PROJECT FINAL REPORT

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4.1 Final publishable summary report

Summary

The EU funded project "*Cost effective Direct to Eye prosthesis SMART Guidance System*" (D2Eye) ran from February 2014 to January 2016. The goal of D2Eye was to develop a navigation system for the accurate positioning of the acetabulum cup within the pelvis, this reducing the number of revisional surgical procedure due to miss alignment. The project team achieved this by applying their unique expertise in state of the art design, manufacturing and evaluation techniques, in leading-edge electronic development, instrument design and data transmission/ communication. As part of this effort, new cost effective processing methods needed to be developed for the electronic PCB manufactures which were needed for the electronic orientation units (EOU'S), the control pads and the heads up display. Verification of the new system was conducted via computational and mechanical testing, ultimately leading to an extensive cadaveric workshop where the guidance system and instrumentation were demonstrated in a fully representative environment by surgeons specialising in hip implantation.

It is accepted that accurate implant placement in all total hip replacements is important in avoiding dislocation, impingement, and edge-loading throughout the patient's postoperative functional range of motion (ROM). Current implants and bearing surfaces now provide the potential for prolonged longevity of the reconstruction, which can be compromised by misalignment of the components outside of designated "safe zones".

The original objective of the D2Eye project was to develop and manufacture a cost-effective smart implant positioning system that will allow the surgeon to position the cups for optimum range of movement for the specific patient and concomitant minimisation of deleterious effects such as edge loading and wear. The aim was to achieve this using a series of electronic orientation units (EOUs) built in to the surgical instrumentation which would give their position in free space. The information from the EOU's would then be projected in front of the surgeons eye so that they would be able identify the correct position for the cup to be implanted. This system would be both easy to use and mobile allowing for transfer between operating theatres.

During the course of the project we developed the miniaturised electronics for the EOU's together with the control unit and head display. To support all of this equipment we also developed a charging station s for the remote induction charging of the complete system. As part of this further development we also designs new instrumentation that would facilitate the EOU's within their handles. In order to validate the EOU's we developed algorithms and a calibration protocol using a multi axial table to which manipulated them to reset positions which were then recoded and verified. With the control unit the original plan had been to develop this from start to finish but due to the advance in technology by external companies it was decided to take an off the shelf table and modify this to meet the needs of the project. Therefore a Nexus 9 table was selected and adapted case was made which contacted circuitry that would allow for communication with the head display unit and the EOU's as well as allow for remote charging. The same situation was also encounter for the head display unit several head display glasses had been introduced on to the market between the time of proposal submission and project start. Therefore we performed a review on three set of glasses tow of which were currently available on the market and one was in the development stage. After several tests and evaluations by our optical partner it was decided to use the Sony glasses as these gave the resolution needed, were considered comfortable to wear and projected. As with the tables the battery pack which houses the interface with the glasses themselves was modified to include the transmitting circuitry and the charging circuitry, this allowed for the communication between the glasses and the control tablet.

To house the circuitry for all of the device a series of enclosures where designed, for the EOU's these comprised of a chassis to hold the PCBs and battery that had a built in spring to dampen the shock loading they would see during the implantation procedure. This was then housed in a non-sterile enclosure which was backfilled with silicon to further dampen the shock loading. As well as the inner non sterile housing a sterile barrier was also developed along with a protocol for the insertion of the non-sterile components in to the sterile components, thus ensuring that the EOU's would be contamination free during the procedure. When it came to the table a case was designed that would

fit around the tablet similar to those currently available on the market with the exception of an additional section that housed the PCB's. The same was done for the glasses a housing was designed and prototypes were manufactured to house the PCB's on the side of the battery pack.

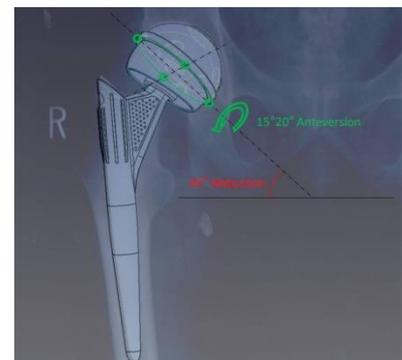
An extensive experimental test programme was conducted to ensure that all of the system would perform as anticipated within the operating theatre and would not interfere with exciting electronic components. These tests showed that the system did not interfere with any exciting equipment and likewise no equipment in the operation room interfered with the D2Eye system electronics. The testing also showed that communication between devices was possible without loss of data. Following on from these trials it was decided to run the system under actual operation condition and therefore cadaver trials were set up.

A team of physicians at the Co. IGLO in Arezzo, Italy have demonstrated in operations performed on cadavers, that the D2Eye system can be used to place the acetabulum cup in the optimum position. Preclinical studies have been completed, and end stage development work is being planned to allow the commencement of clinical studies. Partners in the EU-funded project are MatOrtho, Adler Ortho, Hunt Developments, Maser Mic, Plastitec, and Karl Kaps. The research institutes involved were Fraunhofer IPA, Aurora Medical, CEIT Research Centre and the Universities Hospital Regensburg.

Summary Description of Project Context and Project Objectives

The correct positioning of the acetabular cup prosthesis is crucial to the efficient short and long-term operation of the replacement hip. Just as the natural hip wears with time, the prosthesis will also wear with time. However, if the acetabular cup prosthesis is not correctly seated in the acetabulum, the wear rate of the prosthetic implant can be significantly higher than when the cup prosthesis is in the optimal position. Badly positioned cups are also responsible for early dislocation of the hip often requiring re-operation and or restricted range of motion.

An abduction angle of 45° and an anteversion of 15° - 20° is usually considered optimum for the acetabular cup in hip replacement. This orientation has been arrived at after several decades of success with low friction metal-on-polyethylene devices. The literature provides various examples of reduced outcome at early follow up when the cup placement is not optimal.



It is important to note that the orientation of an acetabular cup is generally defined by the cup face, but the wear performance of the cup relies on the position of the cup edge relative to the load axis. Although the external shape of contemporary large diameter Metal on Metal (MoM) resurfacing cups is equivalent to the polyethylene cups mentioned above (i.e. hemispherical), the bearing surface is not. Low friction polyethylene cups have a hemispherical bearing surface, but large diameter MoM cups have a bearing surface that is less than a hemisphere. Because of this difference, the bearing surface of a contemporary MoM acetabular cup operates at a significantly steeper angle than that defined by the cup face, and hence perceived by the surgeon. This is both manufacturer design and size dependent, and has important consequences in terms of load-bearing and surface wear^{2, 3}. This is the principal problem behind large scale failures of MoM implants over the last few years.

It is accepted that accurate implant placement in all total hip replacements is important in avoiding dislocation, impingement, and edge-loading throughout the patient's postoperative functional range of motion (ROM). Current implants and bearing surfaces now provide the potential for prolonged longevity of the reconstruction, which can be compromised by misalignment of the components outside of designated "safe zones".

Our proposal aim is to develop and manufacture a cost-effective smart implant positioning system that will allow the surgeon to position the cups for optimum range of movement for the specific patient and concomitant minimisation of deleterious effects such as edge loading and wear. This will be

² Tuke et al, JBJS Am, 2008, 90S3, pp134-41

³ Jefferst et al, Bulletin of the NYU Hospital for Joint diseases 2009, 67(2):189-92

achieved using a series of electronic orientation units (EOUs) built in to the surgical instrumentation which will give their position in free space. The information from the EOU's will be projected in front of the surgeons eye so that they will be able identify the correct position for the cup to be implanted. This system will be both easy to use and mobile allowing for transfer between operating theatres.

It is generally accepted that the average life of a hip implant should be approximately 15 years⁴; however, wear testing performed on misaligned hip components⁵ shows that the life of the implant can be reduced by up to 10 years with a mean of 8 years which is almost half that expected for a correctly aligned acetabulum cup. This is of course subject to the age of the patient and their mobility, however it should be noted that currently 10%⁶ of all the implanted prostheses are in patients under the age of 55 years and a further 20%⁷ of prosthesis are implanted in patients aged between 55 and 65.

At a cost of €14,200⁸⁹ per revisional operation and a calculated average of 56,000 revisions each year due to misalignment this will potentially put an additional cost of €795.2 million on the health authorities within the EU27 states. It does not however take in to account the number of days that the patient may be at home recovering were they require daily monitoring. This time is difficult to anticipate but a suggested time would be in the region of 14 days where the patient would need home help during the recovery period. It is estimated that the cost of this additional care based on a typical care nurse costing €300 per day and being able to attend to four patients on a rotational basis currently costs the EU 27 health care authorities based on 33% of all patients leaving hospital needing care approximately €13 million per annum. Additionally, since a significant number of the patients operated on will be of pre-retirement age some loss to the working day is inevitable.

Several solutions have been suggested to overcome the issues of surgical accuracy for positioning the acetabular cup, the most costly of these is a computer guided system for the surgery. In the mid-1990's active (robotic) systems became popular, but early clinical results combined with costs could not justify the widespread use¹⁰.

Currently there are two main types of navigation system, image based and image free. Image based systems rely on the use of CT data to generate the preoperative images¹¹ which are then converted into three-dimensional (3D) co-ordinates of the patient and the virtual image. Fluoroscopic images obtained intra-operatively can also be used¹². Image-free systems are based on kinematic data or point-clouds that are acquired intra-operatively^{13,14,15,16}. Computer assisted navigation systems using pointcloud data make a 3D reconstruction that can be explored on a computer screen.

The image-guided navigation system is similar to the location and directional tracking systems used for cars and ships today - it is, in effect, a global positioning system (GPS) for the surgeon. Informative positioning calculations are displayed on a graphically intuitive screen, which dynamically changes with the individual patient's anatomy. Computer-assisted hip navigation offers the potential for more

⁴ Life Expectancies: You and Your Hip Implant By Level: Basic Rochelle Rottenstein, principal of Rottenstein Law Group, founded the firm specifically to improve how consumer product injury victims could seek compensation for their losses. Many **Article Word Count:** 407

⁵ "in Vivo Wear of Metal – on – Metal Hip Resurfacing Implants Depends Strongly on Cup Alignment" by Morlock et al in 53rd Proceedings Orthopaedic Research Society Poster 1163, 2007.

⁶ Metal on Metal total Hip Resurfacing Arthroplasty. Health Technology Policy Assessment. Completed February 2006.

⁷ Metal on Metal hip resurfacing> J. Roberts, RMD Meek, P. Roberts, and P. Grigoris

⁸ The total cost of hip-joint replacement: a model for purchasers. P.B. Pynsent, S.R. Carter and C.J.K. Bulstrode.

⁹ Joint revision cost effective. American academy of orthopaedic surgeons "Academy News" Sunday February 16th 1997

¹⁰ Honl M, Dierk O, Gauck C, et al., Comparison of robotic-assisted and manual implantation of a primary total hip replacement: a prospective study. *J Bone Joint Surg [Am]* 2003;85-A:1470-8.

¹¹ Widmer KH, Grutzner PA, Joint replacement-total hip replacement with CT-based navigation. *Injury* 2004;35(Suppl 1):9.

¹² Grutzner PA, Zheng G, Langlotz U, et al., C-arm based navigation in total hip arthroplasty-background and clinical experience. *Injury* 2004;35(Suppl 1):90-5.

¹³ Kalteis T, Handel M, Herold T, et al. Greater accuracy in positioning of the acetabular cup by using an image-free navigation system. *Int Orthop*2005;29:272-6.

¹⁴ . Kalteis T, Handel M, Bathis H, et al. Imageless navigation for insertion of the acetabular component in total hip arthroplasty: is it as accurate as CT-based navigation? *J Bone Joint Surg [Br]* 2006;88-B:163-7.

¹⁵ . Kalteis T, Backmann J, Herold T, et al. Accuracy of an image-free cup navigation system: an anatomical study. *Biomed Tech (Berl)* 2004;49:257-62.

¹⁶ . Kiefer H. OrthoPilot cup navigation: how to optimise cup positioning? *Int Orthop*2003;27(Suppl 1):37-42.

accurate placement of hip components and control of leg length and offset. Systems are now available that allow registration of the bony anatomy based on preoperative CT images, intra-operative fluoroscopic images, or imageless techniques based on palpation of the landmarks. In each of these approaches, cup position has been based on coordinate systems formed by identification of the anterior pelvic frontal plane. All systems have shown improved accuracy of acetabular cup placement compared with conventional manual techniques.

However all of these systems have problems such as cup anteversion being less accurate than cup abduction with the imageless approach. Measurements made with the use of navigation systems also have shown a large variation in pelvic tilt or pelvic flexion-extension in a series of cases, which can affect the appropriate cup position for each patient. The results of computer-assisted navigation in the future may be improved by incorporation of measurements of each patient's pelvic tilt, femoral stem position, and hip kinematics. Although this technique can improve accuracy if used properly, it is both time consuming to set up and costly to both purchase and maintain. Another problem with the currently available navigation system is that due to the complexity of use they often significantly increase the length of the operation time^{17,18,19} compared to conventional manual procedures. The difference appears to be between 10 and 15 minutes and is estimated to increase the cost, with a Computer assisted surgery (CAS) procedure costing roughly (€455) more than a manual operation²⁰. In addition to this the additional time also reduces the number of operation the relevant healthcare organisation could perform and ultimately increasing the waiting time for the operation. Further to such systems limitations, they rely on a theoretical position for cup placement and are trying to achieve accuracy to such a placement when the systems for checking the accuracy is itself subject to inaccuracy but more importantly are not necessarily aiming for the correct target for each individual patient with relation to their dynamic demands. Thus better accuracy of a predictable placement may be achieved but it remain the wrong placement for each patient! There is therefore a need for a simple-to-use guide which is effective and affordable.

During the course of this project we intend to overcome these problems by developing a SMART Guidance system that is easy to use, compact (fitting directly to the patient or the instrumentation used in the operation) and giving the added benefit of projecting the correct alignment for the cup directly to the surgeon's eye.

We intend to use the following key innovations developed during the course of the D2Eye project to give us a competitive market advantage over current existing systems

These key innovations include:-

- Independent electronic orientation unit (EOUs) that fit both the patient and in the instrumentation to be used during the procedure. The EOU units will give their coordinates within free space and by attaining their inclination and relationship to each other using a series of the devices it will be possible to use the information to align the cup in the optimum position.
- Development of novel algorithms that will be embedded in the electronics and used to triangulate the positions of the EOU's and to calculate the optimum position for the cup position.
- Development of a head display unit (HDU) which will project an alignment grid in front of the surgeon so that they can align the cup during the procedure thus allowing them to focus on the operation at the same time.
- An innovative control unit will be developed that will process the data from the EOU's and transmit this to the HDU, the control unit will also have a touch screen display so that a visual record of the

¹⁷ Jenny JY, Clemens U, Kohler S, Kiefer H, Konermann W, Miehlke RK. Consistency of implantation of a total knee arthroplasty with a non-image-based navigation system: a case-control study of 235 cases compared with 235 conventionally implanted prostheses. *J Arthroplasty* 2005;20:832-839.

¹⁸ Sampath SA, Voon SH, Sangster M, Davies H. The statistical relationship between varus deformity, surgeon's experience, BMI and tourniquet time for computer assisted total knee replacements. *Knee* 2009;16:121-124.

¹⁹ Macule-Beneyto F, Hernandez-Vaquero D, Segur-Vilalta JM, Colomina-Rodriguez R, Hinarejos-Gomez P, Garcia-Forcada I *et al.*. Navigation in total knee arthroplasty. A multicenter study. *Int Orthop* 2006;30:536-540

²⁰ Bolenz C, Gupta A, Hotze T, Ho R, Cadeddu JA, Roehrborn CG *et al.*. Cost comparison of robotic, laparoscopic, and open radical prostatectomy for prostate cancer. *Eur Urol* 2010;57:453-458.

actual angles from the EOU's can be seen. It is also intended that the control unit will have the capability to have application for different types of hip to be fitted, so the surgeon selects the application for the procedure about to be performed.

- A series of applications that will allow the surgeon to select the correct type of operation to be performed i.e. a total hip operation or a resurfacing operation and which manufacturer's cup they are going to fit as the position will vary depending on the manufacturer's specification.

The D2Eye system will provide the surgeon with a guide to ensure that the acetabulum cup is positioned correctly during the primary operation by giving the surgeon the correct geometrical alignment needed gained from the patient specific optimum position from the trial reduction. . This will be achieved by the use of a series of EOU units with the information being feed directly to the surgeon's eye. By ensuring the primary surgical procedure has aligned the acetabulum cup in the optimum position to prevent wear and subsequent premature failure the D2Eye system will reduce the number of revisional surgery procedures as a result of miss-alignment.

OVERALL PROJECT OBJECTIVES

The main objective is to develop a low cost navigation system that will allow for accurate fitting and alignment of the acetabulum cup. This will be achieved by the unique combination of the best, established technologies, plus the additional advantages of the development of miniaturised electronics, inertial measurement technology and OLED display configuration.

Scientific Objectives

The scientific objectives are those relating to issues of electronic manufacture of the EOU units, wireless communication within the operating theatre, and the development of the Head Display Unit (HDU).

Objectives are:

- Enhance the understanding of how to develop a low cost electronic orientation unit that will be able to determine its orientation in free space.
- Identify which of the ISM frequency bands and channels can be used to communication between the devises in the operating theatre with minimum loss of signal or interfering with other devices locally and at sufficient speed to relay the information. Identify strategies to overcome the problems with fail tolerant software.
- Enhance the understanding of micro-display OLED units for use in the medical field.
- Create a working synthesis of novel electronics and innovative algorithms that will enable us to:
 - Convert the orientation generated by the EOU units into a display image that the surgeon can utilise for the navigation of the impaction instrument for the insertion of the acetabulum cup.
 - Create a series of electronic devices that will be shockproof and withstand the effects of the impact forces used during the operation.
 - Create a series of protocols that will allow for the calibration of the system and will compensate for each variable with each unit.
 - Analyse the positioning of the EOU units both on the patient and in the instrumentation to determine the optimal configuration of the units (i.e. whether we need two units or three units) and where to position them to obtain the best results.
 - Identify if the wireless signal is affected by the surrounding tissue layer of the patient and operating theatre environment

This enhanced knowledge will be attained using the protocol described in work package 1 and will determine the physical design of the component parts, the configuration of the sub-components of the navigation system, and the configuration of the Head Display Unit (HDU).

Technological Objectives for the device: To acquire the science to enable the development of a SMART Guidance system that will allow for the optimum positioning of the acetabulum cup and will:

- Allow for the data from the EOU units to be transmitted in the WBAN across the operation theatre in maximum distance of 2-5m with minimum loss of data and in low latency time.
- Develop an EOU unit that will have an efficient accuracy of $\pm 1^\circ$ and robustness which we know is achievable from the preliminary investigations done at the Fraunhofer.
- Generate a series of protocols that will allow for the easy calibration of the EOU units and take approximately than 2 minutes per unit to setup.
- Develop the electronic circuitry so that it will detect all of the desirable parameters simultaneously and have the ability to transmit this data with low latency time.
- Develop firmware for the control unit with processing the raw sensor data in a fusion algorithm working and show the results on a head display of the surgeon without remarkable time latency.
- Develop the circuitry for the enclosure units so that they will resist the shock loading of 500N generated during the impaction procedure.
- Design the electronic components for the EOU's so that they will fit into an enclosure as small as possible and that should not exceed 55 x 37 x 10 mm
- Ensure that all of the electrical enclosures are sterilisable and conform to IP67 which can resist 0.1 bar for 30 minutes. This may be done by means of a disposable outer case for the units.
- The HDU should not affect the surgeon's field of view and should possibly have an anti glare coating to prevent reflection from the operating theatre lights.
- Develop a short distance wireless receiver for power supply, which required for all the components with chargeable batteries to ensure sufficient energy for one working day in the operating theatre. This wireless charging works with inductive principle (100 kHz) according to Qi standard of Wireless Power Consortium (WPC) and interoperable to all existing transmitters.

Economic Objectives

By the end of year 5 after the project, we intend, through a network of trans-national and cross-sectoral licensees, to sell the low cost high end navigation system both into the healthcare sectors across the EU27, and into the Global market place which we envisage will grow to a larger market sector after this time period. However, during the time between the end of the project and 2020 we estimate to:-

- Gain a European market penetration through direct sales of 2.5% in the second year post project leading to 25% of the market by 2020 and a global market of 1.25% in year two post project leading to 7% by the same time frame.
- Obtain for the SME partnership an additional €85 million over the 6 years post project in revenues from spares/updates for the independent devices.
- We estimate that based on an average set up cost of €20400 for a complete system based on the a control unit costing €8000, the display unit (HDU) costing €400 and the EOU units costing €2000 each (it is anticipated that each hospital will need 3 units for the operation and an additional 3 units that will be in sterilisation, therefore the total cost is for 2 full sets and will = €12000). This will give us a year 1 turnover of €18.25 million in direct sales and this will increase until at the end 2019 we estimate to have a total revenue from both direct sales and support activities of €297 million in the EU27 and rest of world market penetration of €88.5 million this will give us a combined revenue of €386 million over the 6 year period post project.
- The increase in turnover seen in year 5 post project (see section 3 breakdown of costs) will have the effect of increasing employment within SMEs companies based on 1 person per €140,000 by ($\text{€386m} / 140,000 = 2700$) an estimated 2700 jobs.

- With an average of 56% of all hips being incorrectly aligned, resulting in the premature failure of the hip after 8 years, we estimate that up to 450000 European citizens will potentially need a hip replacement before the anticipated life for a correctly aligned hip of 15 years has been reached. At a cost of €14200 per provisional operations and an average of an additional 56,000 operation being needed each year as a result of miss-alignment this will potentially put an additional cost of €795.2 million on the European Healthcare services.

Enabling Innovation Related Objectives

To achieve the societal and economical objectives that come from the dissemination and exploitation of the research results we have defined an enabling set of objectives.

To enable innovation through the project team and to benefit Europe the objectives are:

- To collate and prepare the results of the project into a suitable format and apply for patent protection of the results of the project covering the manufacture of the low cost hip navigation system and the intended applications for this technology by the end of 2014.
- To transfer knowledge from the RTD performers to the SME participants through three technology transfer events and interactions. This will result in one secondment and placement of two staff providing a total of 100 hours of technology transfer.
- To disseminate the results and benefits of the knowledge and technology developed beyond the consortium to potential users such as Hip Knee and other implant surgeons' such as shoulder, ankle etc., trauma surgery, and potentially for use in the alignment of prosthetic limbs:
 - 100 SME companies from the implant, trauma, prosthetic limb manufacturers will be contacted to promote the project results.
 - Three trade or sector specific shows will be attended these will include Medica, MDT and MedTec.
 - 10 SMEs from the non-competitive industrial medical sector stimulated to apply or use the science and technology results in their future product strategy.
 - Four SMEs engaged with, in detailed knowledge or technology transfer, by the end of 2014.
 - 10 licensees to adopt the results in the generation of new products or systems by the end of 2016.

Societal & Policy Objectives are to benefit society by:

- Reduce the number of revisional hip surgeries. Based on the fact that we intend to take 25% of the European market share by 2020 we estimate that the D2Eye project will reduce the number of revisions by 30% for those patient who have had their implants fitted with our navigation system, saving 240,000 patients from the risks, immobility, and discomfort of revision surgery
- As a result of the reduction in the numbers of people requiring revision surgery, the D2Eye project will have the affect of allowing the reallocation much-needed medical resource to other areas.
- The novel navigation system will improve the quality of the hip implant operation by supporting the surgeons with measured data, avoid intuitive positioning of the cup and allow documenting the operation activity.

The Main S&T results / foreground.

Introduction:

In order to deliver the work within the D2Eye project each objective was broken down into a separate work package.

Work Package 1 - Design Foundation

The objective of work package 1 was to define the operational requirements and parameters of the SMART Guidance system with regard to ease of use from a clinical perspective, accuracy with regard to alignment determination and the definition of pre-clinical validation and assessment protocols and procedures.

Literature Search for the Material data

The objective of the work performed during WP1 culminated in the definition of the engineering and pre-clinical testing protocols required during the development of the SMART guidance system components and the validation of the final system design. In order to determine these requirements some initial design work with respect to the system components function and a preliminary operational technique needed to be established. This included the technical customer requirements specification of angular tolerance and definitive acetabular cup prosthesis placement accuracy of $\pm 3^\circ$ relative to the position of the cup trial during trial reduction.

The D2Eye guidance system relies on the determination of optimum alignment of the cup position during the trial reduction (were the surgeon trial fits the now modified femur into the acetabulum) and reproducing that position with the acetabulum cup during impaction procedure. With this system, unlike all the Navigation systems on the market, the surgeon does not have to look away from the wound at any stage of the operation. In order to achieve this three key technology platforms require integration: (i) wireless systems for data transfer and associated power management; (ii) direct to eye information presentation currently employed in aviation and in development for motoring and leisure industries; (iii) miniature orientation/position sensors used in space and advanced transport situations.

Each of these technologies which are well established in other fields of engineering is new in the medical field and operating theatre environment where strict regulatory requirements have to be satisfied.

In order to demonstrate compliance and technical performance a stepwise testing and evaluation program of all component parts has been established and is presented in deliverable 1.2 and summarised in this document.

During WP1 the first step was to define the guidance system requirements (Table 1) for use in the operation theatre, In order to achieve this, a series of studies were conducted and the results were tabulated.

Table 1 General System Requirements

No.	Description	Description or value	Benchmark	Remarks
1.0	Functionality			
1.1	Main task	Guiding system for surgical tools	Required	Orientation in space
1.2	Range of the angles	0 – 360°	Required	
1.3	Resolution of the system	3°	Required	
1.4	Resolution of the sensors	0.3°	Required	

The guiding system will not detect the position of the components in x,y,z-coordinates, it will measure the orientation in space with 3 angles. The sensors used in the components need a resolution 10 times better than the system requirement.

Table 2 Requirements of the mechanics components

No.	Description	Description or value	Benchmark	Remarks
2.0	Mechanics			
2.1	Electronic system with sensors, power management,	Double size of a AA-battery	Wish	

	microcontroller and wireless communication, battery	(14 x 50 mm)		
2.2	Modular electronic sensor for integration in all tools		Wish	Sensor detects the tool

The electronic together with the battery should have cylindrical size and a length of two AA-Batteries. This form is required for the operation tools.

Table 3 Requirements of the electronic components

No.	Description	Description or value	Benchmark	Remarks
3.0	Electronics			
3.1	Communication network			
3.1.1	Max. Range of wireless network	5m	Wish	
3.1.2	Industrial, Scientific and Medical (ISM) Frequency Band	433MHz or 868MHz (915MHz in US&J) or 2.4GHz	Required	
3.1.3	Typ. (Max.) Output Power	std	Required	
3.1.4	Network structure (Topology)	Master-Slave-Model (Star)	Wish	Master: Switch Slaves: Tools
3.1.5	Min. Nodes (Slaves) in the network	3	Required	
3.1.6	Application throughput	> 50 Hz	Required	data rate network
3.1.7	Latency	< 40 ms	Wish	
3.1.8	Security	std		
3.1.9	Robustness	std		
3.1.10	Usability and ergonomic	std		
3.2	Power supply			
3.2.1	Time with max. attention during the operation	60min.	Required	
3.2.2	Power consumption as low as possible		Required	
3.2.3	Inductive charging system	4x coils in a table surface	Wish	
3.4	Electrical Interfaces			
3.4.1	Communication to the Switch and Glasses	WLAN or Bluetooth	Wish	
3.4.2	Data rate: Switch -> Glasses	> 50 Hz	Wish	

The wireless communication has to use the ISM Bands. The size of the network should be limited to the operating room. The number of nodes is limited to a few participants. High data rate and low latency are important for the surgeon to feel a fast response time of the guiding system.

The components have to use rechargeable batteries to reduce waste.

Table 4 Requirements of the User Interfaces

No.	Description	Description or value	Benchmark	Remarks
4.0	User Interfaces			
4.1	Graphical presentation on display	Distance between two crosses show distance to the optimum angles	Required	Display and documentation also of calculated optimum position
4.2	Documentation of the operation	Data of angles stored in the PC	Required	
4.3	Display of measured angles	on PC or tablet	Wish	
4.4	System adaptation to application	Software on PC or tablet	Required	Open system, no Box or dongle

The D2Eye System will use a standard PC or tablet for calculations and communication to the glasses. This will demonstrate an open system also for future applications.

Table 5 Environmental Requirements

No.	Description	Description or value	Benchmark	Remarks
5.0	Environment			
5.1	Sterilisation of the mechanical components	134°C for 20min.	Required	
5.2	Sterilisation of sensor, wireless and battery	Not required	-	

All of the instrumentation for the D2Eye system has to be sterilised with the autoclave process however the electronics will not withstand the temperatures seen in the autoclave. Therefore it is proposed to not sterilise the electronic components but house them in a sterile container.

Following on from the system requirements it was decided to review the current market availability of the head display units as these had progressed significantly since the proposed concept conception. The result of this survey showed that the display glasses market had a lot of activity and pre-announcements for production in 2014. Many of them are still not available. The research showed that Google Glasses offered a good fit for the D2Eye system application.

Table 6 below shows the head display units available in the current market.

Table 6 current market head display units

Producer, Type	Epson, Moverio BT-200	Glassup	Google, Google Glas	Meta, MetaPro	Optinvent, ORA-1	Samsung	Vuzix, M100
							
Display	960x540	320x240	640x360				
Available	May 2014	Sept 2014	Yes	Sept 2014	June 2014		Yes
Costs	700€	300\$	1500\$	3650\$	700€		1000\$
Energy		1 day			8 h		2 h
Remarks	Camera, transparent, external box, smart phone	No camera, smart phone	Camera, transparent	transparent	Camera, transparent	Cable connection	Camera, not transparent

Definition of the required pre-clinical testing and validation protocols for the component parts of the D2EYE navigation system:

As well as the system requirement outlined above the table below defines the regulatory requirements associated with the electrical and communication aspects of the D2Eye system, along with the physical requirements of the surgical instruments. In Table 7 each item defines a test scenario and test protocol that will ensure the D2Eye electrical and communication systems as well as other system components meet or exceed the regulatory requirements in all areas.

Table 7: Testing Requirements

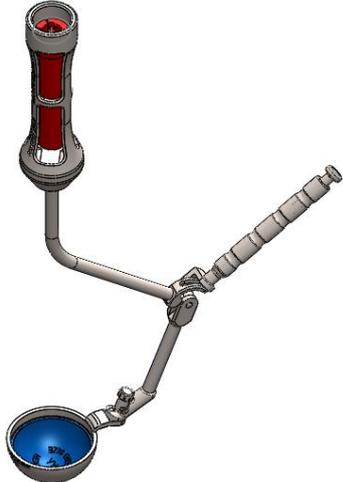
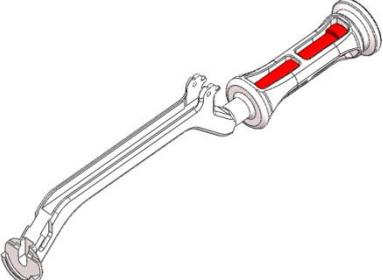
Test ID	Reference	Test Scenario
Test detail and protocol		Electrical
TR 1.	ISO 60601-1-2	The D2Eye system shall not cause electrical interference to other electronic equipment used during surgery.
TR 2.	ISO 60601-1-2	The electronic systems employed in the D2Eye instrumentation shall not be affected by other electronic equipment used during surgery.
TR 3.	ISO 60601-1-2 IEC 60479-1 IEC 60479-2 IEC 60664-1	The electronic systems employed in the D2Eye instrumentation shall not cause harm (electrocution / burns etc.) to either the patient or other user(s) of the system.
TR 4.	ISO 60601	The wireless communication system employed in the D2Eye instrumentation shall not interfere with, nor be affected by local wireless communication devices.
TR 5.	ISO 60601	It shall not be possible for any part of the D2Eye electronics system to become accidentally detached from attached instrumentation during use.
TR 6.	ISO 60601	If there is a power failure in one or more component of the D2Eye system this will be detected and fed back to the surgeon.
TR 7.	ISO 60601	The electronic devices shall have sufficient electrical power to be used during long, complicated procedures.
TR 8.	ISO 60601	The D2Eye goggles will not function fully unless all of the required electronic components are within communication range and specified electronic parameters.
TR 9.	ISO 60601	The calibration of the electronics shall not be affected by repeated impaction.
TR 10.	ISO 60601	During device start up, the D2Eye goggles shall perform a Power On Self-test (POST) that confirms the presence, operational status and battery life of all other required electronic components.
TR 11.	ISO 60601-1-2	Sensor accuracy shall not be affected by the presence of metal objects such as misplaced surgical instruments.
		Instrumentation
TR 12.	ISO 16061	The final seated implant position shall be within the accuracy specified in the Technical Requirement Specification by comparison to the position indicated by the trial reduction / range of motion assessment.
TR 13.	ISO 16061	Repeatability testing shall evaluate accuracy of the seated implant position in relationship to the trial reduction position.
TR 14.	ISO 16061	If an electronic component fails during use there shall be bail out option that allows for the correct placement of the implant.
TR 15.	ISO 16061	The D2Eye instruments and connected electronic devices shall be unaffected by the repeated impacts used during the full seating of the final implant.

Test ID	Reference	Test Scenario
TR 16.	ISO 16061	Once fixed, the position of the pelvis sensor shall not be affected by external forces, such as those seen during trial reduction or impaction of the final implant.
TR 17.	ISO 16061	The augmented reality goggles shall not adversely affect the surgeon's field of view.
TR 18.	ISO 16061	The D2Eye instruments shall be able to assist the correct placement of the final implant regardless of operating approach.
TR 19.	ISO 16061	All size / implant specific instruments or trials will be clearly marked.
TR 20.	ISO 16061	The geometry of instrumented trial components will correctly match the geometry / offsets of the definitive implant.
Biological		
TR 21.	ISO 17664 BS EN 1041 ISO 10993	Instrument disassembly for cleaning and sterilisation shall be intuitive and non-ambiguous.
TR 22.	ISO 10993	Electronic components shall withstand repeated sterilisation cycles.
TR 23.	ISO 10993	Instrument packaging shall ensure device sterility

Using the information generated from the research it was possible to establish the key system component requirements, Table 8 below show the system components to be developed during the course of the project.

Table 8 Key System Components

Component	Image	Description	Physical Interfaces
Sensor Unit		3 identical Electronic units that interface with the Fixed Sensor Attachment Body, Range of Motion Instrument and Introducer. Communicates wirelessly with tablet computer and head display unit Sensors must either be fully sterilisable or fitted within a sterile barrier	Charging Unit Aseptic Barrier (if used) Fixed Sensor Body RoM Instrument Introducer
Fixed Sensor Body		Instrument that attached to the patients pelvis to act as a point of origin that has a constant position relative to their acetabulum.	Sensor Unit Patient

Component	Image	Description	Physical Interfaces
Drill		Used to Drill pilot hole for Fixed Sensor	Patient
Range of Motion (RoM) Instrument		<p>Used to assess the optimum implant position relative to the patients anatomy. Once Ideal position is found sensor position is saved relative to the fixed sensor and the cup face.</p> <p>Size specific Trial Cups and Trial Liners form part of this instrument</p>	Sensor Unit Trial Cup (Size Specific) Trial Liner (Size Specific) Attachment Screw Patient
Introducer		Used to Implant the definitive instrument. Allows surgeon to position the implant in the pre-determined best patient location relative to the fixed sensor	Sensor Unit Definitive Implant Patient
Head Display Unit		Communicates wirelessly with Sensors and tablet computer to aid the surgeon using augmented reality.	Charging Unit
Tablet Computer		Communicates wirelessly with sensors and Head Display Unit	Charging Unit

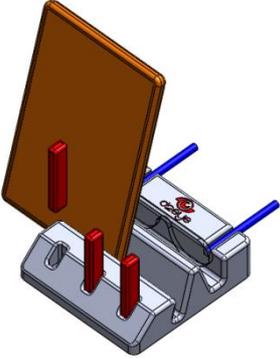
Component	Image	Description	Physical Interfaces
Charging unit		Wirelessly charges all electronic components.	Sensors Tablet Computer Head Display Unit

Table 9 Key System Requirements

#	Key Requirement
1	Each electronic sensor shall have an angular accuracy better than $\pm 0.5^\circ$
2	The overall system shall have an accuracy and repeatability better than $\pm 3^\circ$
3	Wireless communication must not cause interference to other electronic equipment
4	All electronic component will comply with EMC regulation
5	All components, except the Head Display Unit shall be sterilisable (or be fitted into an aseptic barrier to maintain sterility)
6	All of the battery powered components will be wirelessly charged.
8	The electronic sensors shall be able to withstand shock loading caused by repeated impaction of the definitive implant.

As can be seen WP1 focused on defining the parameters for the D2Eye system and more information on the specifics can be found in the deliverable reports.

Work Package 2 – Integration analysis in the operation theatre

The aim of Work Package 2 was to assess the current instrumentation load of typical orthopaedic operating theatres, to assess the likely effects of adding to the load in terms of wireless

The requirements for the communications were analyzed and considered in order to choose the appropriate communication system. The challenges and issues imposed to the wireless communication system by the requirements were assessed along with the wireless communications architecture, which fulfils the analyzed requirements. Additionally a market analysis of possible components for the development of the wireless communications was made.

In addition, the wireless power transfer systems and standards were analyzed in order to choose the appropriate solution. Again, the challenges and issues imposed by the requirements to the wireless power transfer system were reviewed and the architecture of the system was defined. Additionally, a market research of possible solutions for the development of the wireless power transfer system was conducted.

The coexistence of different standards was investigated and solutions proposed. The electromagnetic compatibility of wireless systems was analysed.

The results of these analysis showed that the most appropriate communication standards would be the Bluetoothv4.0 standard at 2.4GHz which is considered the most appropriate for the final solution. Bluetoothv4.0 shows several advantages for this application:

1. It is possible to choose tablets which are compatible with both the Bluetooth Low energy (BLE) version and standard Bluetooth (BT). The BLE version is used in the Fixed Sensor, Positional Instrument and Introducer due to the low power requirements. The BT is used between the Glasses and the coordinator.
2. Bluetooth standard has a good trade-off between the energy consumption and the data rate. Some example numbers are:

- a. Data rate up to 2.1Mbps
- b. Standard power consumption when active: 3V~20mA

The data rate allows high data throughput. In addition, fast communication process in BLE may combine low power consumption, high autonomy and low latency.

3. It uses the 2.4 Ghz ISM band. It is one of the frequency bands defined the IEEE 802.15.6 group for BANs. Given the fact that Bluetooth has been designed to work in the ISM band it includes mechanisms to share the ISM band in order to have robust communications.
4. Bluetooth offers security protocols.
5. There exist modules that fulfil the CE mark and space requirements in the worst case (Introducer handle). Therefore, mechanical constraints can be fulfilled.
6. Glasses available in the market include the Bluetooth as one of their communication standards.
7. Bluetooth operates all over the world.
8. Many available solutions allow power regulation and hence modify the reading range. This is especially interesting as the wireless system is housed in different metallic handles and the fact that the reading range should not reach beyond 5m.
9. At the Bluetooth ISM band antenna sizes are small and chip antennas can be used. This is a key aspect given the size constraint.

The use of a Bluetooth module facilitates the design of the electronics and the wireless communication network because Bluetooth modules already include Bluetooth protocol stack so that the control of the module can be easily managed with an external microcontroller. The microcontroller can then be in charge of both the radio module and the sensing components of the instruments (Figure 1).

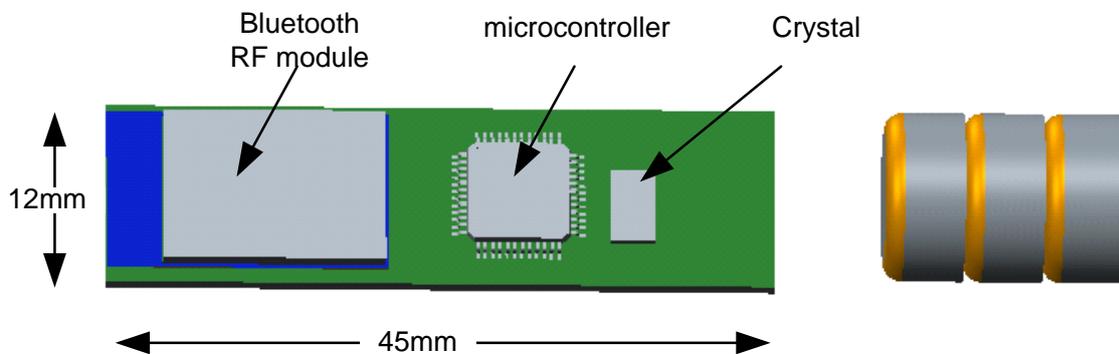


Figure 1 Designed solution for the Wireless Communication system

Microcontroller

Regarding the processor unit, a research analysis was carried out which took into account the most relevant microcontrollers with emphasis on the power consumption. These results are shown in Table 10. The research shows that the best microcontrollers in terms of power consumption are the ones supplied by Texas Instruments within the MSP430 family.

Table 10 Microcontrollers

	Active (RUN) (µA)	Power-Down (SLEEP) (µA)	Power-Save (DEEP SLEEP) (µA)	Standby (IDLE) (µA)
ATMEL	200	0.1	0.75	-

ATmega 48/88/328				
MICROCHIP PIC18F24xx	1300	0.2	-	5.8
FREESCALE MC9S12XDP512	-	2.4	-	10
TI MSP430x1xx	200	-	0.2	1.1
TI MSP430F2xx	220	-	0.2	0.3

Bluetooth Radio module

The Bluetooth module, the clock and the microcontrollers should have very low form factors in order to fit within the desired design envelope. A market research of built-in Bluetooth compatible modules was made. Only some of the modules that fit the size requirement are shown. Table 11 shows that there are a wide range of modules that can be used in the system designed solution. There are also new modules with better characteristic that are planned to appear in short time.

Table 11 Bluetooth Modules

Producer Part	Bluegiga BLE113	Bluegiga WT21	STMicroelectronics SPBT2632C	Panasonic PAN1316	LS Research TiWi-uB1	FUJITSU MBH7BLZ01	ANAREN A2530E24AZ1
							
Aprox. Price (1000pcs)	8.12€	13.00€	15.50€	6.94€	6.40€	9.62€	12.00€
Voltage (V)	2-3.6	1.8-3.6	2.1-3.6	1.7-4.8	2-3.6	1.8-3.6	2.2-3.6
Max Current (mA)	18.2	70	27.5	33	28.1	13	60
Dimensions (mm)	9.15x15.75x2.1	17.1x11.6x2	11.6x13.5x2.9	6.5x9x1.7	11.6x17.9x2.3	10.5x9.2x1.6	11x19x2.5
Remarks							

As mentioned, before even though Bluetooth has several advantages for the implementation of the wireless communication subsystem, there are potential issues regarding unsatisfactory operating ranges. There are several mechanisms to overcome this problem:

1. To increase the output power of the radio module. This, however, only can be done to a limited extent in order to ensure enough autonomy to the device.
2. To re-adapt the antenna. Possibly, the enclosure may affect the performance of the antenna and a re-adaptation or re-design of the antenna may solve the problem.
3. To change the radio module to a smaller frequency standard. In principle, radio modules working at lower frequencies may increase the reading range. Requirements indicate the use of an ISM band, and the 433 MHz or 868 MHz are available ISM band below the 2.4 GHz band. It must be noted that for lower frequencies antenna size can be an issue although it is possible to find low form antenna designs.

As can be seen above the first part of WP2 was to determine the transmission antennas and chip sets along with the optimum frequency. Following on from this analysis it was decided to perform some test on a mocked up system to identify potential problems. These test consisted of:-

1. Evaluation of a 2.4 GHz transmitter. If BLE is chosen as final protocol for the D2EYE architecture, an evaluation of the 2.4GHz band must be done.
2. Influence of Equipment for orthopaedic surgery. The equipment in the operating room for an orthopaedic surgery, identified in literature research, was investigated and evaluated for influence by the wireless communication systems at 2.4GHz like WLAN and BLE. The results of these test showed that:-
 - a. Some equipment has been tested with WLAN and 100mW signal for different distances without significant or unsafe disturbance. A BLE signal in the same frequency range will send with much lower power 1-2mW and the influence to the equipment will be also less significant than WLAN.
3. WLAN coexistence test. Given the fact that the most problematic interference for BLE is WLAN at 2.4 GHz a specific test was performed. The data rate of the radio module was tested against active Channels 1, 6 and 11 of WLAN. With the help of Keysight Advanced Design System (ADS), it was possible to configure the parameters of the 802.11g and download the corresponding IQ signal to an Arbitrary Signal Generator. Once this was done, the channel was replicated at the three different frequencies by means of sinewave signal generators and mixers, and finally combined before feeding the antenna.
4. Testing on the wireless circuitry communication. The communication range of the modules was tested in real conditions.

Conclusions

Based on all these tests, two main conclusions can be extracted:

1. The effect of the hand holding the instrument is low at 2.4 GHz and no more than 3-4 dB can be expected.
2. The effect of the handle depends on the type of antenna used for the signal propagation. The attenuation of the handle is acceptable in the monopole case but significant in the dipole case.
3. The BLE module is not affected by the handle. Given the small dimensions of the antenna, as long as it is slightly separated from the handle walls, its behaviour is unaffected and only low attenuation is expected. The sensitivity of the modules is -94dBm. As the worst received power at 2m was -78dBm (-74dBm and 4dB less for the hand effect) we still have 16dBm margin. A rough estimation of distance (6dB of power reduction each time distance is doubled) indicates that maximum distance reaches more than 12m. Therefore, there will be no coverage problem for a target distance of 5m.

For full details on the work performed please read delivery report 2.1 and 2.2

Work Package 3 –Sensor design and miniaturisation

The main objective of this work package was to design the EOU navigation units including miniaturisation of the units to support on-instrument sensor deployment. Design the circuitry so the EOU units will give a location of $\pm 1^\circ$ with respect to one another. To develop the algorithms for the conversion of raw data from the sensor components of the EOU units into predicted angles of the unit.

The prototype of the EOU were developed using cost effective miniaturised components of a suitable quality for the task. The components were chosen in the smallest SMD packages available and the PCB was routed with the focus on cost efficiency and realisation. The analysis of energy storage possibilities for mobile electronics showed that realisation of non-sterilised electronics in a sterilised case is the favourite solution for D2Eye project.

The EOU electronics used universal circuitry so that they were interchangeable between instruments. The application of low power components ensured that the limited energy resources could be managed by the small battery. The sensor tests showed weaknesses in the reliability of movement detection in Z-direction. Several concepts and tests were undertaken to overcome the potential problem.

The EOU were subjected to shock loading test which showed no visible mechanical damage to the PCB after testing. This test has demonstrated that encasing the electronics inside a rubberised body reduces the acceleration forces resulting from impact by around 90%.

The first part to this work package was broken down in to the development of the electronics for the EOU's, including the induction charging as well as the selection of the rechargeable battery that would supply enough power for the system while fitting into the confines of the housing that would fit into the instrumentation. The following design was the outcome of all of this work:-

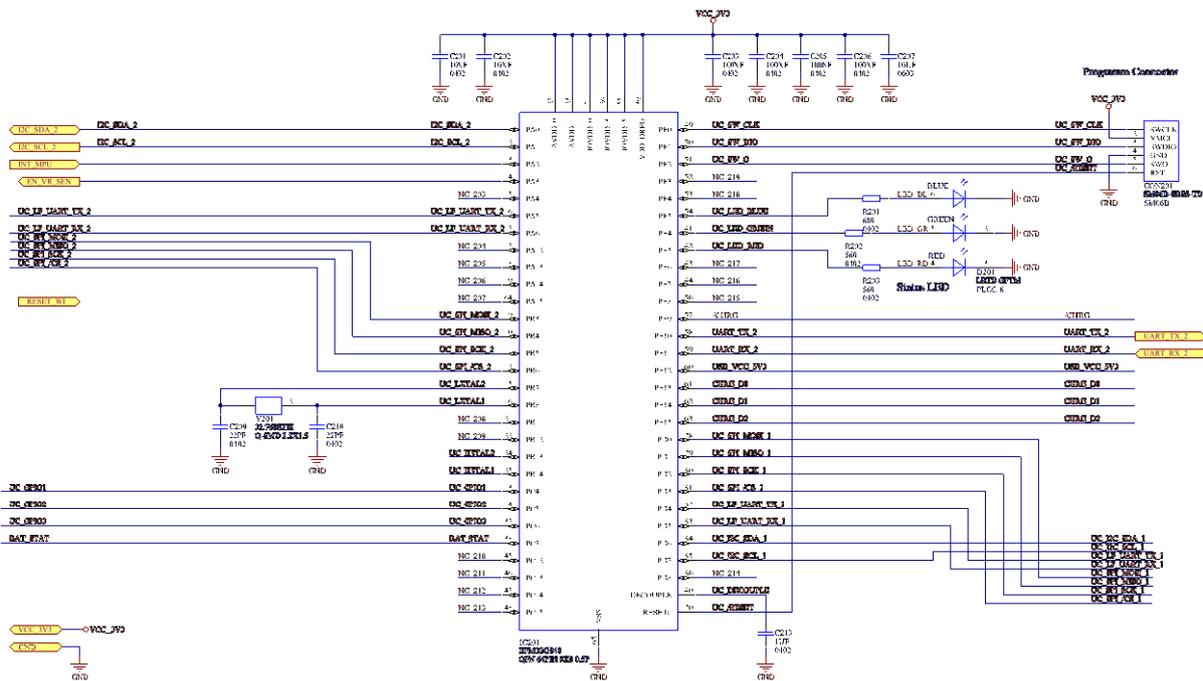


Figure 2 Microcontroller with crystal, LED and programming connector

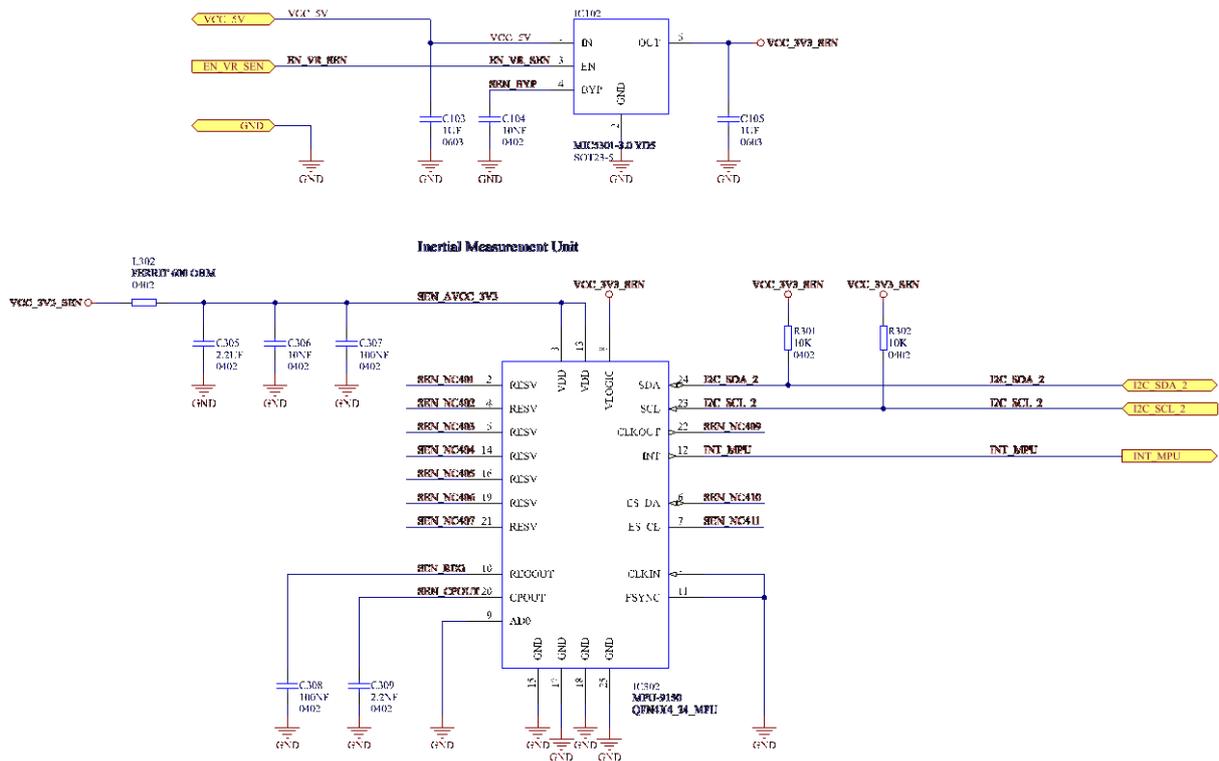


Figure 3 Sensor chip with voltage regulator and passive components

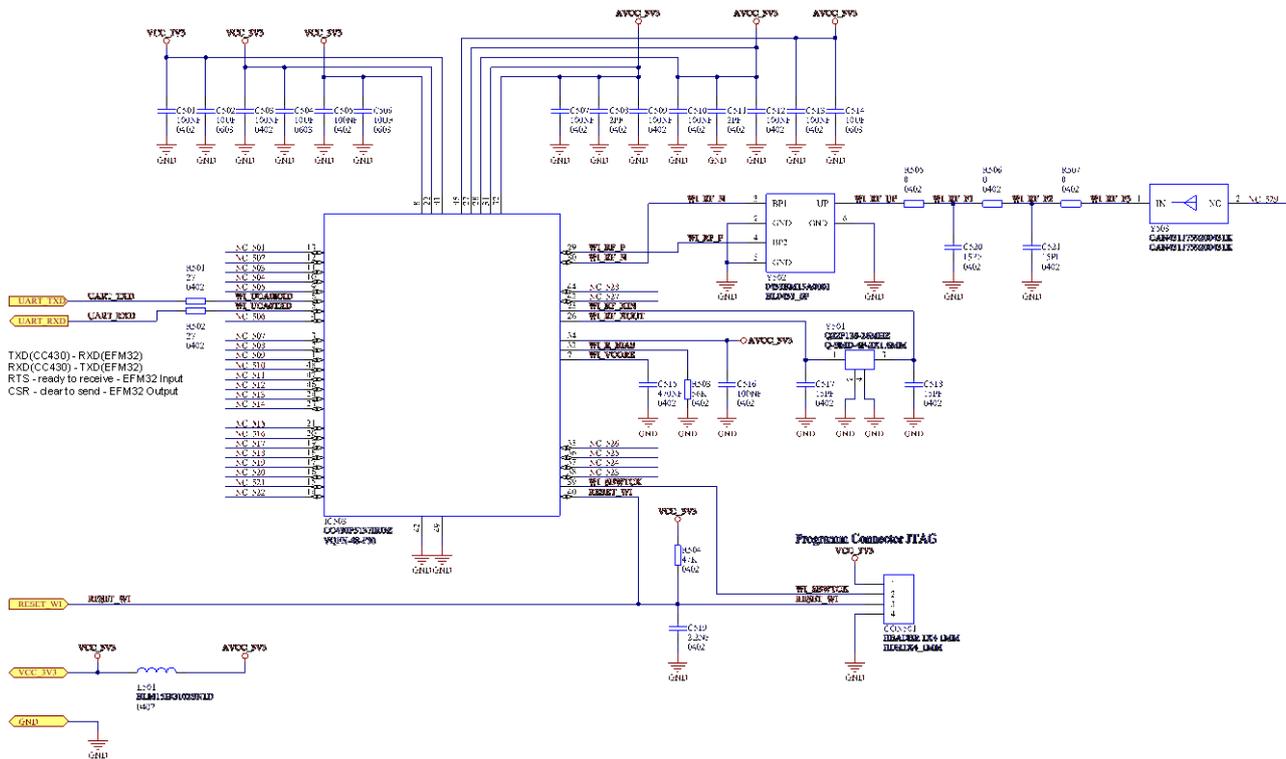


Figure 4 Wireless module

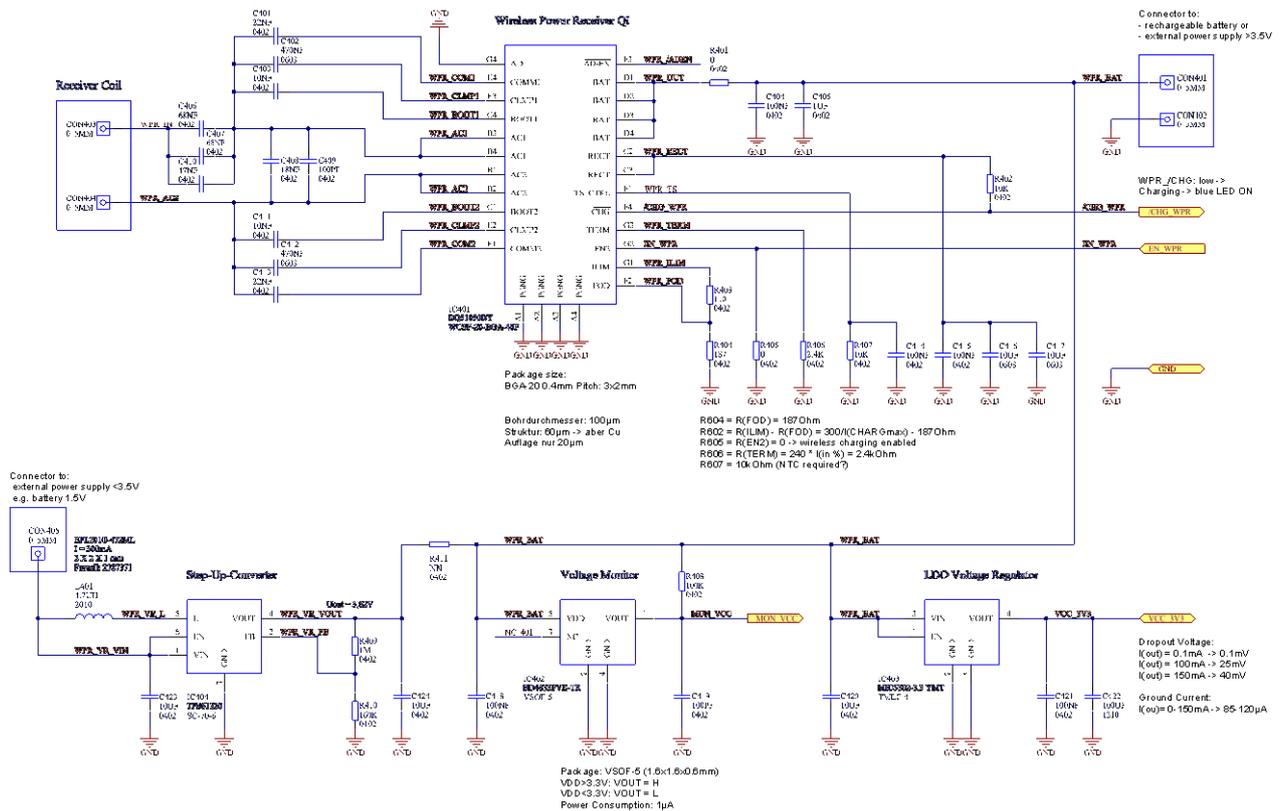


Figure 5 Wireless Power Receiver and power management

Using the circuit diagrams above, (Figure 2 to Figure 5) it was possible to select the optimum components of a suitable size to allow the EOU circuitry to fit in the handle of the instrument.

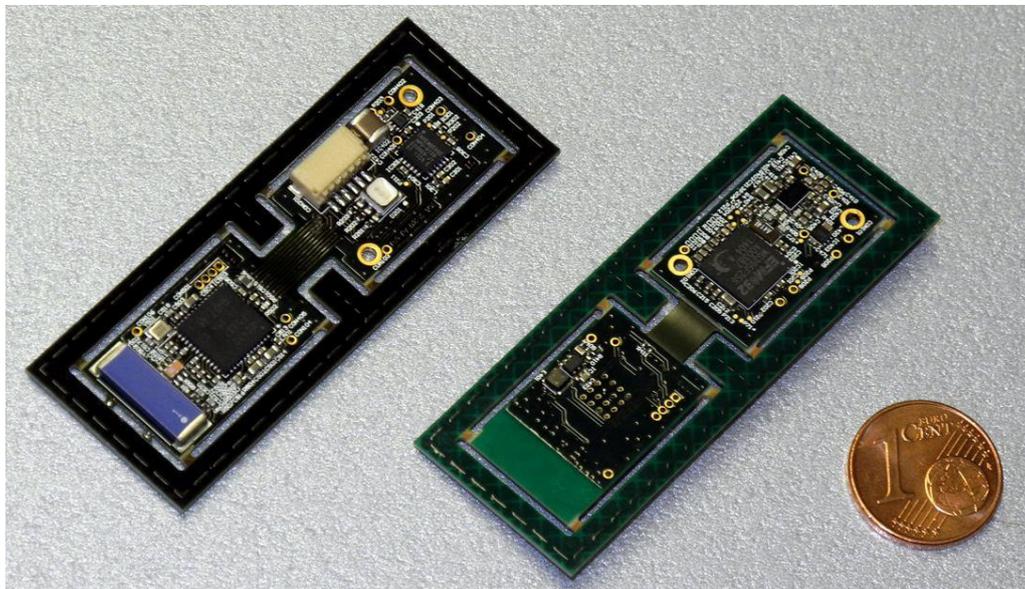


Figure 6 PCB

The picture (Figure 6) above shows the results of the miniaturisation work carried out during WP2, as can be seen the final product is a similar size to that of a 1 cent coin. It should also be noted that the circuitry will hinge and subsequently fold to have the size shown.

Work Package 4 – Wireless system, control unit and power management

This work package focused on the design the control unit electronics which will include the integration of the touch screen display, communications with other devices within the operation

room and the wireless receiver and transmitter capable of receiving and transmitting data in real-time. Algorithms will also be developed for deployment on the control unit to triangulate the data from the EOU units to establish the orientation of the full complement of EOU units. Finally, develop the algorithms and Human Machine Interface to support the display with data to the surgeon in order to facilitate the orientation of the hip components.

During the course of the project it was decided to utilise an “off the shelf” tablet for the interface between the EOU’s and the glasses. The control unit will perform the calculation and conversion of the data from the EOU’s. Several options for a tablet were considered but following an in-depth review it was decided that a nexus 9 tablet would be the best choice. However, the tablet still needed additional circuitry to act as an interface between all devices. Almost all tablets incorporate Wi-Fi – 802.11 b/g and Bluetooth communications and, it goes without saying that has a touch screen. But, the tablet PC also requires wireless charging and 433MHz wireless communication electronics. The solution was to replace the back cover of the tablet with a custom made housing that integrated the missing circuitry (wireless charging and 433MHz communications).



Figure 7 Visualization of the solution concept

The prototype of the Control Unit was developed and miniaturised. The electronics and components are described in deliverable 4.2 and the performance of the Control Unit is included. The Control Unit electronics cover several aspects:-

1. Master communication module with the EOUs (Electronic Orientation Unit) that are placed in the instrumentation devices.
2. Secondary graphical interface during surgery.
3. Master communication with the Display Unit.
4. Wireless charging receiver of the Control Unit (CU) device.

Specifically, the Control Unit is based on a commercial tablet, as this already has a built-in graphic interface and standard wireless communication (Bluetooth and Wi-Fi). The extra electronics: communication with the EOUs and wireless charging are implemented in a communication module through to the USB connector. Deliverable 4.2 also includes the design of the electronics.

A series of algorithms were developed to convert the data generated by the EOU’s into visual format that was easier for the surgeons to understand and coordinate. The output of the EOU data was represented by a series of concentric circles and a cross hair. The closer the cross hair is to the centre of the circles the more accurate the position of the acetabulum cup.

The final part of this work package focused on the analysis of the circuitry including the PCB design to ensure that they met current standards and were easy to manufacture with long term stability.

The following points were analyzed:

- Problem with the BOM: All observations related to the BOM. For example, a wrong manufacturer code.

- General requirements for production: All observations related to the production. For example, the lack of fiducials.
- Component: All observations related to the components. For example component overlaying or obsolescence.
- Weld quality: All observations related to the weldability of the components. For example the implementation of the Thermal-relief.
- Problem with footprint: All observations related to the component's footprints or PAD's dimensions.
- Problem with test: Analysis of different test-points required by the customer test requirements.
- Other assembly problems: All observations not classifiable in previous points.
- Other problems not related with assembly: All observations about points not related to MASERMIC. For example, the manufacturer of the PCB.
- Client feedback: Critical and key points advised by the customer are documented.

Work Package 5 – Display design and optics integration

Work focused on the design the OLED display screen and circuitry in order to project the required information in the HDU so that it has the correct focal length for the surgeon to view and allow it to be incorporated into a pair of glasses. The device will have the ability to receive data from the Control unit via a wireless signal.

Part of this work package was to develop the Head Display Units (HDU) for projecting the positioning image in from of the surgeon's eye, and when the project proposal was originally written there was a need to develop these as there was nothing commercially available. However, shortly after the start of the project Google released a head display unit that would form a good foundation for the HDU. Therefore it was decided to utilise and adapt them to comply with the project requirements. This adaptation involved the integration of both the wireless communication and charging circuitry as well as reviewing the optical system to ensure that it was convenient for the surgeon. We also modified the software to display the guidance information.

The Google Glass employ a processor with the Android operating system. The D2Eye application software (App) was developed to work on this platform. The display show a fixed structure of a cross and several circles both in red colour. A white cross moves over the display and indicates the deviation of the position of the operation instrument. The optimum position is in the middle of the red cross.

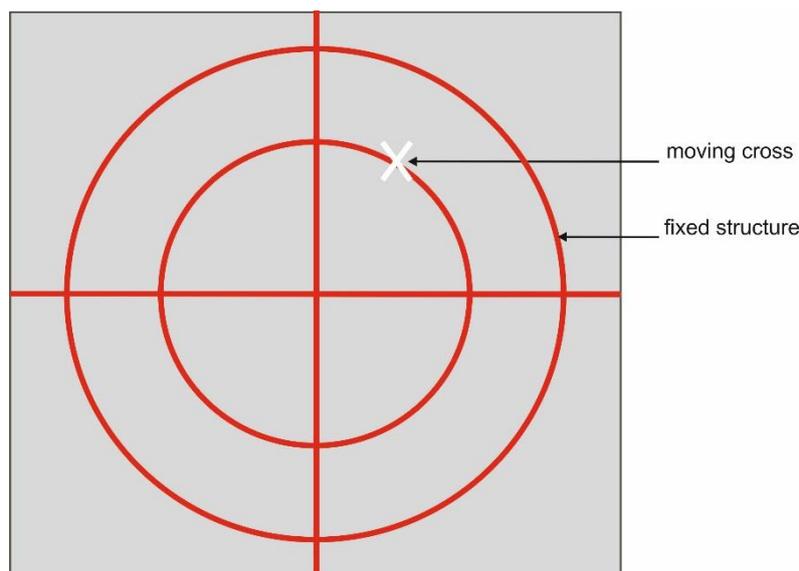


Figure 8: D2Eye elements in the display

The position of the white cross was calculated in the tablet with the position data of the operation instrument and only this data was sent to the glasses. The communication between glasses and

tablet was wireless WLAN at 2.4GHz. To avoid observable time delay the refresh rate was 50Hz as defined in the requirements.

In order to communicate with the control unit and to charge the glasses remotely, independent circuitry was developed that located on the side of the glasses. As well as the development of the wireless communication and charging circuitry it was decided to manufacture a charging station for all of the system components.

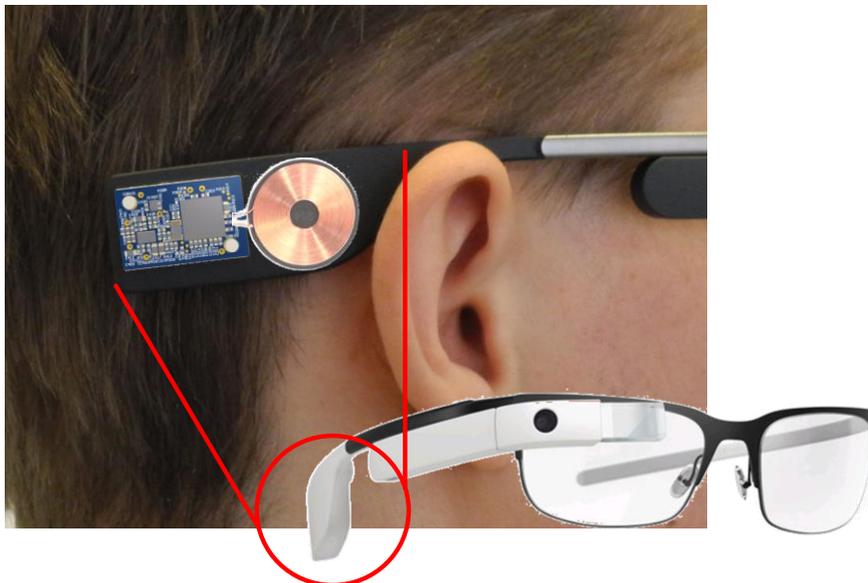


Figure 9 Receiver wireless charging module at the DU

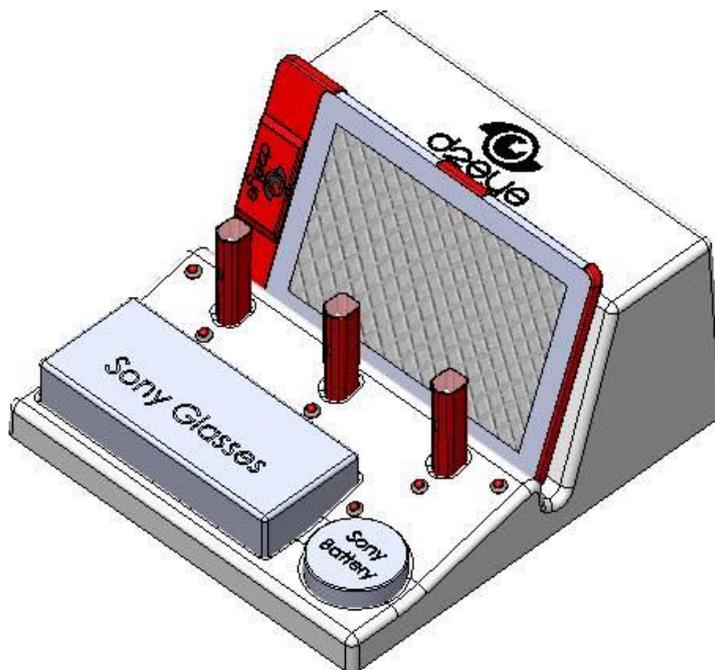


Figure 10 Base charger with D2EYE devices

As with the control unit an evaluation was performed on the circuitry including the PCB design to ensure that they met current standards and where easy to manufacture with long term stability.

Work Package 6: Instrumentation design and enclosure integration

The aim of this work package was to design the surgical instrumentation that can incorporate the required sensors to facilitate hip replacement surgery using a variety of surgical approaches and to produce prototypes of the enclosure for the control unit and the EOU's. These enclosures will be sterile and will protect the electronics from both contamination and ingress of moisture but must still allow the surgeon to access the relevant information from these units via an embedded display. The units will also allow for wireless recharging of the embedded battery and will protect the EOU's from shock loading during the impaction of the hip components. We also developed the head display glasses and enclosure for the OLED screen and associated electronics.

During this work package a number of instruments and enclosures were designed and prototypes were manufactured, these included:

- The charging station which consisted of an outer case which covers a steel chassis.
- The Table chassis which clips around the tablet and docks with it via the mini USB.
- The EOU housing which consists of several different components. The first being the housing that contains the electronics, these will be placed in the housing which will be back filled with a shock proof resin. This housing will then be placed in a sterile barrier with sterile cap during the surgical procedure. In order to prevent cross contamination a series of tools was developed to insert and remove the electronic housing from the sterile barrier.
- A case for the electronic which fits to the head display glasses.
- A EOU electronic chassis designed to hold the PCB and battery within the enclosure. The design of this component was generated following the shock loading trials and incorporates a moulded in spring to act as a dampener during impaction of the acetabulum cup into the pelvis.

The development of the enclosures was only part of the work performed during this work package a large amount of work was also focussed on the design and development of the instrumentation need. These instruments included:-

- K-Wire(these are a single use instrument) for the location of the fixed sensor of the pelvis.
- Fixed sensor holder. This will locate the fixed EOU on the opposite side of the pelvis to the operations site.
- Sterile barrier fitting shield. This will be used to prevent cross contamination during the insertion of the EOU housing.
- Range of motion (RoM) instrument. This will be inserted into the prepared acetabulum and the femoral head will be re-engaged and manipulated until the optimum range of motion has been identified at which point the position of this instrument will be fixed in relation to the fixed EOU. From this the introducer will obtain the optimum position for the insertion of the cup.
- RoM cup trials, these are size and devise specific depending on the implant to be used i.e. ADLER Ortho or MatOrtho implants. There are 12 different sizes which correspond to the different cup sizes supplied by the manufacturers.
- Cup introducer, two prototype introducers were manufactured one which conformed to the ADLER Ortho design and one which conformed to the MatOrtho design. These reason two were required is that these are specific to the cup design to be implanted, however , it should be noted that each introducer handle will take the standard EOU housing.
- EOU removal instrument. This is required to remove the EOU from the instrument handle following the completion of the surgical procedure.

Full details of the work performed here can be seen in deliverable 6.1 and 6.2.

Work Package 7: System integration

Work Package 7 objective was to integrate the components together and to conduct initial testing of the equipment in the laboratory in order to verify that the components will perform as outlined in WP1.

In order to ensure that the EOU's were providing correct data with respect to each other and within predefined limits a calibration protocol was developed. In order to achieve this calculation of

orientation angles for the accelerometer and gyroscope were made and each EOU was tested on a multi axial table. The sensors were measured in defined positions and different rotation and the calibration data generated was compared to a known reference. The calibration data of the magnetometer were generated outside the building avoiding any disturbance by power supplies or metallic objects. The result of these test showed that martensitic materials (the same materials as the instrument handles) had an effect on the calibration of the sensors. Therefore different steel materials were tested to those commonly used for the instrumentation the results of this showed that austenitic steel was the best choice.

The initial sensor calibration trials used wired sensors and data transfer of 50Hz for the calculation of the orientation angles. However, later trials in the operating theatre were conducted during the cadaver trails which showed that the complete system with wireless communication between the EOU's, tablet and glasses proved successful.

A coil producing an alternating magnetic field was used as reference in the planar plane. The results showed that the magnetic field of the earth could not be used as a reference because it has a lower field density that's distorts easily. The comparison of steel materials showed that the magnetic materials, like martensitic steel, disturbed the magnetic field and cannot be used for instruments in close proximity to the sensors.

In order to ensure that the complete system was sterile or at least decontaminated as it will not be possible to sterilise some of the components due to their sensitivity. A protocol for the sterilisation and decontamination of the instruments was developed. The D2Eye system comprises a number of items which are supplied as sterile single use medical devices (SUDs) and a number of items which are supplied non-sterile reusable, also known as reusable medical equipment (RME), which are either part of the point of sale (POS) kit or loan instruments.

The SUDs are supplied sterile and are treated as clinical waste after the procedure and the RMEs will be decontaminated to remove or destroy contamination to ensure patient and clinical staff safety. The SUDs must be disposed of after use, these devices cannot be reused.

The protocol look at the following aspects:-

Decontamination

Decontamination of the reusable devices is a combination of cleaning, disinfection and sterilisation. The level of decontamination required is dependent on the level to which it has been contaminated and is required to prevent micro-organisms or other contaminants from reaching the patient.

Table 12 Aspects of decontamination

Cleaning	The physical removal of contaminants including dust, soil and organic matter, along with a large proportion of micro-organisms. Thorough drying following cleaning will cause a further reduction.
Disinfection	Utilising heat or chemicals to reduce the number of viable micro- organisms to a level which is not harmful to health.
Sterilisation	Renders the object free from viable micro-organisms, including bacterial spores and viruses

Managing devices

As part of the manufacturer's responsibility to manage medical devices, it is important to consider the follow aspects throughout the product's lifecycle: product acquisition, deployment, maintenance, repair, disposal and training.

Processing RME's

The point of sale (POS) kit contains all the reusable electronic devices. Supplied as non-sterile, they will be packaged in appropriate point of sale packaging which will offer suitable protection in transit. The kit will require a clear instruction for use (IFU) to cover the processing before and after the devices are used clinically. Appropriate guidance will reduce risk of delay, injury and cross-infection.

Processing of POS kit once acquired

To ensure the devices are safe for continued use once they are in circulation, understanding of how the devices are handled within the theatre/clinic's central decontamination unit (CDUs) is required.

As the devices are supplied non-sterile, upon acquisition they will need to be processed as if they have been used clinically following a decontamination cycle, which will require appropriate cleaning and disinfection.

Assuming that all components of the POS kit will qualify an appropriate IP level for sealing effectiveness, the component parts can be disinfected with appropriate biocide such as 70% isopropyl alcohol (IPA), 30% water.

However, the POS kit are temperature sensitive; in particular, the batteries within the EOU cannot exceed 50°C. This limits methods of sterilisation. A risk-based assessment would be required to determine if/what sterilisation is required at the CDU.

Processing loan kit

All additional instruments and substituted introducer are made from existing materials such as Stainless Steel 316, Stainless Steel 630 (17/4) and Acetal (POM). Therefore, there are no obvious reasons to change decontamination method for the loan kit following the standard process route for RMEs.

Processing SUDs



The single use devices (SUDs) are low-cost items supplied sterile by gamma irradiation in a single kit, packaged with more than one barrier to ensure effective sterility. As there are sharp components within the SUD kit it would be appropriate to use a blister pack/tray to protect the components from compromising sterility.

Processing of SUD kit once acquired

Processing of SUDs is far more straightforward. The kit does not need any inspection or decontamination before use. Once the kit is acquired, the device selection needs to be verified against the information on the label and then the kit can remain in storage until ready for use (observing the shelf life of the product).

Besides the decontamination protocol a packaging and sterilisation protocol was prepared which cover the following:-

Packaging and Sterilisation

Packaging Validation

All our testing is compliant with ISO and international ASTM standards where relevant and a report is supplied with each test. In the case of shelf life, a test plan would need to be supplied by Adler Ortho and MatOrtho.

Ageing



Ageing is a testing technique that evaluates a product's ability to perform in the future. As the product gets older, material degradation might occur and intended performance might drop. This testing is used to justify expiry date.

Accelerated Ageing

Accelerated age testing is not a requirement but does allow for justification of longer expiry date. By stimulating the real-time age of materials, a manufacturer can choose to gain anything between 1 month to 5 years, although longer periods can be validated. A big advantage is that it allows products to get to market quicker.

This testing uses temperatures elevated above those at which they are normally held (ambient) to stimulate the ageing process. Whilst the product is held at an elevated temperature it ages quicker;

therefore, a year's ageing could be conducted in a few months. For example: 1 year's shelf life is equivalent to 6.5 weeks if elevated to 55°C from the product ambient temperature of 25°C.

Adler Ortho and MatOrtho can choose to retain the aged samples for further testing or Hunt can retain the samples to perform additional stability testing (for example, packaging integrity or seal strength).

Complies with: [ASTM F1980](#) and [ISO 11607](#), Packaging for terminally sterilized medical devices.

Real-time Ageing

Real-time ageing is an evaluation of the real-time effects that time and ageing has on a product and this is usually done in conjunction with an accelerated ageing study, so the real-time ageing can catch up with the accelerated ageing to strengthen the claim but reduce delay to market.

It is common for this testing to be done by the manufacturer as it is important to understand that the product should be controlled in an environment that is typical to its storage conditions. Either Adler Ortho, or MatOrtho, or both can choose to do this or Hunt can offer to conduct this testing in a temperature controlled and monitored environment.

Burst

Burst testing is a method of determining the strength of packaging by forcing pressurised air into the package until burst failure and then recording the burst pressure.

The SUDs are likely to be packed in a single use pouch and, depending on whether a porous or an impermeable material is chosen, this will have an effect on the rate at which gases escape. We would qualify this process and would demonstrate that the seal strength meets the required standards.

Complies with: [ASTM F1140](#), Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages and [ISO 11607](#), Packaging for terminally sterilized medical devices.

Packaging Shelf Life

Packaging shelf life tends to vary a great deal from one product to another as it should simulate clinical use, therefore, there are a number of factors which affect the testing method which include: type of packaging/configuration; the number of times the packaging is handled before use; storage/shelving; conditions whilst in storage (e.g. temperature, RH); other barrier materials. Adler Ortho and MatOrtho would need to determine the number of storage intervals required, but typically they are 30, 60, 90, 365 days. We recommend sharing the test plan with the appointed local regulatory authority prior to testing.

Complies with: Association of Operating Room Nurses ([AORN](#)) standard.

Seal Peel

Seal peel testing is measured on a tensile testing machine. We would recommend using this method for determining the peel seal strength for the single use pouches.

Complies with: [ASTM F88](#) and [ISO 11607](#), Packaging for terminally sterilized medical devices.

Dye Migration

Dye migration or dye penetration (dye-pen) testing is a quick method of establishing packaging integrity. This testing typically takes 20 seconds to apply per barrier so it is a very easy way of establishing if there are any leaks, especially at the seal. In the case of multiple sterile barriers, two for the D2Eye SUDs, this test should be conducted for both.

Complies with: [ASTM F1929](#) and [ISO 11607](#), Packaging for terminally sterilized medical devices.

Sterilisation

For the SUDs we need to choose a sterilisation method appropriate for the application. There are several types of sterilisation process available but the two most popular methods are radiation or ethylene oxide.

Validation

The sterilisation dose will need to be established. We will need to provide evidence that it is delivered evenly throughout the packaged product and then further monitor batches to demonstrate consistency.

Radiation validation



To claim Sterile R, we would need to conduct dosimetry, bioburden and sterility testing.

Complies with: [ISO/TS 13004](#)

Dosimetry

Dosimetry testing is measurement of an absorbed dose of ionising radiation. This is done by placing dosimeters inside the packaging which then reveal the amount of radiation which has reached the dosimeter.

Bioburden

Bioburden testing is the measurement of the number of bacteria living on a surface that has not been sterilised. This is done using a bioburden recovery efficiency process with a sub-lethal verification radiation dose. As devices differ, a validation would be required to determine the dose amount for each component.

One of the most popular methods for doing this is a Verification Dose Maximum (VD_{max}).

We would suggest using VD_{max25} which is a verification dose maximum 25kGy.

Ethylene Oxide Sterilisation



To claim Sterile EO, the contract facility would need to provide the relevant Installation Qualification (IQ) and Operational Qualification (OQ) documentation. We would then need to work with Adler Ortho and MatOrtho on a Performance Qualification (PQ) which will cover both microbiological and physical testing

Complies with: [ANSI/AAMI/ISO 11135 Part 1 & 2](#).

Sterility

Sterility can be assessed using biological indicators (BIs) or chemical indicators (CIs).

Using these methods provides sterility assurance for both irradiated and ETO sterilised product.

Chemical Indicators

Chemical Indicators (CIs) are designed for quick and easy detection of potential sterilisation failures as a result of deficient packaging, incorrect loading or malfunctioning steriliser equipment.

Biological Indicators

Biological Indicators (BIs) are designed for quick and easy detection of potential sterilisation failures as a result of deficient packaging, incorrect loading, or malfunctioning steriliser equipment.

Non-Sterile



It is not uncommon for reusable equipment to be supplied non-sterile which is then subject to the theatre/clinic's decontamination process, where they will be processed for the first time as if they have been used clinically. This processing is managed by CDU; refer back to Figure 1) Processing of RMEs.

The POS Kit is likely to be labelled as non-sterile.

The final part of this work package was to ensure that all system components fit within the enclosures and that the enclosures located within the instrumentation. Testing was also conducted to ensure that the communication between all system components allowed for data transfer in real time. The result of this analysis showed that the full system work as anticipated and that all circuitry could be integrated within the designed enclosures.

Work Package 8 – Verification testing and cadaver trials

The aim of this work package was to perform verification testing to determine the accuracy of the EOU devices and the ability of the system to accurately and speedily communicate across the various components supporting real-time feedback to the surgeon. Cadaver trials were conducted to assess the system using various operation approaches. Surgically implant the femoral components using the new instrumentation developed in WP3-6 this included:

Identification of a surgical group willing to conduct preclinical experimentation of cadaver models under surgical conditions.

Perform implantation trials on the femoral and acetabulum components to determine the instrumentation effectiveness under surgical conditions.

Evaluation of correct alignment following the implantation procedure.

An operation technique was prepared for the surgery. A series of calibration protocols were generated in order to maintain the accuracy of the EOU units.

Before testing the D2Eye system under real operation conditions the surgeons had to prove the mechanical components of the instruments first. The ergonomics of the system were tested while at the same time allowing the surgical team became more familiar with the handling of the instruments. From a project point of view the most important part of these trials was the usability of the electronic components such as the EOUs, the handling of the sterile barrier, display of the guiding system and the glasses for head display unit (HDU).

The simulated operations were performed first followed by the cadaver trails. All events were documented with sensor data, which register all movements and changes in magnetic fields around. The insertion position/orientation of the acetabular cup including feedback from the surgeon group was obtained and used to improve the system: as well as this the simulated operation tested to ensure that the system with respect to being able to transmit and receive data wirelessly across the operating theatre was achievable. As stated the initial trial; were conducted on skeletal model in order to ascertain that the correct position for the acetabulum cup had been achieved (Figure 11).



Figure 11 Investigation of the Range of Motion tool

Tests with EOU guiding system

All EOU's were placed on the table for initialization this is required to ensure that all EOU's read the same before starting. During the tests, the Range of Motion and Introducer instruments containing the EOU's were moved into defined positions. Each tests lasted for approximately 2-3 minutes. For the best performance, the position of the cross and circle should be the same place and the two pointers also. The tests were made several times with nearly the same result. The maximum difference in the displayed angles was 10-20° (see Figure 12).

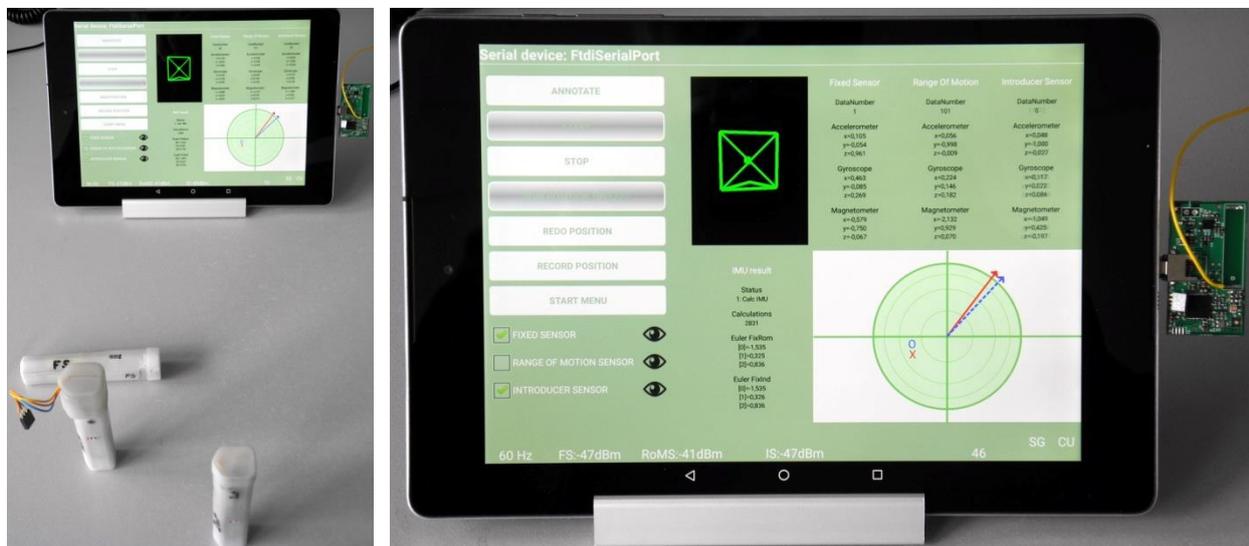


Figure 12: Range of Motion and Introducer sensor moved in a 90° position to the Fixed Sensor

Cadaver trails with D2Eye guiding system

The cadaver trails were carried out with support of the project partner Adler Ortho at Co. IGLO in Arezzo, Italy. In a wet laboratory, specimen legs were prepared for simulation hip implantation using the D2Eye system (see Figure 13) the result of this trial showed that the instrumentation worked well. However there were some problems encountered with data loss between devices which will be rectified following analysis.



Figure 13 Range of Motion tool with EOU sensor for detection of the optimum position of the cup

Operating Technique

To ensure the safe and proper use of the electronic devices and surgical instruments that make up of the D2Eye system as set of user instructions is required. Therefore an operative technique (procedure) was generated which outlined the steps need to be taken during the hip operation and covered the use of the D2Eye system both before and after the procedure.

The operative technique covers the following aspect (and is outlined in full in deliverable 8.2):-

Pre-Operative Electronic Device initialisation

- Magnetic Field Set Up
- Device Charging
- Tablet PC Start up
- Control Unit connection
- HuD Power up & donning
- Prepare the tablet and Sony SmatEyeglass Startup
- HuD D2Eye application launch
- Tablet D2Eye Android application initialization
 - Step1: Initialization window
 - Step2: Operation Data
 - Step 3: Control window

Fit Sterile Barriers

- EOU Sensor Sterile Transfer Protocol
 - Sterile Transfer Step 1
 - Sterile Transfer Step 2
 - Sterile Transfer Step 3
 - Sterile Transfer Step 4
- Tablet PC Sterile Transfer
- Attach Sterile EOU's to Instruments
- Fixed Sensor Holder

Range of Motion Instrument

- Cup Introducer

Prepare Patient

- Attach Fixed Sensor
- Attach first K-wire.
- Attach Second K-Wire
- Attach Fixed Sensor

- Register Fixed Sensor with Tablet PC
- Prepare Femur
- Prepare Acetabulum
- Range of Motion Study
- Fit Femoral Trial
- Prepare RoM Instrument Fitting correct size cup for patient.
- Ensure correct location or RoM instrument handle.
- Attach Cup Trial
- Attach Cup Trial Liner
- Perform Range of Motion Study
- Articulate RoM Instrument
- Register RoM EOU with D2Eye System
 - Start capturing the data of the RoM
 - Register the RoM position
- Remove Trial components
- Remove RoM Instrument
- Remove Femoral Trial Components

Fit Implants

- Femoral Component
- Cup
 - Attach Cup to Introducer
 - Verify communications between Tablet PC & HuD
 - Implant Cup using HuD or Tablet PC for guidance
 - Register the Introducer position
 - Complete Procedure

Reduce Joint and Close Wound.

Remove Fixed Sensor

- Complete In App Information
- Disassemble instruments
- Remove EOU Sensors from Instruments
- Remove EOU Sensors Sterile Barriers
- Remove Sterile Barrier Lid
- Remove EOU from Sterile Barrier
- Remove EOU Cover
- Remove Tablet PC from Sterile Barrier
- Place all electronic components on the charging station

Using the information provided in the full procedure outlined above the surgeon and theatre nurses will have a full and comprehensive understanding of the operating technique.

4.2 Use and dissemination of foreground

Potential Impact

As part of the industrial and economic validation for the D2Eye guidance system an analysis was performed on the potential manufacturing cost compared to the cost of manufacture and sterilisation of equipment. The result of this analysis showed that the D2Eye system could be manufactured more cost effectively than similar products that have been released since the project start and those that existed prior to that. All of the electrical components that populate the PCB's throughout the system are mass produced and relatively low cost. The PCBs can be manufactured on a mass production scale and as such will be produced on a cost effective basis. As already discussed the SME partner Maser Mic have performed an in depth analysis on the circuitry developed during the project which included a cost analysis. The result of this analysis suggested that the circuitry could be made for significantly less than first predicted in the original proposal. Using this information it is

intended stimulate market sectors for new low cost guidance system that will prove a viable alternative to the current technologies.

During the course of the project the process route for the production of the D2Eye components was evaluated and estimations of the cost for the manufacture of the components was determined. From this evaluation it was decided to make some minor changes to the design of the circuit boards in order to facilitate the manufacture of the PCB's and provide a product that would withstand the environment they are going to work in. Prototypes of the full system comprising of the EOU's, control unit, head display, charging station and the instrumentation required for the implantation were of the components were produced and have been demonstrated to a group of surgeons for their feedback. Evaluation by the surgeons approached to perform a review of the D2Eye system show a good response, as well as the surgeon review the system was also showed to operation room nurses for feedback on the ease of use. The response from both bodies was positive and it is believed that a good uptake of the system will be made by potential surgeon. It is also intended to use the web site generated during the project to facilitate in the technical transfer of information, however it should be noted that all of the partners have a comprehensive understanding of the technology as a result of attendance at the technical and managerial meetings.

Cost Analysis Discussion

As already discussed the analysis of the system from a manufacturing prospective showed that the manufacturing cost would be lower than those of current navigation systems. Following investigation it was determined that the average cost of current navigation systems hip prosthesis components range from is approximately €50,000 to €250,000 whereas we estimate that the new D2Eye system will retail for approximately €6250 which as can be seen is significantly less than anything currently on the market. The reason for this is that we have generated a system which is more mobile and utilises exciting products currently available. The other main reason is that we have developed self-contained electronics which do not require cameras and patient markers to define the system location. By 2021 we would look to have increased our presence within the global prosthesis market sector by taking a 25% share of this market giving us an estimated €128 million annual turnover with a predicted €17.8 million profit per annum.

With the current cost of navigation system be so high, along with the maintenance cost for these devises be in excess of what we would charge for a complete system. We envisage the demand for the D2Eye system will be driven by a cost down approach taken by most healthcare authorities in Europe. We have already been contact by several patient groups and surgeons who have indicated that they would like more information on the new system. We feel that this increased awareness and demand for an alternative to the current bulky and often cumbersome system will inevitably result in the increase of our market share for this product. It is also intended to look at transferring the technology developed in to other areas such as knee operations and potentially shoulder joints.

Process production parameters.

During the course of this project the route for manufacture of the D2Eye system components has been reviewed at regular intervals to make sure that the components could be manufactured cost effectively. As a result of this process the design of the final components was modified. In the case of the PCB's and the subsequent components that will populate them small changes were made to ensure that the manufacturing routes would be optimum. A manifest was generated for the electronic components and an analysis was performed to ensure that they would be available for the foreseeable future. The electronic housing also underwent a series of modifications in order to facilitate the production process and modification of the PCB designs. These modifications include the development of a case which would allow the interface between the USB connectors on both the table and head display unit. The results of the modification has resulted in the tooling costs being greatly reduced and that the complexity of the tooling has been made as simple as possible, allowing for reproducibility of cost effective and geometrically accurate components.

Market Stimulation of the Endure prosthesis

Prototype D2Eye systems have been manufactured and presented to a group of orthopaedic surgeons and theatre nurses for their feedback with respect to ease of use and ergonomics. These samples were manufactured to promote market interest in the new technology. Samples of the D2Eye system were supplied to surgeons for cadaver trials and the information gained from these trials was used to refine the instrumentation. The feedback was also used to critique the operating procedure and from this an operation method was generated for training purposes.

Using the feedback from the cadaver trials it was possible to edit a series of photos taken during the procedure in order to show the potential of the new system to new surgeons demonstrating the system should be used and showing the result obtainable, including the accuracy of the final implanted prosthesis. Using the still photos and the prototype system including the instrumentation it is intended to demonstrate the technology at several predefined exhibitions and conferences such as the MedTech Stuttgart, Orthotech Zurich and the international conference for orthopaedics.

Technology transfer and case study demonstration

To facilitate the transfer of knowledge during the course of the project a web site was setup and updated on the regular basis, this gave the partners the opportunity to review the technology and add comments and articles of interest. It is intended to make sections of this web site available to both surgeons and the general public once the patent claims have been finalized. MatOrtho in conjunction with Adler Ortho will also hold training days with both surgeons and theatre staff to ensure that the technology developed is transferred in a manner that will ensure the success of the product once in the market place. Besides the official web site for the project several partners have also added the project details to their own website so if a general enquiry is made through the internet for hip guidance systems then this should lead to either the official web site or one of the partners sites.



Figure 14 Showing a view of the web site for D2Eye.

D2eye

Approximately 600,000 hip operations are performed annually in Europe. In 26% of these operations, the components, in particular the cup, are not aligned correctly; this misalignment alters the biomechanics of the system, such that excessive wear of the cup occurs. The subsequent reduction in implant lifespan will affect ~40,000 European citizens, an average of 30,000 per year. In financial terms, the annual cost to European healthcare institutions is in the region of €1.05bn euros. In addition to the increased likelihood of re-revision and associated aftercare costs.

There are two types of navigation system currently on the market: (1) Image-based which uses CT data to generate 2D preoperative images, and (2) Image-free systems which rely on kinematic data or point-clouds acquired intra-operatively to generate a 2D reconstruction that can be explored during the operation on a computer screen. Both systems have demonstrated improved accuracy over manual surgery. However, current systems entail a large initial cost (~€220k) with high maintenance costs; in addition, most systems take an extra 15 minutes to setup, using valuable theatre time.

The D2eye project will develop a single to use, low cost, fully mobile guidance system with reduced set-up time. The guidance system will allow the surgeon to position the cup accurately, allowing for optimum range of movement and as a result will prevent premature failure of the implant normally associated with misalignment. This will be done using a series of electronic orientation units built in to the surgical instruments which will give their position in free space. The information from the units will be projected in front of the surgeon's eye in real time, allowing them to identify the correct cup implantation position; such a system will enable implant lifetimes to be extended beyond the current average 12 year lifespan, significantly reducing the burden on the healthcare system.

Project Partners



Figure 15 Shows the D2Eye project being promoted on one of the partners web site.

D2EYE

Project Overview

Title

High-Performance Cost Effective PAEK Knee Arthroplasty

Abstract

Approximately 800,000 hip operations are performed annually in Europe. In 56% of these operations, the components, in particular the cup, are not aligned correctly; this misalignment alters the biomechanics of the system, such that excessive wear of the cup occurs. The subsequent reduction in implant lifespan will affect ~450,000 European citizens, an average of 30,000 per year. In financial terms, the annual cost to European healthcare institutes is in the region of €426m euros, in addition to the increased likelihood of re-revision and associated aftercare costs.

There are two types of navigation system currently on the market: (1) Image based which uses CT data to generate 3D preoperative images, and (2) Image-free systems which rely on kinematic data or point-clouds acquired intra-operatively to generate a 3D reconstruction that can be explored during the operation on a computer screen. Both systems have demonstrated improved accuracy over manual surgery. However, current systems entail a large initial cost (~€250K) with high maintenance costs; in addition, most systems take an extra 15 minutes to setup, using valuable theatre time.

The D2Eye project will develop a simple to use, low cost, fully mobile guidance system with reduced set up time. The guidance system will allow the surgeon to position the cup accurately allowing for optimum range of movement and as a result will prevent premature failure of the implant normally associated with misalignment. This will be done using a series of electronic orientation units built in to the surgical instruments which will give their position in free space. The information from the units will be projected in front of the surgeon's eye in real time, allowing them to identify the correct cup implantation position; such a system will enable implant lifetimes to be extended beyond the current average 15 year lifespan, significantly reducing the burden on the healthcare system.

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Figure 16 Shows the project being disseminated on yet another partners web site.

The result of the project have been published on several of the partners web site, as a result of this publicity the Fraunhofer and rest of the partners have been inundated with request for more information. At present the consortium member have received approximately 25 emails from both surgeons and the general public wishing to learn when the technology will be made available. This significant interest in the technology developed has spurred the consortium on to the next phase of development and they are currently look at the clinical trials that will be needed to gain the relevant regulatory approvals.

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Objective: "Approximately 800,000 hip operations are performed annually in Europe. In 56% of these operations, the components, in particular the cup, are not aligned correctly; this misalignment alters the biomechanics of the system, such that excessive wear of the cup occurs. The subsequent reduction in implant lifespan will affect There are two types of navigation system currently on the market: (1) Image based which uses CT data to generate 3D preoperative images, and (2) Image-free systems which rely on kinematic data or point-clouds acquired intra-operatively to generate a 3D reconstruction that can be explored during the operation on a computer screen. ...

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Figure 17 Showing just one of the independent article available on the internet which demonstrates the D2Eye system.

Dissemination Activities During Period

Despite the early success of the D2Eye project to date, the project remains at an early stage, particularly with regard to exploitation and dissemination of the project results and developed technology. However, the project Consortium and particularly our Exploitation Manager, Carlo Dottino, have extended considerable efforts to lay the foundations for the exploitation of the project, with several early successes achieved to date. To facilitate the dissemination of the project results

AldeOrtyho together with MatOrtho have made extensive plans for dissemination and exploitation by the creation of interest within the surgical groups and with surgeons across the orthopaedic sector.

As already discussed the project results have been featured in several articles on the website which we plan to exploit and present article in some of the leading magazines such as the European Medical Device technology, American orthopaedic and the medical device development magazine. As well as these publications and as already discussed we have put project information on the partner website which again has stimulated a great deal of interest from both surgeons and general public alike. The technology developed during the course of the project has also been presented at.

The 30th Conference on Design of Circuits and Integrated Systems (DCIS 2015) – has been sponsored by the IEEE Circuits and Systems Society.

Link: <http://ieeexplore.ieee.org/xpl/mostRecentIssue.jsp?punumber=7383376>

It is the aim of the partner to also present the project results at the following conferences and exhibition during the remainder of 2016 and 2017, these include the DesignMed Europe conference, Orthotech conference and exhibition as well as MedTech conference Stuttgart 2017. The following table highlights a number of potential dissemination activities that the Consortium intend to carry out (Note that while we have identified these events and technical papers they will not happen until after the project has ended):

Table 13 Conferences and training targets

Event	Date	Place	Website	Target	Benefits/display	Capacity
Bristol hip Meeting	November 2016	Bristol, UK	www.bristolhip.org	Surgeon panel member	Meeting confirmed with David Woodnut (approached for Orthopaedic surgeon panel)	~100
Med-Tech Innovation Expo	April 2017	Coventry, UK	http://www.mtiexpo-uk.com/	Competitors Surgeon Supplier NHS Procurement	Flyers Dissemination and education	~100
EFORT	May 2017	TBC	https://www.efort.org/	Surgeon, healthcare professionals, competitor companies	Exhibiting: TV loop Flyers Posters/ podium Dissemination and education	~7,000
SOFCOT	November 2016	TBC	http://www.sofcot.fr/	Surgeon, healthcare professionals, competitor companies	Flyers Posters/ podium Dissemination and education	Unknown
British Hip Society Meeting	March 2017	London	https://www.britishhipsociety.com/	Surgeon, healthcare professionals, competitor companies	Flyers Posters/ podium Dissemination and education	~3,500
Italian/British Hip Society Meeting	November 2016	Milan	https://www.britishhipsociety.com/	Surgeon, healthcare professionals, competitor companies	Flyers Posters/ podium Dissemination and education	Meeting TBC
Italian Orthopaedic Meeting	TBC 2016/2017	TBC	http://www.siot.it/pagine/about/	Surgeon, healthcare professionals, competitor companies	Flyers Posters/ podium Dissemination and education	TBC
Ghent Hip Resurfacing Meeting	May 2017	Ghent, Belgium	na	Surgeon, healthcare professionals, competitor companies	Flyers Posters/ podium Dissemination and education	Unknown

Event	Date	Place	Website	Target	Benefits/display	Capacity
American Association of Hip and Knee Surgeons	November 2016	Dallas, USA	http://www.aahks.org/	Surgeon, healthcare professionals, competitor companies	Flyers Posters/ podium Dissemination and education	~1,500
American Association of Orthopaedic Surgeons Annual Meeting	March 2017	Florida, USA	http://www.aaos.org/home.asp	Surgeon, healthcare professionals, competitor companies	Flyers Posters/ podium Dissemination and education	14,000

In addition to planning project dissemination, the Consortium has already consulted with a patent attorney regarding the potential for protection of the project IPR. Having reviewed the IPR generated during the course of the project we have concluded that the most appropriate form of protection and indeed most robust will primarily be through patenting the completed system which we anticipate to result from the project. A second patent will be taken out on the EOU's and more specifically their ability to know their position in free space. The Consortium will however remain vigilant of the need to protect the project developments and will continue to take appropriate advice from both our patent attorney and the IPR help desk where appropriate.