Project no:- FP6 - 513134

Project acronym:- RASPED

Project full name:- A single use device for the implantation of hip prostheses that will reduce the stress generated within the femur during surgery preventing intra/post-operative femoral fractures consisting of a Reverberating Abrasive Single use Piezo Electric Drive device.

Type of Instrument:- Co-operative

Deliverable reference number and title

D21:- Delivery of six month progress report, midterm review report and final report.

Period Number : 1 & 2

Due date of deliverable:-01/05/07

Period covered: from:-01/11/04 to:-30/10/06

Date of preparation:-30/04/07

Date of submission:-04/05/07

Start date of project:- 01/11/04

Duration:- 27 month

Project coordinator name:- Dr Andy Taylor
Project coordinator organisation name:- Finsbury

Revision [draft, 1]

Organisation name of lead contractor for this deliverable:-Finsbury

Project co-funded by the European Commission within the Sixth Framework Programme (2002-2006)		
Dissemination in level		
PU	Public	
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	**X**
CO	Confidential, only for members of the consortium (including the Commission Services)	

PROJECT NO: FP6-513134

CONTRACT NO: COOP-CT-2004-513134

RASPED

A single use device for the implantation of hip prostheses that will reduce the stress generated within the femur during surgery preventing intra/post-operative femoral fractures- consisting of a Reverberating Abrasive Single use Piezo-electric Driven device.

Co-operative Research (Craft)

Horizontal Research Activities Involving SMEs

1 to 27 Month Period Activity Report
Date of issue of this report: April 2007

Start Date: 1st November 2004 Duration: 27 Months

Lead Contractor: Finsbury (Instruments) Ltd
SME Contractor: Nisaform S.R.O.
SME Contractor: S.C. Incerplast SA
SME Contractor: Hunt Developments (UK) Ltd.
SME Contractor: Cedrat Technologies S.A.
SME Contractor: Bester Medical System SP.zoo

Other Contractor: Molnlycke Health Care AB

RTD Performer: Pera Innovation Ltd
RTD Performer: Biomatech
RTD Performer: University of Southampton

Version 01

CONTENTS

1 SUMMARY OF PERIOD OBJECTIVES AND ACHIEVEMENTS

1.1 Executive Summary

This report is prepared to inform the Partners and the EC of progress to date and is a summary.

TECHNICAL PROGRESS STATEMENT

Year 1

- The Shock Impact test Rig has been designed, manufactured, tested and operated together with the associated monitoring and measuring electronics. The results were used to determine clinical and mechanical model data to enable development of the rasp.
- The optimum cutting stroke and angles were determined.
- Ten rasp designs, having a variety of different geometries, have been produced.
- Two selected examples were modified to permit manufacture as SLA models. These full sized, non functional models have been produced in epoxy resin.
- Work is underway on the displacement and force required by the cutter.
- An appreciation of bone material removal characteristics by the rasp has been achieved.
- Work continues to determine insertion force and oscillatory displacement optima with respect to bone removal vs. instantaneously induced and residual stress in the proximal femur.
- The required force used in preparation for femoral stem insertion during total hip replacement surgery, was measured.
- Using the traditional impact method, a sample of four patients, male and female, over a 22 year age range, was monitored. The results of these procedures showed that there was a variation of between 4 and 13 strokes measuring 26 to 34 kN with a time base of approx. 0.13 m/secs to profile the cavity within the femur and achieve an interference fit with the prosthesis.
- The age and gender of the patients may explain the variation in results.
- The force generated during this procedure should equate to the maximum during the profiling of the femur by current or future methods, however, it should be noted that a PZT device should require a lower force.
- A portable system for accurate, high speed impact data acquisition that could be used in operative conditions was developed
- To form the cavity in the intramedullary canal of the femur using a traditional ‘impact’ broach requires high force and a small number of discrete hammer blows at relatively long, (seconds), and intervals. The proposed PZT system uses a much lower force and a large number of high frequency blows. Upon the assumption that a linear relationship exists between displacement of bone by broaching, and cutting bone by sawing, an experiment was conducted at Southampton University (UOS) using a Tuke Saw operating at up to 330Hz and 1.5 to 2.0 mm rotary displacement on porcine tibia to determine the force required. **(See appended report No 2).** The calculated force value was 160kN providing data for the RASPED PZT Actuator.

Year 2

The initial samples of the rasp tool were designed with three different cutting faces. Testing was performed on the three cutting edges to determine the most efficiently cutting edge for the removal of

both cortical and trabecular bone tissue. Development of the auxiliary tooling was performed and as a result of this work an acetabulum reamer was developed. Initially three cutting configuration concepts were designed, however following testing only two of the concepts gave acceptable material removal comparable with exciting devices.

Two configurations of the hand held Piezo driven device (PZT) have been designed and manufactured. One of these designs was discussed in the month 12 meeting and consisted of a mechanical amplification. The other was designed using in-line PZT stacks to generate a direct force through the rasp unit. This unit was tested with the associated monitoring and measuring electronics. The results of the PZT showed it to be incapable of providing enough force or stroke to generate sufficient cutting action.

- Using the data from work package (WP) 1 the optimum cutting stroke and angles have been determined and have been used in the manufacture of the rasp. Three different types of cutting teeth geometries have been designed to identify whether full length strait cut, small cusps or angled full length teeth work worked more efficiently.

- Ten rasp designs, having a variety of different geometries, have been produced. Testing has determined three out of the ten to be chosen for further trials.

- Work has been carried out on the displacement and force required by the cutter and a new Piezo driven device was designed and manufactured.

- An appreciation of bone material removal characteristics by the rasp was used to define the final design of driving devices. Further trials using the different configuration of cutting teeth were used to optimise the drive unit design.

- Work to determine insertion force and oscillatory displacement optima with respect to bone removal vs. instantaneously induced and residual stress in the proximal femur was performed.

- Testing using the optimum rasped design with the calculated optimum conditions for the drive unit were performed. The results of this testing showed that the drive unit was incapable of producing sufficient force or movement to allow for material removal. Therefore it was decided to stop testing with the PZT and concentrate on an alternative device. The alternative device considered was that of the woodpecker a device used for initial testing during year 1.

- Methods of producing working prototype rasps without major tooling investment have been investigated and quotations were obtained.

- Since CAD models can be readily scaled, prototype rasps have been produced quickly and at low cost having sizes appropriate to the bovine femurs. These have provided more meaningful results.

- A variety of methods for volume manufacture of the rasps has been investigated. A further design change to the rasp was made to allow for ease of manufacture and thus allow it to be easily integrated into commercial manufacture.

- A number 316L stainless steel samples were supplied to for Cytotoxicity testing for bio-compatibility. These were in two forms, the first being flat plates with a known surface area and weight the second samples were of the actual rasped units and acetabulum reamers. The results of this testing showed that the sample remained negative.

- Work has been done on the auxiliary tooling required for the rasp introduction in to the femur and for the formation of the acetabulum cup into the pelvic.

- This work included:
    - Development of a series of drills for the generation of the pilot hole within the femur to allow the rasp unit to enter.
    - Development of the acetabulum reamer and drive coupling for the formation of the spherical cavity in the pelvic.

EXPLOITATION / DISSEMINATION STATUS

POSITIVE ASPECTS

- Good progress was made during the course of the project with rasped unit being manufactured, tested and evaluated by groups of surgeons. It is expected to have the acetabulum reamer in the market place within the next 6 month period and the rasped units within 6 month of that. The partner within the project have worked together successfully to achieve the final goal and are continuing this effort to make sure that the product reaches market.

NEGATIVE ASPECTS

- Due to the re-designing of the rasp unit and the changes made to the PZT configuration some time delays occurred. However as previously reported, it was anticipated that the manufactures of the rasp unit and the PZT drive would have been completed by the end of the project. Some of the original prototype tooling designed in this period proved ineffective in the early stages of testing. Due to insufficient force generation and movement it is unlikely that the PZT drive system will be used for the rasped unit insertion.

DEVIATIONS FROM PLAN

- Apart from the extension to the project there were no significant deviations from the technical plan during the course of the project.

CONCLUSION STATUS

- Methodology for the implementation of objectives was clearly understood thus preventing further time delays. All the partners were satisfied with the overall performance throughout the project.

FINAL POSITIVE CONCLUSION

- The progress made in this period has been very satisfactory with good advances being made in the rasp tool development. Test results have been encouraging both in the cutting tool and with the acetabulum reamer. The new rasp design increased the cutting area and also overcame tooling difficulties that became apparent during the course of the project. Due to the 3 month extension period, tooling was designed that was extra to the original plan that provided a further selection of single use instruments that added further value to the project.

2 PROJECT'S PROGRESS AGAINST OBJECTIVES, DELIVERABLES AND MILESTONES

The specific objectives for the six-month period of 1 Nov 2005 – 31 May 2006 of the project are summarised in the table below.

Deliverable No	Deliverable title	Delivery date Month date Month	Nature	Dissemination level	Progress Towards Achieving Objectives	% Complete	Date Submitted to the EC
D1	Generation process development analysis data that can be used in the development of the drive mechanism.	4	O	CO	A test rig for the drive development was manufactured to determine the correct force and frequency needed to cut trabecular and cortical bone tissues.	100	31/10/05
D2	Develop a drive mechanism that will remove cortical bone tissue and material from the intramedullary canal	5	O	RE	A drive mechanism has been developed by Cedrat for testing with bone. Initial trials have been satisfactory.	100	31/10/05
D3	Produce detailed report outlining the results of the testing performed during this WP1	6	R	RE	A detailed report was generated for both the work performed on the materials testing and for the drive mechanism actuator.	100	31/10/05
D4	Produce a draft plane for the use and disseminating the knowledge	12	R	RE	A draft plane for the dissemination of the result has been produced.	100	31/10/05
D5	From the results of WP1 produce detailed designs for the production of the rasped pre-forms incorporating the cutting edges required for the optimum material removal.	7	O	CO	Several designs of the rasped unit have been done and cutting geometry analysis has been performed.	100	31/10/05

D6	Produce report for the materials to be used internally with respect to the bio-compatibility within the body	8	R	RE	Two main materials have been identified for the rasp body (a carbon steel and a carbon steel with a titanium coating and a low grade stainless steel); Also the materials for the connector have been identified but not yet tested as the final material will depend on the exact method for driving the rasp. Cytotoxicity testing is currently on going and should be complete for the initial material analysis before the next meeting.	100	31/10/05
D7	Using the results from WP1 produce a series of designs that will allow for the manufacture of the drive mechanism and associated components.	8	O	CO	Preliminary designs for the drive unit has been generated, however the final design for the drive mechanism has not yet been determined as the final actuator for the drive mechanism is still to be specified.	100	31/10/05
D8	Show the results of the development work performed on the materials to be used during this project with respect to their resistance to ultrasonic agitation and mechanical strength	9	R	RE	The work performed on the drive mechanism rig has showed that the PZT will not be driven at ultrasonic frequencies and therefore will not affect the mechanical strength of the polymeric material. However, testing has shown that the material used for the connector has to be rigid in order to prevent loss of drive capability.	100	31/10/05

D9	Develop tooling to produce the rasp pre-forms	12	O	RE	Designs of the rasp body have been generated and the manufacture of the prototype tooling has been started.	100	31/10/05
D10	Production of 60 rasp samples for test evaluation	16	P	PP	All samples have been manufactured, tested and evaluated. This has resulted in a number of samples (in 3 formats) being chosen for further testing.	100	30/04/07
D11	Production of hand held drive mechanism	14	P	RE	Two hand held drive assemblies have been produced with the integral electronics being supplied by Cedrat. Both have been evaluated, one has been chosen for further tests	100	30/04/07
D12	Production of electronic amplitude generator	14	P	RE	The electronic amplification unit has successfully been produced and insertion into the amplification unit is currently being performed.	100	30/04/07
D13	Test and evaluation of the drive mechanism	17	O	RE	Two configuration of the drive unit have been produced and tested. The first was the PZT mechanically amplified unit which was unable to generate the required force for cutting through the saw bone tissue. The second PZT drive unit had the PZT disks in-line with the rasp unit and was able to generate the required force to drive the rasp unit into the saw bone material..	100	30/04/07
D14	Test and evaluation of the rasp device	17	O	RE	Testing of the initial rasp design has taken place. The results from this showed that the rasp would not cut fully into the materials as a result of the seam in the centre not having any cutting edges. To overcome this series of new rasp designs were manufactured, were	100	30/04/07

					the cutting edge is across the full radius of the raps unit. Trials of these new designs are still ongoing and are expected to be finished before the next meeting.		
D15	Pre-clinical test results compliance analysis	22	O	PP	Testing of the raped unit was performed to determine the at the new unit would both cut and remove material but also that they would reduce the amount of stress generated by conventional devices.	100	30/04/07
D16	Pre-clinical micro analysis and debris evaluation	19	O	PP	Cytotoxicity tests have been performed on material samples and finished rasped unit, the results of which showed no bacterial growth being found. Sterilisation and packaging trial have been conducted for both the rasped unit and the acetabulum reamer.	100	30/04/07
D17	Prototype components, including cost benefit analysis	24	O	RE	Cost analysis was performed on the raped units and as a result some minor changes were made to the rasped design in order to ensure that a cost effective product was achievable. Samples of the rasped unit have been manufacture and used for dissemination and market stimulation.	100	30/04/07
D18	Design Guide Production	24	O	RE	Technical papers of the results from the work performed during this project were presented at a major seminar in New York USA. Dissemination activities were also performed at local hospitals within the UK.	100	30/04/07
D19	Industrial & Economic Validation	24	O	RE	As part of the industrial and economic validation for the rasped unit market analysis was performed in the potential manufacturing costs	100	30/04/07

					compared to the cost of manufacture and sterilisation of existing devices.		
D20	Organise kick-off, mid term and final meetings.	0	O	CO	The kick off meeting was held at Pera in the UK and was attended by most of the partners.	100	30/04/07
D21	Delivery of six month progress report, mid term review report and final report.	6	R	RE	A month 6 progress report was generated and issued to all of the partners; this was also placed on the web site for the project along with all other information relating to the project.	100	30/04/07
D22	Delivery of a month 12 report, Submission of the cost statements	12	R	RE	Delivery of the month 12 progress report together with the cost statements was submitted on schedule.	100	30/04/07
D23	Delivery of a month 24 report, submission of cost statements.	24	R	PU	Deliver of the month 27 report together with the cost statements has been submitted.	100	30/04/07
D24	Delivery of the finished Plan for the Use and Disseminating the Knowledge.	Finished 24	R	RE	A plane for the use and dissemination has been done and issued on schedule.	100	30/04/07
D25	Provision of audit certificates and amended consortium agreement (if applicable)	24	O	RE	The collation of the audit certificates is in progress at this present time, this has taken longer than expected and proven difficult to achieve.	85	30/04/07
D26	Report on gender, societal and ethical issues of exploitation	24	R	RE	All animal materials used during this test have been obtained from beasts that were killed for their meat products. The disposal of this material following testing was done in accordance to the legislation of the country involved.	100	30/04/07

Problems/Issues During First Reporting Period

Problems encountered during this period were primarily due to the complexity of the rig design/build/instrumentation for the bone/rasp drop tests. Attaching strain gauges to the bone also proved difficult and as with most of the equipment, cleanliness was a big problem due to working with animal tissue.

Originally the actual basic rig design was relatively simple, although when testing began it became obvious that modifications were necessary to achieve stability of the rig during the actual dropping of the weight onto the bone. Instrumentation was showing inaccuracies due to instances like:

- Rig vibration during impact between bone and weight due to instability
- Strain gauges becoming dislodged during testing.
- The weight hitting small screw heads in the plastic tubing as it was falling.
- Difficulty in clamping the bone securely due to excess animal tissue on the bones.

Keeping the rig and the instruments clean became a problem as following every test a thorough clean was necessary to remove blood and bone tissue. The strain gauges had to be regularly remounted onto “clean bone” which had been previously trimmed close to the femoral head. To overcome the instability of the rig during impact the actual platform supporting the bone was lowered to a few centimeters above the ground making the rig more stable thus reducing vibration. The instruments detected a noise which originally could not be identified. Further investigation found the noise to be the weight actually catching two small screws during descent through the plastic tube. The screws fastened the tube to the rig and were positioned just above the bone, close enough to interfere with instrument readings when struck by the weight.

Further modifications to the rig were necessary during testing to eradicate noise and unwanted vibration’ also regular adjustments to the rig were required as every bone was obviously different in size.

The second rig, used for testing single tooth cutting on cortical and trabecular bone also had initial stability problems especially when cutting the very hard cortical bone. The rig was reworked and further strengthening struts were added which overcame the problem.

3 MILESTONES UPDATE MONTH 1 – MONTH 27 MILESTONES LIST

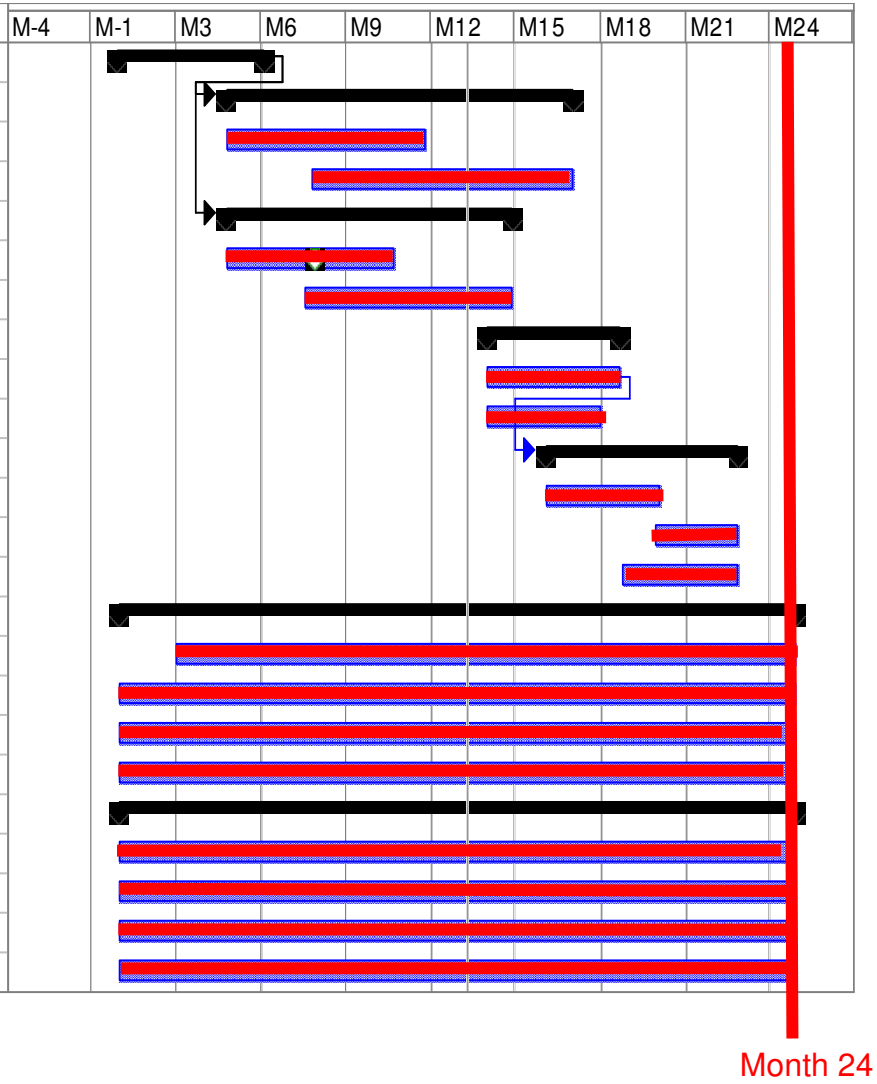
Milestone No.	Milestone Title	Completion Date	Verification Level
M1	**Generation of process development analysis data and the design of a drive mechanism that will remove cortical bone and material from the intramedullary canal.**	**5**	**RE**
M2	**Production of the rasp development tooling**	**12**	**RE**
M3	**Production of the rasp samples**	**16**	**RE**
M4	**Production of rasp and associated components including driver device and electronic amplitude generator**	**14**	**P**
M5	**Successful demonstration of drive mechanism and rasp device**	**17**	**P**
M6	**System demonstration. Demonstration of bio-compatibility and mechanical performance**	**24**	**P**
M7	**System demonstration. Case study production, exploitation & industrial validation. Agreement by partners that the components produced satisfy the medical devices directive (93/42/EEC)**	**24**	**CO**
M8	**Prototype system assessment and testing by third party users and experts.**	**24**	**R**
M9	**Demonstration to the EC and partners that all knowledge is created, managed and co-ordinated in a coherent manner. Verified by achievement of deliverables, effective reporting, and satisfaction of the contractual obligations to ensure that technical activities, legal aspects and other issues are co-ordinated. Also verified by mid-term agreement on achievement of deliverables and probability of achieving objectives.**	**12-24**	**R**

R=Report RE=Restricted to Group Specified by the Consortium (inc. Commission Services)

P=Prototype CO=Confidential, only for member of the Consortium (inc. Commission Services)

4 PROJECT PROGRESS AGAINST PLAN

Task Name
WP1 Characterization of Component Concept
WP2 Development & Production of the Rasp Unit
T2.1 Rasp Development & Material Evaluation
T2.2 Prototype Rasp Production
WP3 Drive Mechanism Development & Prototype Production
T3.1 Drive Mechanism Development & Prototype Production
T3.2 Development & Prototype Production of the Electronic Amplitude Generation Unit
WP4 Mechanical Validation & Trials
T4.1 Drive Mechanism Validation Trials
T4.2 Rasp Cutter Evaluations Trials
WP5 Pre-Clinical Validation & Trials
T5.1 Pre-Clinical Trials of the Rasp & Drive Mechanism
T5.2 Post Test Femoral Examination
T5.3 Sterilization and Packaging of Rasp
WP6 Exploitation & Market Stimulation
T6.1 Exploitation & Market Stimulation Plan
T6.2 Case Study Component Production
T6.3 Design Guide Production
T6.4 Industrial & Economic Validation
WP7 Consortium Management
T7.1 Knowledge Management & Innovation Related Activities
T7.2 Co-ordination of technical activities at the consortium level
T7.3 Co-ordination of Legal Issues
T7.4 Co-ordination of Other Issues



6 DEVIATION FROM THE PLAN AND CORRECTIVE ACTIONS

Apart from the extension in time to the project there was no significant deviation from project plane.

7 CONSORTIUM MANAGEMENT

All project and technical meeting have been well attended by most of the partners.

Project Review Meetings

	Date	Purpose	Location
1	14/12/2004	Kick off meeting	Pera
2	26/01/2005	Technical meeting	Finsbury
3	04/02/05	Technical meeting	SOU
4	08/03/2005	Month 3 meeting	Cedrat
5	20/05/2005	Technical meeting	Pera
6	03/06/2005	Technical meeting	SOU
7	05/07/2005	Month 6 meeting	Finsbury
8	29/07/2005	Technical meeting (progress report)	Pera
9	09/09/2005	Technical meeting	SOU
10	26/11/2005	Technical meeting	Pera
11	3/11/05	Technical meeting with Molnlycke	UK
12	28-29/11/05	Month 12 meeting	Romania
13	06/02/06	Technical meeting with Hunt	Hunt Dev
14	23/02/06	Month 15 meeting	Brussels
15	24/02/06	Technical meeting with UOS	UOS
16	8-9/03/06	Technical meeting with UOS	Pera
17	31/05/06	Month 18 meeting	Warsaw
18	12/06/06	Technical meeting with Finsbury	Pera
19	18/06/06	Technical meeting with Finsbury	Finsbury
20	10/08/06	Technical meeting with Finsbury	Frome
21	18/08/06	Technical meeting with Finsbury	Finsbury
22	13-14/09/06	Month 21 meeting	Hunt Dev
23	03/10/06	Technical meeting with Finsbury	Finsbury
24	17/10/06	Technical meeting with Finsbury	Pera
25	24/10/06	Technical meeting with UOS	UOS
26	31/10/06	Month 24 meeting	Finsbury
27	18-20/11/06	Technical meeting with UOS	Pera
28	28/11/06	Technical meeting with Finsbury	Pera
29	09/02/07	Technical meeting with Finsbury	UOS
30	11-12/01/07	Technical meeting with Nisaform	Pera
31	08/02/07	Technical meeting with UOS	UOS

8 CONSORTIUM STATUS

The consortium has working well together providing valuable input and direction for the research programme.

Objectives

- To ensure that the knowledge management processes are conceived and implemented in a coherent manner.
- To ensure that all aspects of the EC requirements for communication and reporting are met.
- To co-ordinate the overall legal, contractual, financial and administrative management of the consortium.
- To co-ordinate gender equality, ethical and science and society aspects of the project.

Plan for Use and Dissemination of Project Results – Outline

- Business
- Commercial
- IPR
- Dissemination

Exploitation & Dissemination Activities Undertaken

The exploitation of the final rasp units including the auxiliary tooling was discussed at the month 18 meeting. During this discussion the targeted unit costs for the rasp unit and auxiliary tooling was discussed and based on this information preliminary sales figures will be generated. The consortium has started to disseminate some of the results from the project, this has been done by both presenting test results at seminars and presenting samples of the components manufactured at exhibitions. A technical paper has already been presented at a major seminar in New York.

Protection and Licensing of Knowledge (IPR)

A patent on the technology from this project has been applied for by Finsbury and will protect the rasped unit design.

Dissemination Method

Following discussions at the month 18 meeting several conferences and exhibitions have been identified for possible dissemination activities and as a result of this an abstract has been submitted for approval at the International Society for Technology in Arthroplasty Conference (ISTA) to be held in New York USA. This conference was attended and a paper was presented covering the testing and development work performed during the project.

9 SUMMARY OVERVIEW OF TECHNICAL PROGRESS (MONTH 1 – MONTH 27)

Work Package 1 – Characterisation of Component Concept

Task 1.1 - Bone Shearing Force Test Model Specification
Task Leader - Finsbury

Objectives:

To create a series of test that will generate clinical and mechanical testing models data to enable the development and subsequent manufacture of rasp drive mechanism.

Progress:

To quantify the amount of stress generated around the femoral head during hip surgery and the amount of pressure generated within the femur a drop test rig was manufactured designed to simulate these conditions. The test rig comprised of a weight dropped from pre-determined heights acting on the top of a broach which was inserted into a bovine femur (see Figures 1 and 2). The tests rigs generated stress and impact load measurements which were used in the determination of the PZT actuator. As well as this testing a series of bone cutting tests were performed using a Tuke saw and a woodpecker to determine the stoke and cutting force needed by the rasp to cut through both cortical and trabecular bone tissues.

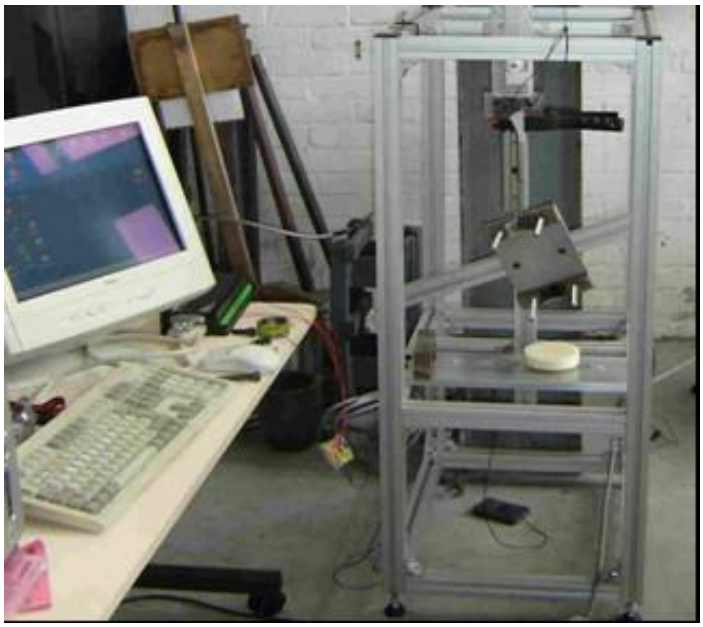


Figure 1 Photo showing the Drop test rig for the impaction of the bovine femurs with conventional broaches.

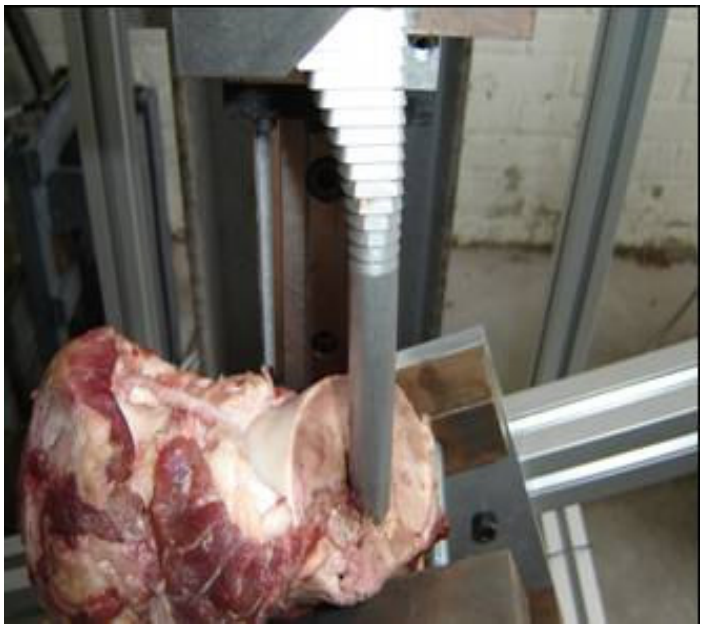


Figure 2 Photograph showing the bovine femur being impacted by one of the broaches that is currently used during surgical procedures.

Deliverable Status (D1):

Test data generated was used to determine the most appropriate PZT actuator. The data will be used as a baseline to validate the new rasp design. More work will be need on the bone drop test to finish off the strain measurements around the femoral neck of the bovine femur.

Task 1.2 - Bone Cutting Movement Test Model Specifications
Task Leader - Pera

Objectives:

To define the optimum cutting stroke and angle for the removal of bone tissue from both the cortical and intramedullary canal.

Progress:

To generate information for the optimum cutting angle of the semi-shears on the rasp body a cutting tool test rig was manufactured. This rig consisted of a sliding table that can be drawn past the bone tissues which is attached to a angle plate. The rig was designed so that the tool post could be precisely incremented to achieve an accurate depth of cut. Several tools were tested with varying cutting angles and negative rake angles (see Figure 3). The cutters were drawn across both trabecular and cortical bone with the load required to cut through these materials being recorded. The results of these test showed that a cutting angle of between 10 to 15° with a negative rake of 3° produced the best chip geometry and the lowest cutting forces to penetrate the cortical and trabecular bone.

Figure 3 Photographs showing the bone cutting rig cutting through trabecular and cortical bone tissue.

Deliverable Status (D2):

All the testing is on target and the data collected has enabled the cutting angles on the rasp semi-shears to be determined.

Task 1.3 - Drive Mechanism Characterisation

Task Leader - Cedrat

Objectives:

To analyse the amount of movement and forces required by the cutter and design an appropriate drive device that will for fill these requirements.

Progress:

The PZT test rig was developed to perform simulation testing using a PZT actuator, the aim of the testing was to determine the frequency and amplitude required to cut through simulated bone materials (see Figures 4 to 6). The rig was set up in to main geometries that of a free-free configuration were both the actuator and rasp were allowed to move independently and that of a blocked free configuration were the actuator was fixed and the rasp (in this case a round wood rasp) was allowed to move freely.

Measurements were taken of the displacement of the actuator the amplitude of the actuator and the rasp the force generated and the frequency of the actuator, the temperature of the actuator was also measured to ensure that the PZT's were not over heating. The results of this testing were used to determine optimum conditions required to cut through the different bone tissues. Cedrat used this information to calculate the best configuration for the actuator and to determine the most suitable actuator for the required application.

Figure 4 Photograph showing the PZT actuator test rig and monitoring equipment.

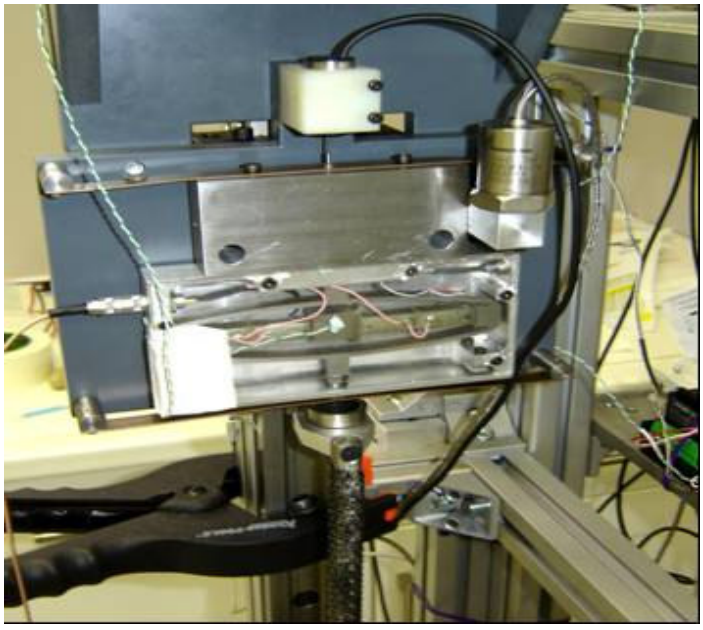


Figure 5 Photograph showing the PZT actuator in free-free configuration.

Figure 6 Photograph showing the bottom of the rasp starting to penetrate the simulation bone material.

Deliverable Status (D3):

The Piezo drive testing using the Cedrat attachment was carried out along with representatives from Cedrat, Finsbury and Pera. All the data collected is at present being analyzed by Cedrat to enable a system configuration to be designed to improve the movement and cutting force of the drive mechanism.

WP2 Development and Production of the Rasp unit.

Technical Objective:-

To produce a series of prototype rasps and associated tooling

Progress made during period 1

Progress:

Two materials were considered for the manufacture of the rasp and auxiliary tooling, the materials selected were a low grade martensitic stainless steel, a plane medium carbon steel and medium carbon steel with a titanium coating. The results of these tests are still ongoing and should be finished in the first quarter of the second year.

Several designs of the rasp body have been generated each with a different configuration of the semi shears and profile (see Figures 7 to 9). As well as looking at the different rasp shapes a study of the connector for the rasp was performed with regards to the different types of connector currently used and the best to obtain the maximum transfer of load and frequency from the drive unit.

Figure 7 CAD image of the rasp body prototype with straight semi-shears across the curved edge of the profile and half round semi-shears on the side faces.

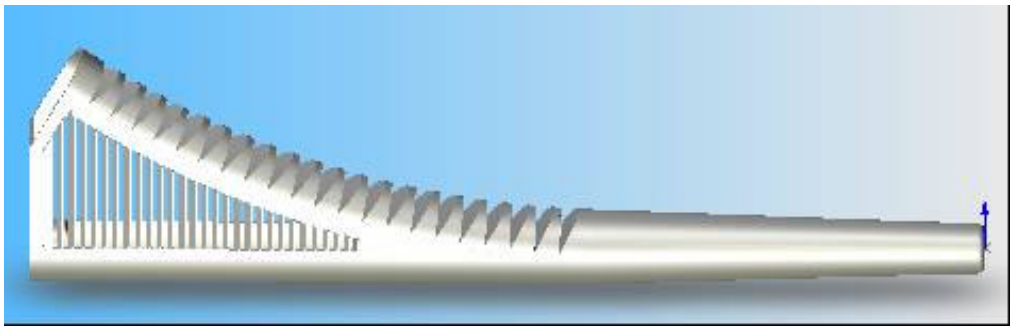


Figure 8 CAD image of the rasp body prototype with straight semi-shears across the curved edge of the profile and on the side faces.

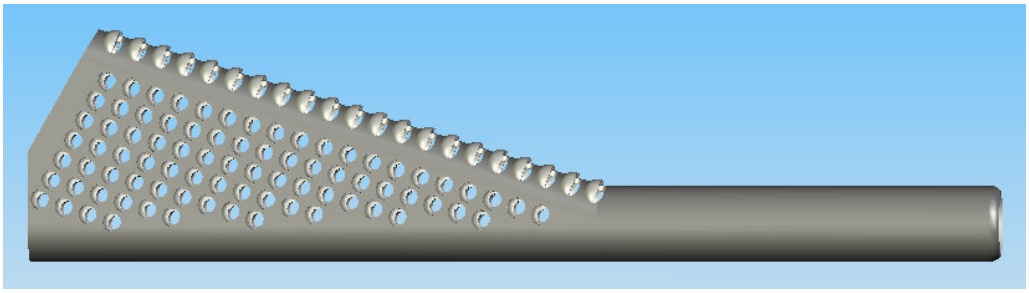


Figure 9 CAD image of the final shape for the rasp body prototype with half round semi- shears across the curved edge of the profile and on the side faces.

Deliverable Status (D5):

A series of materials have been identified for the manufacture of the rasp bodies, these include high carbon steel, titanium coated high carbon steel and martensitic stainless steel samples. Samples of these materials have been supplied to Biomatech for Cytotoxicity testing. Drawings of the rasp have been supplied to Nisaform for design evaluation with respect to manufacturing capabilities SLA models of the rasp body have been manufactured for assessment by the partners and a group of engineers in order to determine the feasibility of manufacture.

Following assessment by Nisaform of the rasp body drawing it was decided that a new design should be made for the rasp. The new rasp body design was developed to simplify the manufacturing process.
An investigation into the types of connectors fitting currently used for attaching devices to exciting equipment has been carried out. A series of drawings for the auxiliary tooling have been supplied to Nisaform and they have looked at alternative ways in which these tools could be made.

Task 2.2 - Prototype Rasp Production

Task Leader – Nisaform

Objectives:

Produce a series of prototype rasps and associated tooling.

Progress:

Tooling for the manufacture of the rasp body has been designed and is currently in the process of being manufactured. The tooling consists of four tools a blanking tool (Figure 10) for the production of the rasp blank, a primary forming tool (see Figure 11) to roll up the edges of the rasp. A dimple tool (see Figure 12) for the formation of the semi-shears and a final form tool (see Figure 13) which will fold the rasp into its final shape. As can be seen from the cad drawings the semi-shear form tool will put a single row of dimples across the rasp blank, this has the advantage of allowing for the pitch of these and the angle at which they attack the bone tissue to be altered in order to achieve the optimum cutting geometry.

These tools should be finished before the month 15 meeting and samples from these should be ready for evaluation at that meeting.

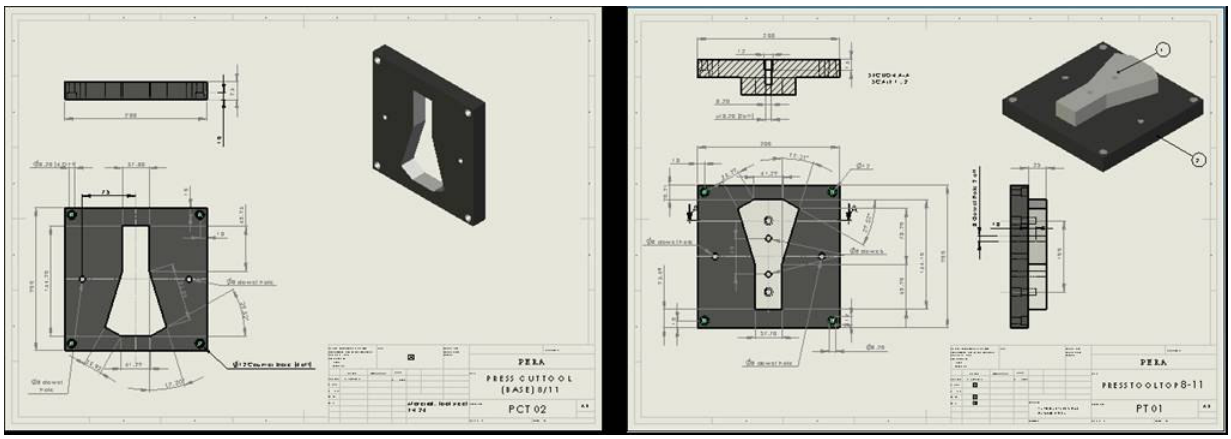


Figure 10 CAD drawings of the punch and die for the creation of the rasp blank.

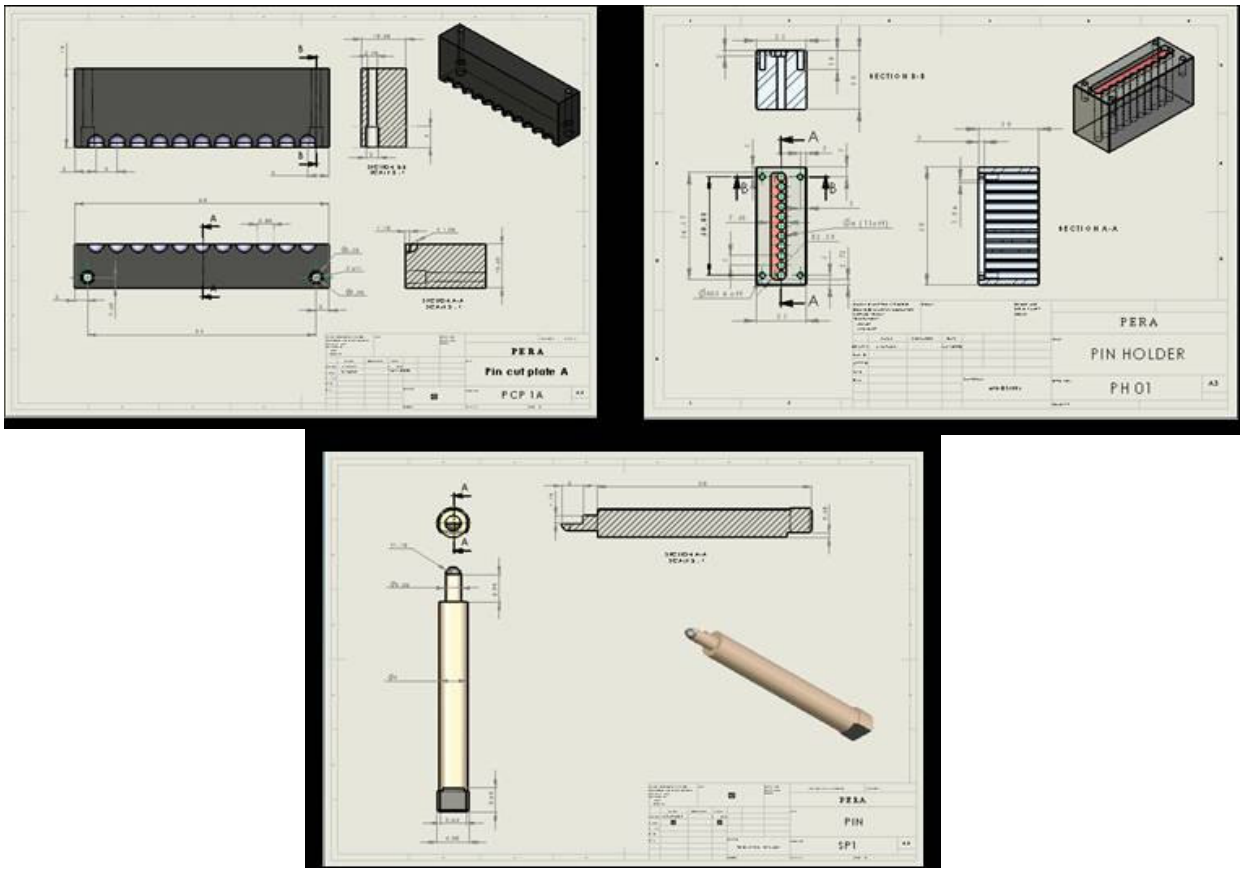


Figure 11 CAD drawings showing the dimple tool for the formation of the semi-shears.

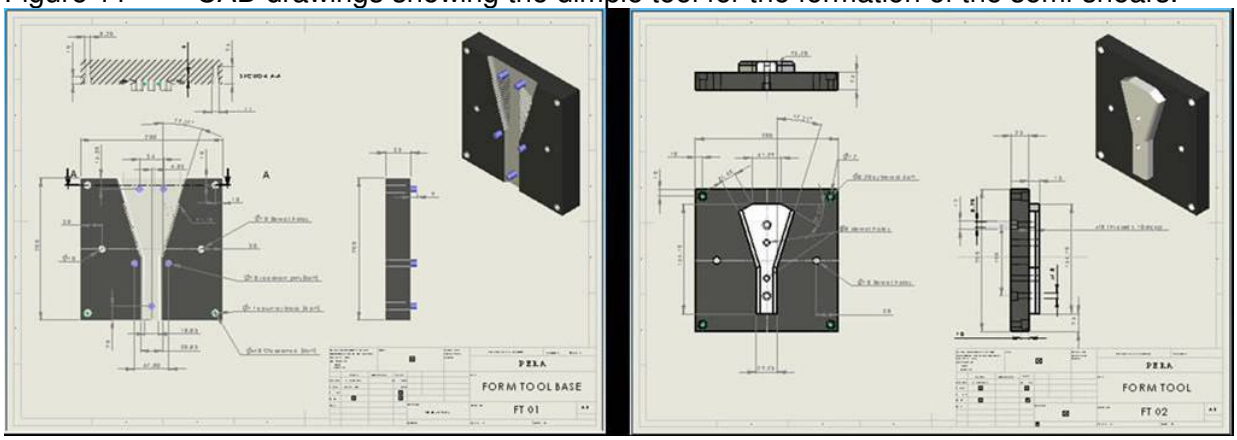


Figure 12 CAD drawings of the form punch and die for the formation of the roll on the edge of the rasp blank.

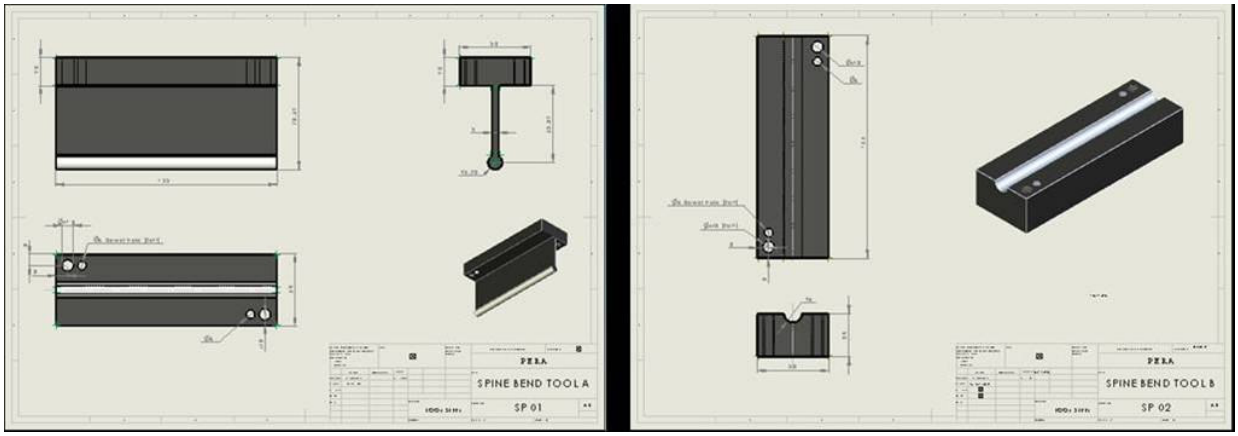


Figure 13 CAD drawing of the final form punches and dies.

Deliverable Status (D9):

- A series of press cutting tools have been designed and are currently being manufactured for the generation of the rasp body template and the semi shears that will for the cutting edges.
- Form tooling has also been designed and is currently being manufactured. The form tools will create the final shape of the rasp body, a material thickness of 0.8mm has been allowed for in the design of these tools.
- A mould tool is currently being designed for the top of the rasp body; these mouldings will house the connector for the rasp and the tubing for flushing and evacuation of the core of the rasp. It Is expected to have samples of the rasp bodies within the next two weeks.

Progress made during period 2

- Modifications were made to the rasp body design and samples were re-made (Figure 1).
- The robot for the grinding of the rasp units was modified and some of the rasps were sharpened ready for testing.
- Tooling for the production of rasps was manufactured and was modified as changes occur to the design following testing and evaluation.

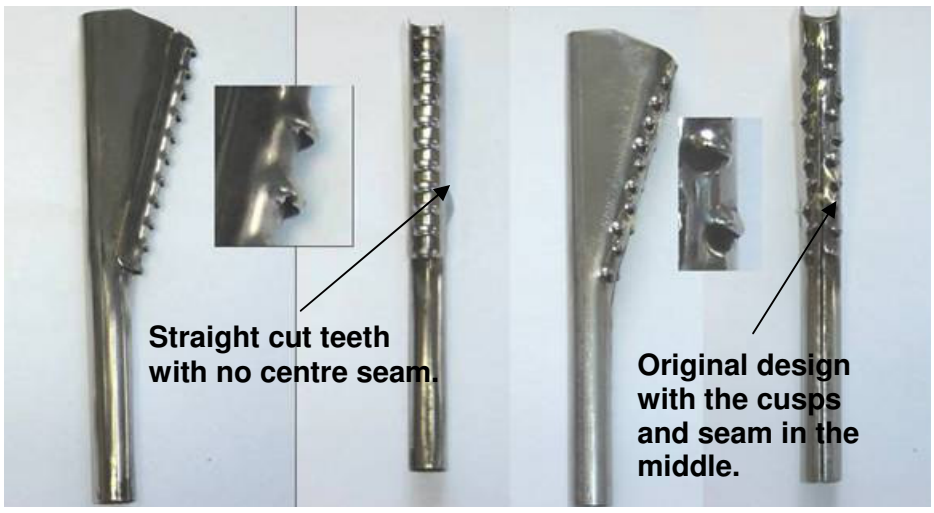


Figure 1: First design revision of teeth formation.

- The main re-design was due to the seam that ran down the middle of the original concept design, this created a wedging action when inserted inot the bone material.

- To overcome this problem it was decided to manufacture the cutting edge as a separate unit (see Figure 2).

Figure 2: Photo of the rasp body and separate cutting edge.

- Several cutting tooth configuration were manufacture to determine the optimum cutter geometry.

Using the information on the polymer materials tooling was made to produce the rasp drive coupling end caps and the insertion guild (see Figure 3).

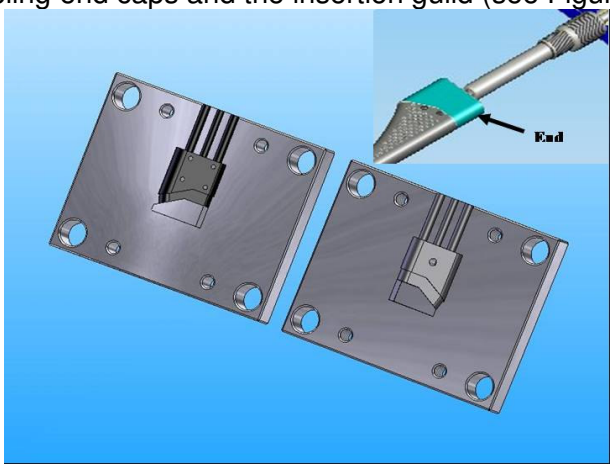


Figure 3: CAD image showing the tooling for the manufacture of the injection moulded rasp unit end drive cap design (see inset).

WP3 Drive Mechanism Development and Prototype Production

Technical Objectives:-

- To develop the process science for the production of the drive head that will carry the rasp device and any additional tooling that may be required during the operation.

Progress Made during period 1

Progress:

- Following the series of tests carried out using a prototype Piezo drive to determine voltage frequencies required to cut bone tissue, Cedrat are now using the data to develop the drive further.

Deliverable Status (D 7):

Using the data from the PZT drive rig, Cedrat have been able to use this information to characterise the drive mechanism and PZT actuator.
Designs of the drive unit will be made once the final drive actuator has been identified.

Task 3.2 - Development and Prototype Production of the Electronic Amplitude Generation Unit

Objectives

To develop and Produce a unit for the generation of the required voltages and frequency's to drive the piezoelectric stacks contained within the drive mechanism.

Progress:
This task cannot be started until the final drive mechanism actuator has been identified. It is intended that this task be started before the next meeting.

Deliverable Status (D9):

Tooling for the manufacture of the rasp body units has been designed and tooling is currently being manufactured to these drawings. Prototypes of the rasp body units should be ready for testing before the next meeting

Progress made during period 2

- The drive mechanism progressed from the original design (using the APA500 actuator supplied by Cedrat) which was considered not to have sufficient force generation for the insertion of the rasp unit, following the manufacture of the hand held unit it was also considered too large for manipulation by a surgeon (Figure 4). As a result of the insufficient output from the mechanical actuator a second actuator was designed with the PZT's stacked in-line with the rasp unit, this produces a larger force generation however, it also decreases the amount of stroke that can be achieved (Figure 5).

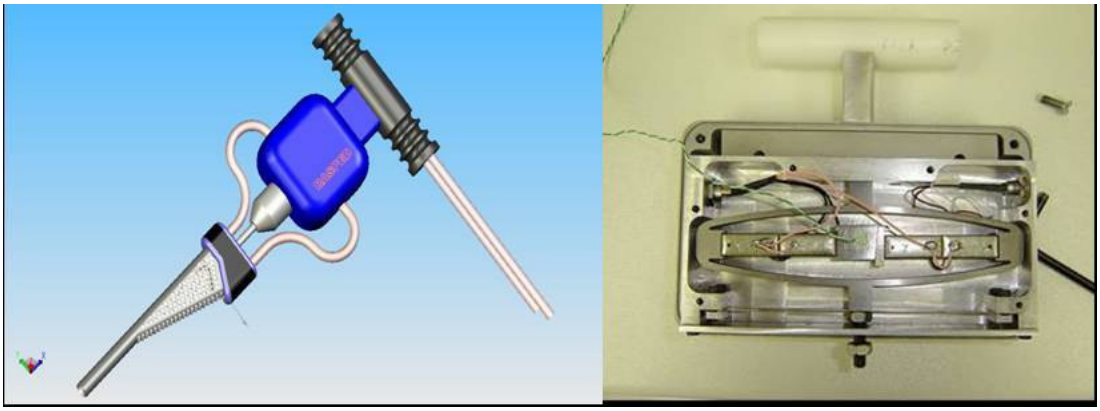


Figure 4: Proposed body design for Piezo Drive and photograph of the actual body fitted with a mechanical PZT drive.

- The newly designed PZT drive mechanism went through several re-designs before the final configuration was decided upon. The new unit consists of a pistol grip housing incorporating a PPA 60L PZT actuator (supplied by Cedrat) (see Figure 5).

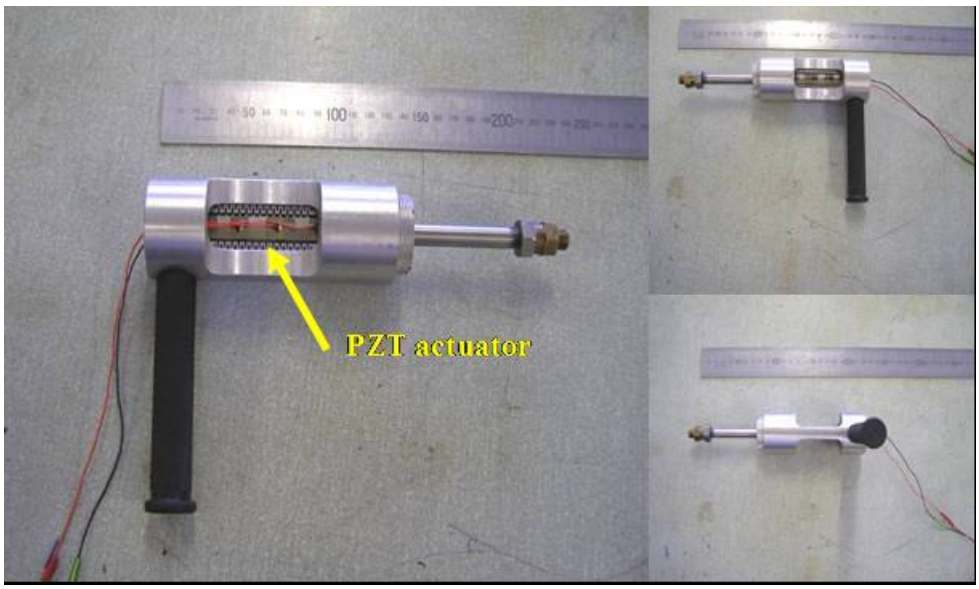


Figure 5: Photograph showing the new drive housing incorporating the PPA 60L PZT actuator

- To drive the new PZT actuator a bespoke circuit board was designed and manufactured (see Figure 6). The board was designed to fit into the amplifier used to drive the original mechanical APA500 actuator, once incorporated this unit will had the flexibility to allow the PPA 60L unit to be drive at either set frequencies or with the incorporation of a variable resistor the frequency could be changed.

- Following test with the new modified cutting edged rasped unit the PZT tests were re-done. The results of this test showed that the PZT drive unit produced insufficient force or movement to drive the rasped unit into the saw bone femur.

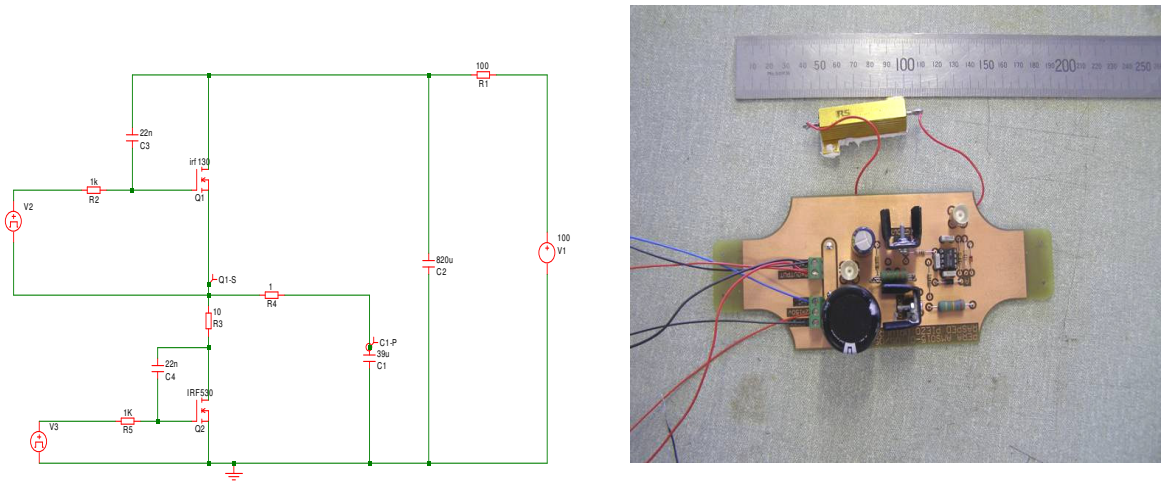


Figure 6: Circuit design and production for the electronic amplitude generation unit

Work Package 4 Mechanical Validation and Trials

Technical Objectives

- Validation of the Drive Mechanism with Respect to the Movement and Force Generation
- Evaluation of the Rasp will be Performed to Determine the Optimum Material Removal Rate has been Achieved

Progress

Using the circuit board designed for the PPA 60L, PZT actuator bench tests were performed to optimise the rise time in order to generate the maximum mechanical output from the PZT stacks. Following these bench tests the newly designed drive unit were attached to a rig designed to allow the rasp to increment into saw bone material in a controlled manner. Trials were performed to evaluate performance of the drive mechanism with respect to it cutting potential in saw bone material and to identify the optimum material removal from the rasp unit was being achieved (Figures 7 to 9).

During the course of the testing the signal generated by the amplification unit was monitored so the optimum parameters could be monitored. As a result of this some small changes to the circuit board were made so that the optimum response time from the PZT actuator was obtained.

Figure 7: Photographs showing the modified mechanical PZT testing rig and the associated drive unit for powering the PZT at the correct frequency.

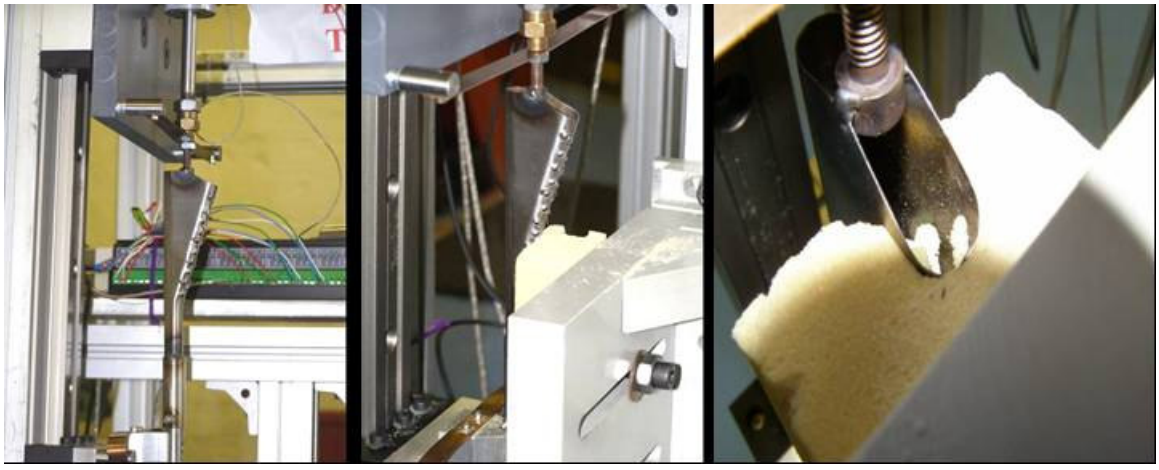


Figure 8: Photographs of the rasp cutting into simulated trabecular bone tissue.

Figure 9: Photograph showing the chips removed from the rasp following simulated trabecular bone cutting test.

Revised Sample Tool Manufacture following tests

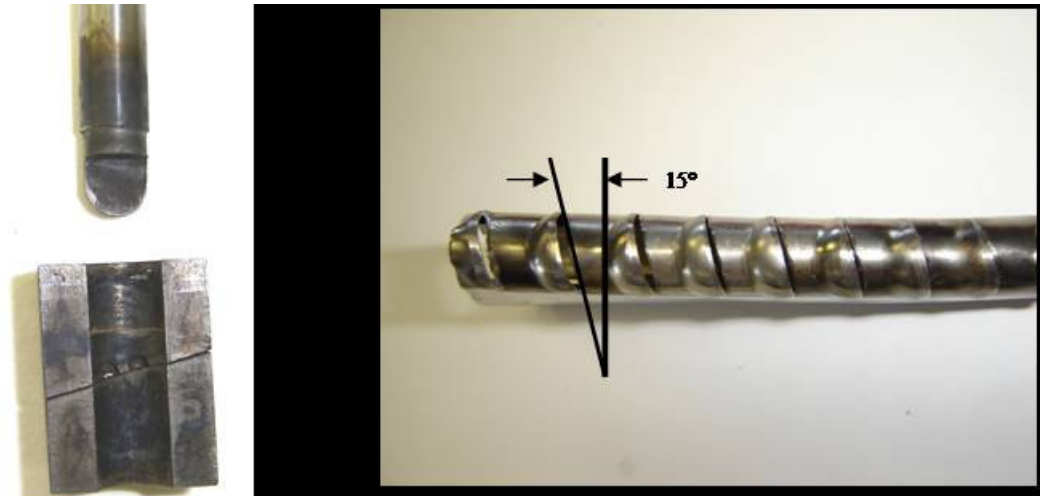
Testing using the rasp unit in conjunction with the new PZT drive unit was performed and as can be seen from the previous section good chip geometry was obtained. However, these tests identified several problems with the current rasp design. The first of these being the absence of teeth along the seam of the cutting edge this had the effect of allowing the rasp unit to become wedged in the material or to displace material instead of cutting it. Another problem encountered was during the forming process of the cutting edge. Although the press tools had been modified with recesses to protect the teeth, there was evidence of cracking as the material was formed around the radius (see Figure 10). .

Figure 10: Shows initial design (left) and the difficulty in forming after blade cusps following pressing.

To overcome these problems it was decided to manufacture the rasp unit in two sections (see Figure 11) with the cutting area being made separately and welded onto the main body. This allows the teeth to be generated around the full cutting face of the rasp units, it also allows for the generation of a series of new cutter designs which would lend themselves to changes in the cutter geometry.

Figures 12 and 13 show two variations of the new configuration of cutting teeth, they also show the additional press tools manufactured to create different cutting edges. The advantage of forming a separate cutting edge is that the cutting teeth/cusps can be generated on completion of all the forming operation thus preventing tearing at the side of the teeth/cusps.

Figure 11: Rasp made in 2 pieces



Figures 12 Tooling for angled cutting teeth (full width)

Figures 13 Tooling for parallel cutting teeth.

To form the cusped cutting edge it was decided to generate some of the cusps prior to forming the final shape then finish the interstitial cusp following the forming operation. To achieve this aim it was decided to adapt some of the existing tooling (see Figures 14 to 16).

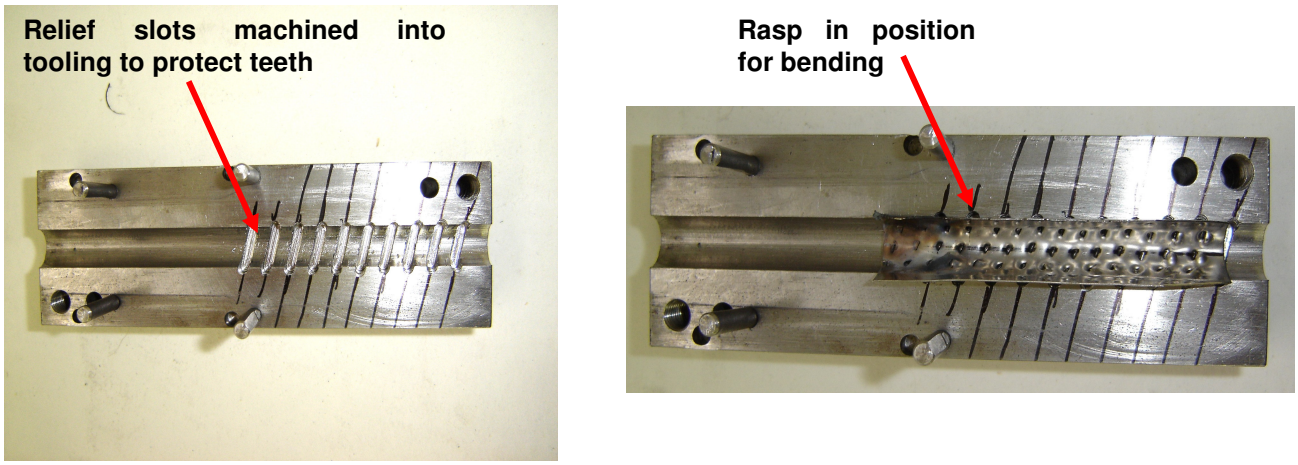


Figure 14: Photographs of modified tooling designed to protect the pre-cut cusps during the forming operation.

Figure 15: Photograph showing the hole punch tool for the formation of the cusps.

Figure 16: Photograph of the final rasp with the cusped cutting edge

The three new rasp designs have been supplied to Hunt Developments for analysis with respect to sterilization and packaging.

In summary earlier testing with the initial samples highlighted design problems with the cutting edge and for this reason a new configuration of cutting edge was generated that would facilitate several different cutting geometries.

- Cutter tests were performed using the re-designed cutter test rig.
- Testing on simulated saw bone material showed that the new PZT actuator and associated electronics were not capable of driving the rasp unit.
- The chips generated by the rasp (Figure 9) unit had a uniform shape, thus indicating a correct cutting angle was used for their formation.
- Testing using the saw bone showed that the cutting teeth pitch was not correct on the rasp unit and that the middle section of the rasp (were the units will be laser welded) needed to have cutting teeth as well. The rasp unit bottomed out on these sections and thus drive through the materials was not achieved.
- In order to overcome this, a new shape of rasp unit cutting geometry has been designed and manufactured
- Prototype Acetabulum reamers with different cutting patterns were produced along with a drive tool (Figures 16 and 17) and tested satisfactorily during the extension period.
- A selection of alternative drill bits (Figure 18) for initial “pilot drilling” of the bone were also produced in this reporting period

Figures 16 and 17: Three types of acetabulum reamers and the drive unit.

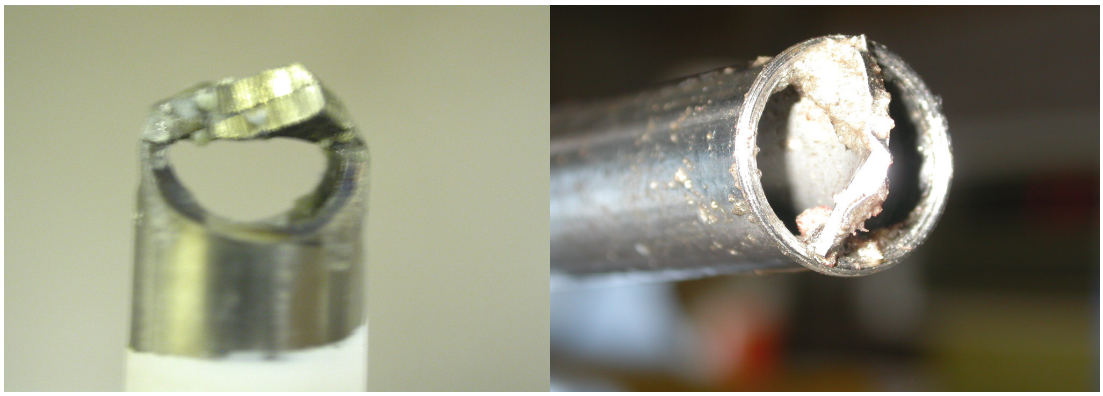


Figure 18: Alternative drill bits

Rasp cutter evaluation trials

- The newly developed prototype auxiliary tools for the formation of the pilot hole in the femur and for the formation of the recess in the acetabulum have been tested.
- The results of this testing showed that the drill bits clogged at approximately 50-75mm or the tips of the drill bits became loose and thus the cutting action was lost due to rotation of the tips.
- Three variation of the acetabulum reamer were tested:-
- 1/ had a series of cusp/teeth in a spiral pattern around the hemisphere.
- 2/ had a series of cups/teeth in a crossover pattern over the hemisphere.
- 3/ had a series of slotted teeth across the hemisphere.
- The results of this test (Figure 19) showed that the crossover cusps/teeth gave the best results. All the testing was initially done on saw bone material then on actual bone tissue.
- Five new shaped rasp cutters were provided to Southampton who satisfactorily performed tests with them.

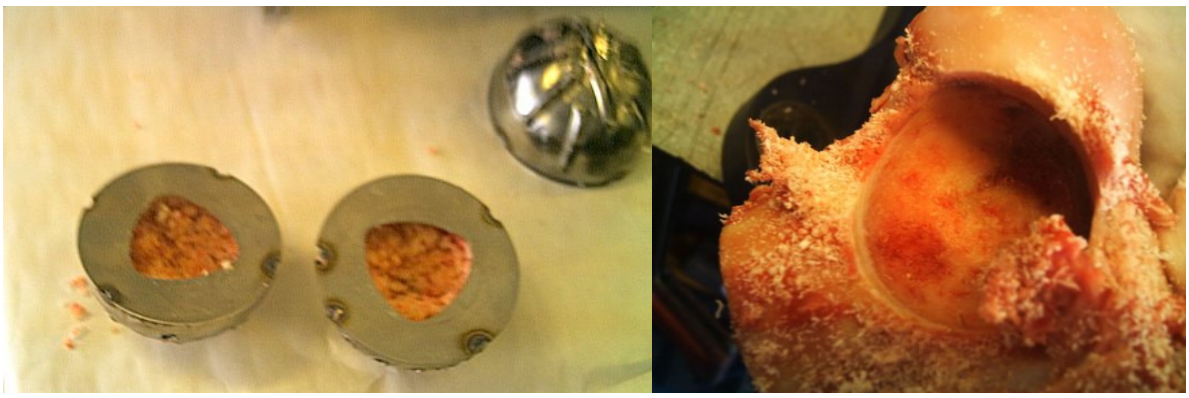


Figure 19: Acetabulum reamers with the cut debris in them. The bone used in the test shows the perfectly formed hemisphere.

WP5 Pre-clinical Validation Trials

Technological Objectives:-

- To determine the optimum process for the sterilisation of the rasp components.

Progress

- The final materials for the rasp unit has now been identified as 316 stainless steel and polypropylene Moplen HP500N for the drive interface, sample made in these materials were sent for sterilisation and cytotoxicity testing.

- As series of designs for the packaging were developed based around both the rasped unit and acetabulum reamer. From these designs blister packs were manufactured and tested for their burst pressure.

- To demonstrate the blister pack seal integrity by means of accelerated aging of sealed blister packs containing representative samples of EN 316L stainless steel rasped units and to ensure a shelf life of 3 years. Samples were prepares and tested in accordance with the requirements of ASTM F 1980-02. The results indicated that there was no detrimental effect on the package seals and the blister pack burst pressure was twice that required by the specification for this type of device.

- Samples were tested in accordance with the ISO 10 993 for CE marking of a device of this nature. Cytotoxicity testing of the samples showed no bacterial deposits and as such were consider inert and suitable for use within the body.

WP6 Exploitation & Market Stimulation

Technological Objectives:-

- To develop and establish exploitation mechanisms for the project results.

Progress made during period 1

Progress:

- Patent searches have been made to review what is currently on the market and Finsbury have applied for a patient to cover the rasp unit. Likewise Cedrat have looked at the possibility of patenting the drive mechanism.

- Deliverable Status (D4):

- A draft plane for the dissemination of the project technology has been done and a copy of the DUP is attached to this report.
- The SLA's that have been manufactured will also be used for this purpose.
- As already mentioned a rasp prototype is currently being manufactured, these will be used for market stimulation of this technology.

- Records have been filed researched of various manufacturing techniques for the rasp tool

- A web site for the project has been set up and contains all of the information (reports photos and cad drawing) for the project.

- All of the partners have a link to this site and are able to view this information. This information can also be used for the stimulation of the technologies developed during the course of the project.

- Molnlycke have started to look at ways for the dissemination of the technologies developed during the course of this project. They will use the data and samples manufactured to help with this market stimulation.

Progress made during period 2

- A patent has been applied for and the claims are currently in the process of being finalised.

- A paper on the raped testing was presented at the International Society for Technology in Arthroplasty Conference (ISTA) to be held in New York USA (see Figure 20).

- Samples of the rasped unit have been presented at the Medical Device Technology exhibition in the UK.

- The rasped unit together with the acetabulum reamer have been presented to surgeons for the feed back and comments. This exercise has also been used for market stimulation of the devices.

- The web site has been maintained with all of the project information and contains all of the reports photos and CAD drawing for the project.

- From this web site all of the partners have been able to keep themselves up to date with the project progress and us it for dissemination of the project results to their staff.

A SINGLE USE DEVICE TO REDUCE STRESSES GENERATED IN HIP PROSTHESIS SURGERY

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****Finsbury Development, Leatherhead, Surrey, United Kingdom*

Introduction

The impaction of a tamp or broach into the intramedullary canal can result in high stress generation within the femur resulting in intra-operative femoral fractures. This effect may be exacerbated by the compaction of bone debris during broaching[1]. A further possible complication of reusable devices such as these is the potential for cross-contamination due to inadequate sterilisation between operations[2].
The present work aims to address these potential problems by developing a cost effective, efficient, single use broaching device, or rasp.

Methodology

The optimum cutting edge geometry for the single use device was ascertained using a dedicated planing device. A series of single use devices were then manufactured from sheet steel incorporating these design features; a final rasp design was proposed based on the relative cutting performance of these rasps – Figure 1. To reduce costs, the rasp had a hollow design which allowed bone debris to be collected within the rasp during impaction.

A standard stainless steel broach and the single use device were compared via impact tests on sawbone (Sawbones Europe AB, Sweden). Each sawbone was strain gauged to allow strain to be monitored in the most highly stressed region of the bone – Figure 2. The broach/rasp was repeatedly impacted into the prepared intramedullary canal with an equivalent force of ~25kN – Figure 3. Strain development in the analogue bone and penetration per impact were monitored.

Figure 1 - Hollow Rasp

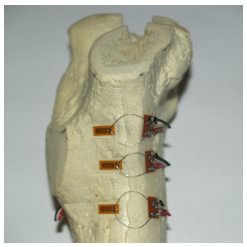


Figure 2 – Strain gauged sawbone femur

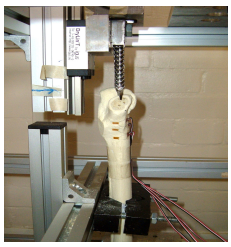
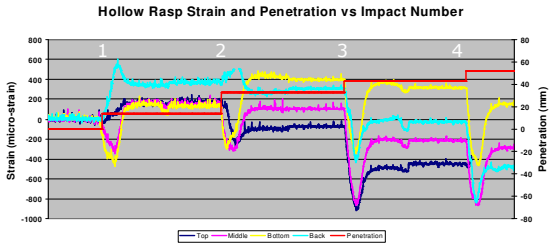


Figure 3 - Drop test set-up showing hollow rasp above prepared sawbone

Results & Discussion

Shallower cutting angles gave the least force required to shave the analogue bone. The use of a serrated blade further reduced the force requirement.
Impact tests demonstrated that the rasp was more efficient at penetrating the sawbone intramedullary canal, achieving up to 60% increased penetration for the same number of impacts. Using a hollow rasp, the contents of the intramedullary canal can potentially be removed rather than compacted leading to lower instantaneous and residual strains. The plots show that the hollow rasp produced a consistent penetration per impact, and the strain reached an equilibrium level sooner – Figure 4. In contrast, the penetration reduced with number of impacts for the solid broach. The total strains induced as a result of solid broaching were higher than those from rasping (up to 350% in one case).
Up to ten impacts were required by the solid broach before the strain induced had converged to a maximum value (up to 600 microstrain); this coincided with the broach reaching its maximum possible penetration. Conversely the hollow rasp tended to reach maximum penetration after 4 impacts, with the strain maximising at ~400 microstrain. These results indicate that in the clinical situation, less damage would occur in the surrounding tissue, and the possibility of initiating fracture would be reduced.



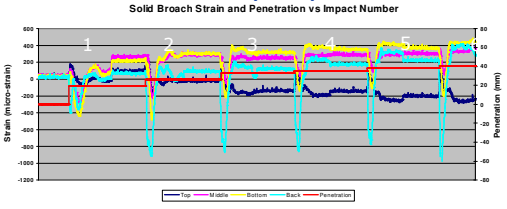


Figure 4 – Typical Strain/Penetration plots during impact for the (a) Hollow Rasp (above) and (b) Solid Broach (below)

Conclusions

The results show that the hollow rasp is a promising alternative to the solid broach. Increased penetration was consistently produced with lower strains during impact tests. The elimination of cross contamination with a single use device further highlights the potential of this technology.

References

- Soren, K. et al, Clin. Orthop. Rel. Res. 408:180-188, 2003.
- Sterilisation may not kill CJD – BBC Aug 2006; http://news.bbc.co.uk/1/hi/health/5281100.stm

Acknowledgement

The authors would like to thank the EU for sponsoring this project under the 6th framework.

PERA THE INNOVATION COMPANY FINSBURY ORTHOPAEDICS

Figure 20: Paper presented at New York seminar.

WP7 Project Management

Technological Objectives:-

- To ensure that all knowledge is created, managed and disseminated in a coordinated and coherent manner, along with all technical activities, legal aspects and other issues.
- To ensure that all aspects of the EC requirements for communication and reporting are met.
- To co-ordinate the overall legal, contractual, financial and administrative management of the consortium.
- To co-ordinate gender equality, ethical and science and society aspects of the project.

Deliverable No	Deliverable title	Delivery date Month	Nature	Dissemination level
D10	Production of 60 rasp samples for test evaluation	16	P	PP
D11	Production of hand held drive mechanism	14	P	RE
D12	Production of electronic amplitude generator	14	P	RE
D13	Test and evaluation of the drive mechanism	17	O	RE
D14	Test and evaluation of the rasp device	17	O	RE
D15	Pre-clinical test results compliance analysis	22	O	PP
D16	Pre-clinical micro analysis and debris evaluation	19	O	PP
D17	Prototype components, including cost benefit analysis	24	O	RE
D18	Design Guide Production	24	O	RE
D19	Industrial & Economic Validation	24	O	RE
D20	Organise kick-off, mid term and final meetings.	0	O	CO
D21	Delivery of six month progress report, mid term review report and final report..	6	R	RE
D22	Delivery of a month 12 report, Submission of the cost statements	12	R	RE
D23	Delivery of a month 24 report, submission of cost statements.	24	R	PU
D24	Delivery of the finished Plan for the Use and Disseminating the Knowledge.	Finished 24	R	RE
D25	Provision of audit certificates and amended consortium agreement (if applicable)	24	O	RE
D26	Report on gender, societal and ethical issues of exploitation	24	r	RE

Progress made during period 1

- A draft for the dissemination of the knowledge for this project has been generated and some potential seminars and exhibitions have been identified. Co-operation between the partners is good and co-ordination of the task between the partners is progressing well with some of the tasks already being completed.

- Deliverable Status (D4):

- A draft plan for the use and dissemination activates has been generated.

- The six month report has been issued to the Commission and a copy of all the reports has been placed on the project web site. Several working party meeting have been attended by partners as well as technical meeting with all partners present. The year one cost statement are currently being prepared and will be submitted to the commission, an extension to the delivery of these has been requested and granted by the commission.

- Deliverable Status (D20/21/22):

- A kick off meeting was held at Pera for the commencement of the project, a six month report was issued with a copy being placed on the web site. The month 12 report will be issued along with relevant cost statements.

- To co-ordinate the overall legal, contractual, financial and administrative management of the consortium.

- A consortium agreement has been signed by all partners and a review of this has taken place during the technical management meeting.

- **Progress made during period 2**

- All of the information generated during the course of the project can be access by all of the partners and the European Commission at any time *via* the website. The information on this site is secure so that only etherised personnel can use the information for dissemination activities.

- All deliverable reports have been submitted to the European Commission within the reporting period. The month 12 activity and financial report were delivered to the commission on time and the finale reports will accompany this one.

- All management progress meeting have been well attended by all partners.

Progress made in period 1

D1

A test rig for the drive development was manufactured to determine the correct force and frequency needed to cut trabecular and cortical bone tissues

D2

A drive mechanism was developed by Cedrat for testing with bone. Initial trials have been satisfactory.

D3

A detailed report was generated for both the work performed on the materials testing and for the drive mechanism actuator.

D4

A draft plane for the dissemination of the result was produced.

D5

Several designs of the rasped unit were done and cutting geometry analysis was performed. From this data a final design of the rasped unit was manufactured.

D6

Two main materials were identified for the rasp body (a carbon steel and a carbon steel with a titanium coating and a low grade stainless steel); Also the materials for the connector was identified and was tested during the second reporting period of the project. Cytotoxicity testing was performed on the initial material.

D7

Preliminary designs for the drive unit was generated, however the final design for the drive mechanism was not finished until period 2. Two designs for the rasped unit were produced and tested.

D8

The work performed on the drive mechanism rig has showed that the PZT will not be driven at ultrasonic frequencies and therefore will not affect the mechanical strength of the polymeric material. However, testing has shown that the material used for the connector has to be rigid in order to prevent loss of drive capability.

D9

Designs of the rasp body have been generated and the manufacture of the prototype tooling has been started. This work was subsequently finished during period 2

Progress made during period 2

D10

Samples of the rasped unit were manufactured and evaluated during deliverable 14, from the result of this testing modification were made to the raped unit and additional rasped units were manufactured.

D11

Two Type of PZT drive devices were manufactured, in both cases they were designed around the size and shape of the actual PZT drive units being tested. The first design proved to large and cumbersome to manipulate due to the size of the PZT unit being used. Therefore a second unit was designed with a pistol type housing incorporating a cylindrical PZT Unit.

D12

An amplification circuit board developed and manufactured to drive the PZT units at the correct frequency allowing for the optimum force generation. This circuit boar was then integrated with controller used to drive the PZT.

D13

At test rig was manufacture for the testing of the PZT drive unit and a rasped unit was attached to the end of the PZT. Testing with this showed that the rasped unit had a design problem which was subsequently modified and the testing was repeated. The result of this testing showed that the PZT drive did not have sufficient power to generate the required forces or movement and therefore a decision was made not to use the PZT as the method of driving the rasped units into the femur.

D14

Testing of the raped unit showed that the initial design had a problem with the seam down the centre of the cutting edge. To over come this problem the rasped unit was re-designed and new rasped units were manufactured with a separate cutting blade. The results of the new rasped configuration showed that it was capable of removing material from the intramedullary canal of a saw bone femur with out too much difficulty.

D15

Rasped sample were tested to look at the amount of force required for insertion into the femur compared to the existing techniques and to observe the amount of material removed during this operation. The results of this test showed that the new rasped configuration reduced the impact force and hoop stress generation compared to the existing broaches currently used.

D16

Rasped unit were supplied for packaging and sterilisation trials, these included blister pack burst testing and accelerated aging of the pre-packed devices. Following this Cytotoxicity testing was performed and the result showed that no bacteria was evident following this so the samples were classed as inert.

D17

During this work package the process route for the production of the rasped 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 rasp unit in order to facilitate the manufacture of the components. Rasped unit were produced and have been demonstrated at exhibitions and seminars both within the UK and USA. Evaluation of reproducibility was considered and it was determined that due to the manufacturing route chosen that this would not be a problem. 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.

D18

To disseminate the results of this project seminars were attended were papers were presented. As well as presenting to international seminars local dissemination activities were also performed. These took the form of presentation of the project results to local hospitals and during internal information strategy presentations within some of the organisations that participated in the project.

D19

As part of the industrial and economic validation for the rasped unit market analysis was performed on the potential manufacturing cost compared to the cost of manufacture and sterilisation of existing devices. The result of this analysis showed that the rasped and acetabulum cup units could be made for less than that of the sterilisation. Using this information it is intended stimulate market sectors for reusable instrumentation.

D20

Andy Taylor welcomed the attendees and went through the meeting agenda giving apologies for those members that could not attend. The purpose of the **kick-off meeting** was explained and that the project had been under way since the 1st November 2004. He also explained that due to the start date documentation not arriving from the EC until the end of November this had been the earliest possible time to have the meeting. Andy then gave apologies on behalf of Fotini Zianga the European Commission's Scientific Officer who was unable to attend.

The month 12 meeting was hosted by Incerplast and held at the Times Golden Tulip Hotel in Bucharest Romania. The meeting was started by welcoming the partners for attending and giving apologies for the partners that could not attend. Following this presentations were given on the project progress by the relevant partners and RTD performers. During the course of the meeting work needed to be performed over the next reporting period was discussed. Following the meeting a tour of Incerplast was give highlighting their current product ranges and process capabilities.

Dr Andy Taylor opened **the month 24 meeting** and welcomed the attendees to Finsbury.
The attendees commenced by discussing positive ways to take the project forward. From the discussions that took place, it was established that there was an urgent requirement for further prototype samples of acetabulum reamer – to enable essential trials to take place for joining together of the dome shaped cuter to the back driving disc. These need to be urgently manufactured by PERA and delivered to Hunts.

D21

A six month and 12 month progress report were submitted to the European Commission and all questions arising from the reports were answered. This year 2 period report will be submitted but will be late by approximately 4 days after the reporting period.

D22

The Month 12 management report was delivered to the European Commission within the reporting period.

D23

The month 24 management report will follow this activity report but is expected to be late by approximately 5 days after the reporting period and will need to be amended as the collation of the audit certificates is proving to be time consuming.

D24

The plane for use and dissemination has been completed and as already mentions some of the dissemination activities have already started.

D25

Audit certificates will follow this report as soon as they become available, as already stated this is proving to be a difficult and time consuming task.

D26

The aim of this deliverable is to provide information on ethical and gender issues relating to this project. The animal materials used for the testing of the rasped unit were obtained from animal already sacrificed for their meet products and were not sacrificed as a result of any work performed during this project. Every effort was made to ensure that all gender issues were covered fully during the course of the project, this was done by ensuring that 29% of the technical input to the project was from female staff. All research was performed on both genders to evaluate potential difference that may occur between male and female prosthesis