Moulding the Future of Patient Specific Instrumentation – the Shape of Things to Come

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INTRODUCTION

It is well known that the accurate placement of orthopaedic hardware such as arthroplasty prostheses into a biomechanically derived optimum position is of paramount importance in the long term success of these interventions[1,2,3]. Similarly, in many orthopaedic procedures it is advantageous or even essential to know the exact placement of hardware such as screws or pins, for example in spinal surgery or complex fracture reduction. Two main technologies have been developed to facilitate accurate placement: bespoke patient specific instrumentation such as rapid manufactured guides and orthopaedic surgical robots. Both technologies enable good results but are hindered by well-known significant drawbacks such as very high cost, incredibly complex logistical chains, poor versatility and long set up times[4,5].

This paper presents a radically new technology developed to overcome many of the drawbacks of existing approaches whilst providing a means to accurately place any orthopaedic hardware according to a pre-operative plan. The approach allows accurate bespoke drill/cutting guides to be rapidly produced intraoperatively at minimal cost per patient using a simple low cost hardware element and disposable consumables. In this paper, the technology is described around the framework of a total shoulder arthroplasty, more specifically, the placement of the glenoid component according to a pre-operative plan. The results of an ex-vivo validation and accuracy study will also be provided.

Materials and Methods

The method comprises two main intraoperative components: A re-usable hardware element and two disposable sterile consumables. The hardware component is made up of an optical 3D scanner (HDI 120, LMI Technologies, Delta, BC Canada), a 2 axis Computer Numerical Control (CNC) drill with replaceable sterile drill bit and a 3 axis CNC receptor assembly for the sterile disposables. The sterile disposables comprise a plastic element with standard geometry coated on one side with a body of mouldable material able to be rapidly solidified, for example by exposure to air, heat or light and a carrier element to allow an interface with the non-sterile surfaces of the receptor assembly. The disposable component is able to be inserted into the hardware element receptor in a known way by virtue of its standard geometry. With the exception of the mouldable element, all elements of both components remain spatially and positionaly calibrated with respect to one another.

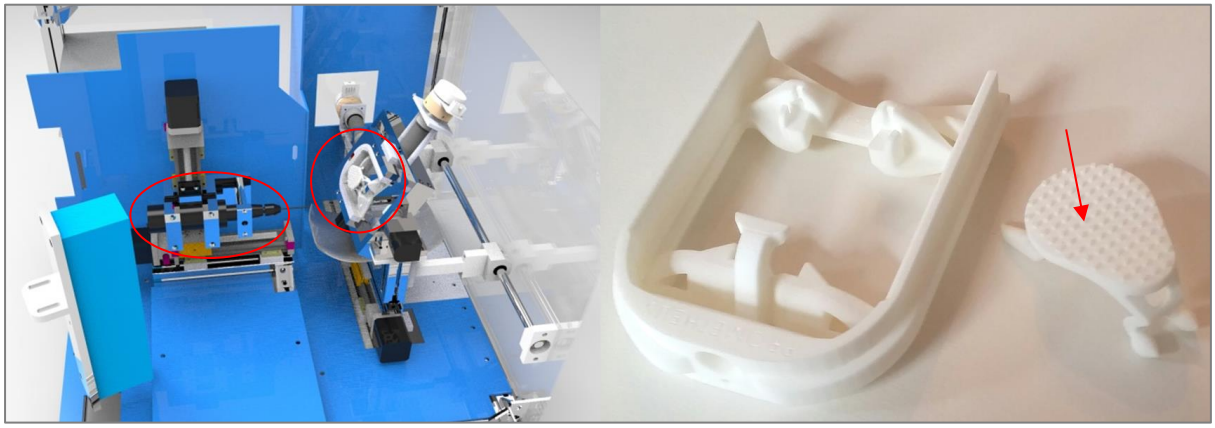

Figure 1 – Left image: interior of the re-usable hardware element showing CNC drill and CNC receptor assembly for the sterile disposable component (red circles from left to right). Right image: Sterile disposable element (red arrow). The indicated surface has a body of mouldable material when in use. Image also shows a sterile enclosure lining allowing the sterile element to be placed into the non-sterile hardware and independently removed easily.

The approach consists of 9 steps in the intraoperative production of a functional guide.

1. A patient undergoes a conventional MRI or CT imaging study. As usual, this data is used to plan the axial and spatial position of the hardware requiring placement. In the case of this example, a guide wire to be placed into the glenoid cavity to define the eventual position of a glenoid prosthesis. The planning process defines the guide wire position as a vector within the coordinate frame of reference of the digital scapula model. This plan may be carried out at any time convenient for the surgeon. It is only required to be completed by step 6 of the process hence may be carried out whilst in theatre on the hardware inbuilt computer.
2. The operation begins and the surgeon exposes the surgical site in the conventional manner. In this case, the humeral head is dislocated and sectioned exposing the osseous anatomy of the glenoid cavity.
3. The sterile disposable consumable is handed to the surgeon. The mouldable side of the component is pressed into the surgical site (the glenoid cavity) and quickly solidifies forming an impression of the glenoid cavity and its edges.

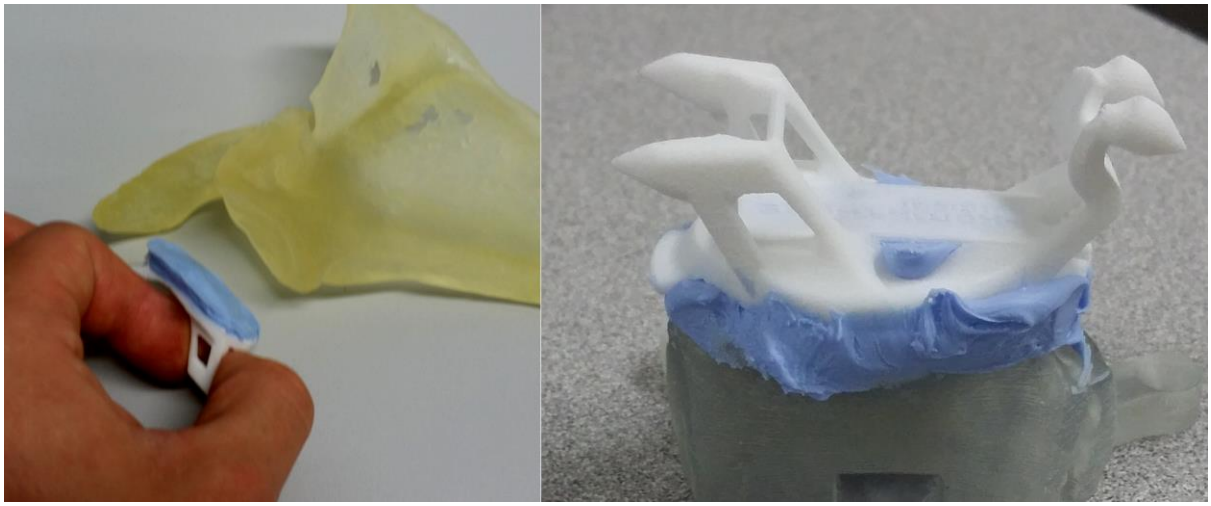

Figure 2 – sterile disposable element being pressed into glenoid surface forming a mould. In this figure, the operative site is represented by a 3D printed scapula and glenoid model respectively.

4. The component is removed and placed into a set position within the sterile disposable carrier which in turn is placed into the corresponding receptor assembly of the hardware element.
5. The optical scanner scans the surface of the mould, in this case modified with an impression of the glenoid cavity.
6. The scan data is inputted into a software registration module based on the classical Iterative Closest Point (ICO) algorithm, which registers the glenoid surface mould scan with its corresponding position on the imaging derived patient anatomy. In this way, the scanned glenoid surface model is automatically placed into the same coordinate frame of reference as the original 3D patient scapula model. As a result, the vector describing the location of the guide wire may now intersect the digital glenoid surface mould model. From this data, a CNC drilling path is now created.

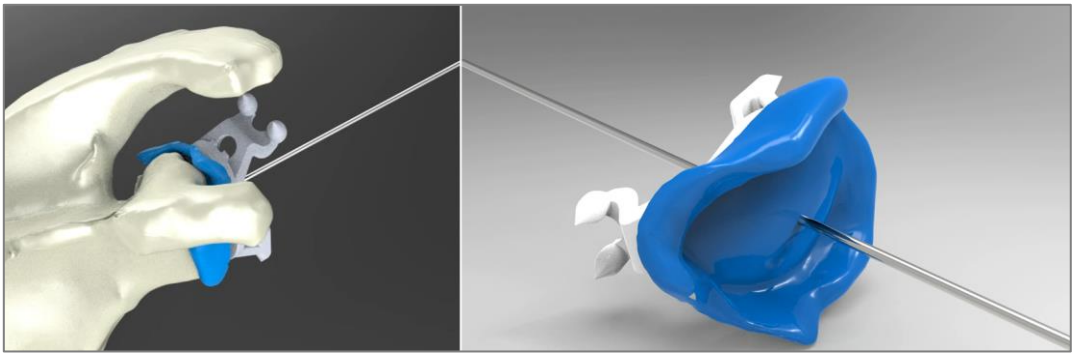

Figure 3 – Visual representation of the algorithm process. The registration process places the virtual disposable (as defined from the optical scan) onto the digital patient anatomy as shown in the left image. The guide wire geometry may now be expressed in the same frame of reference as the disposable (as shown on the right image) hence a drilling path may be calculated in order to modify the physical disposable itself.

7. The CNC drill fitted with a sterile drill bit and the CNC receptor assembly is repositioned according to the output of the planning module, which is based on the registered scan data, in order to drill through both the mouldable element and the standard component such that the hole drilled matches the geometry of the guide wire vector passing through the digital glenoid surface mould model.

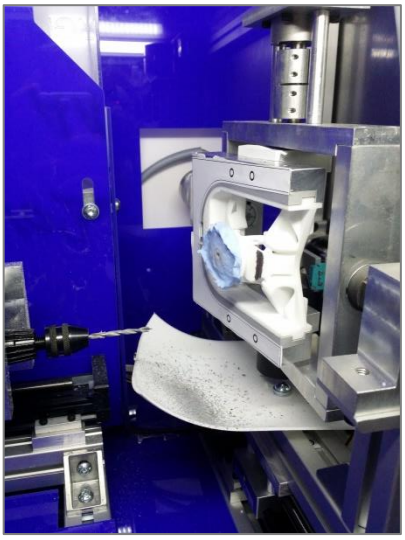

Figure 4 - The CNC drill (fitted with sterile drill bit has been completed its modification of the sterile disposable element seen in the centre of the image. The drill and sterile disposable receptor assembly both configure themselves such that the hole drilled exactly corresponds to the pre-operative plan.

8. The sterile disposable element is removed from the machine by the surgeon and placed back into the operative site. Its solidified moulded geometry guides it back into the identical positon from where the mould was taken. The prepared guide hole may now be drilled through by the surgeon placing a guide wire into the exact pre-planned position. Once this is complete, the disposable may be slid off the guide wire and discarded leaving the wire in a pre-operatively planned position.

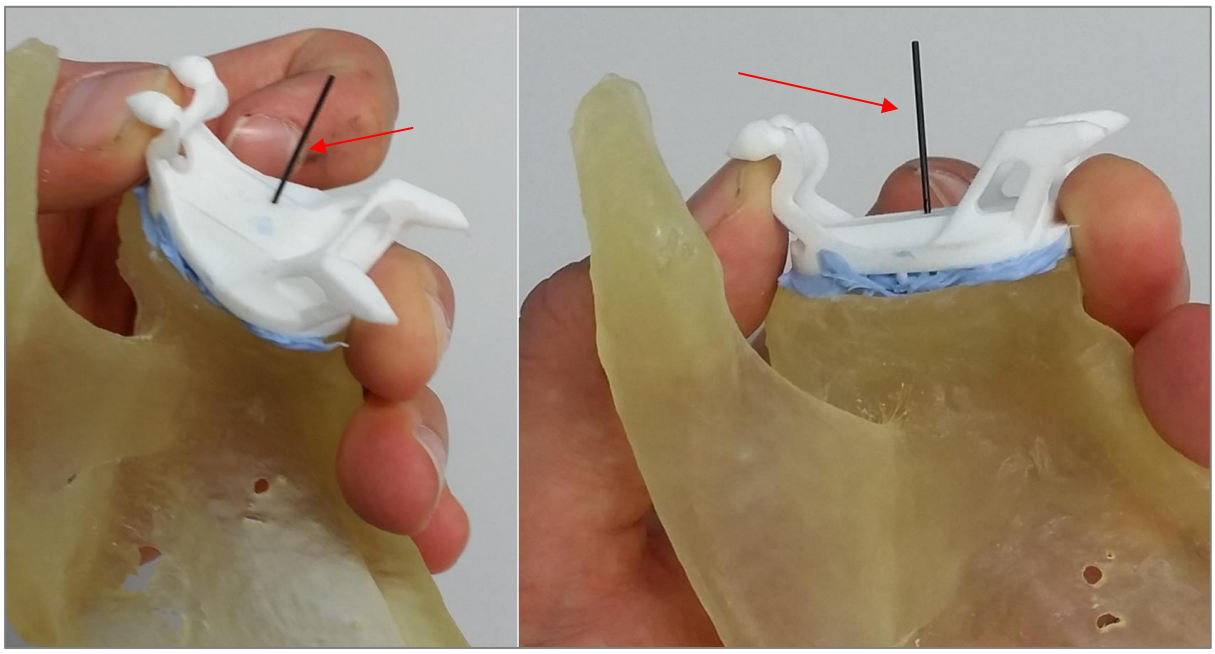

Figure 5 – The modified disposable element can now be placed back into the exact location on operative anatomy from where the mould was taken. The element 'locks' into place by virtue of the solidified impression on its underside. A guide wire (indicated by red arrow) can now be drilled through the guide in the correct position.

9. The surgery may now continue in the conventional manner.

A prototype device was constructed from a combination of 'off the shelf' components and specifically designed 3D printed parts. Bespoke software was created in order to allow all of the above steps to be carried out in one computer programme. The prototype is controlled either with the use of a built in touch screen PC or an external desktop computer. The prototype is able to demonstrate a full operative surgical workflow including the maintenance of sterility of all parts that come into contact with the patient and operated by scrubbed personnel.

A rapid setting dental bite registration material (GC EXABITE II NDS) was used for prototype testing however it is conceived that any sterile, non-toxic rapidly setting mouldable material may be used in its place.

Full ex-vivo testing was carried out to assess the feasibility of the approach in terms of accuracy, manufacture time and ease of use.

10 anonymized shoulder CT scans of patients requiring arthroplasty were collected and thresholded to produce a 3D model of patient anatomy. A consultant orthopaedic surgeon with arthroplasty experience planned the ideal guide wire position in each scapula in order to place the glenoid component into an ideal position. Three planar markers were also added to each glenoid model so as to create a reference plane upon which to compare guide wire placement accuracy. A pair of each scapula glenoid was 3D printed (Objet Eden, Stratasys company USA) to produce two groups of 10 identical models: a guided group and a conventional group. The surgeon manually placed a guide wire into all glenoids in the conventional group according to the bespoke plan created for each glenoid. The prototype was then used in the guided group to place guide wires according to identical bespoke plans for each glenoid.

Guide wire placement was subsequently analysed in both groups and compared to the pre-operative plan. Accuracy was measured in two ways: minimum distance between planned glenoid entry coordinate and achieved vector axis of physical guide wire (mm) and absolute angle (º) between planned guide wire axis and achieved physical guide wire axis.

RESULTS

Full guide manufacture was completed in an average of 5 minutes including planning, moulding and device set up. In the conventional group, placement accuracy was 1.580mm and 6.815° in comparison to the guided group achieving 0.747mm and 1.772º. Student's t-tests were applied to the minimum distance and the absolute angle metrics and they were both shown to be statistically significantly affected by the method (manual vs. automatic) at the 95 % confidence interval ($p < 0.05$).

	Conventional Group		**Guided Group**	
Glenoid #	**Minimum distance (mm)**	**Absolute angle (°)**	**Minimum distance (mm)**	**Absolute angle (°)**
1	0.843	5.425	0.218	1.769
2	1.626	6.196	1.005	1.451
3	1.684	16.629	0.278	1.675
4	1.562	5.784	2.496	1.858

5	2.027	2.705	0.876	0.075
6	0.804	7.51	1.307	1.718
7	2.413	11.329	0.345	1.468
8	3.224	5.409	0.173	2.248
9	0.490	1.193	0.123	3.628
10	1.133	5.976	0.653	1.838
Average	**1.580**	**6.815**	**0.747**	**1.772**

Table 1: results from ex vivo testing on 3D printed models.

DISCUSSION

With a total guide manufacture time of 5 minutes, extremely cheap consumables, a simple hardware unit and the ability to accurately place orthopaedic hardware into a pre-planned positon it is evident that this approach combats many of the drawbacks of existing orthopaedic guidance technologies.

Whilst carrying out the testing it became clear that one of the major and easily rectifiable sources of error in the guided group was difficulty keeping the drill axially placed with respect to the guide channel whilst drilling the guide wire. If the drill is moved slightly, a large torque can be exerted on the guide channel resulting in flexion and subsequent angle deviation from the planned position. This may be rectified by designing a thicker, stronger disposable component in order to counteract any torque exerted by the surgeon.

Whilst not yet specifically tested, the prototype was designed to facilitate the placement of orthopaedic hardware such as implants at any operative site where osseous anatomy is exposed. A new sterile disposable may be designed for a different operative site. In the hip, for example, the disposable would be designed to be bulbous in its initial configuration to better mould to the acetabulum and acetabular rim. One or more guide wires may easily be placed for direct use, however, if the situation demands, they may be placed such that a standard cutting block may be passed over and used to guide any relevant osseous anatomy modification. This process would be useful in knee arthroplasty as it would overcome the necessary increase in complexity, time and cost required if the device was configured to mill, for example, osteotomy cutting slots as seen in conventional 3D printed knee cutting guides. Work in these areas is ongoing at time of writing.

In conclusion, this paper describes a completely new approach and validation for the intraoperative rapid production of bespoke patient specific cutting guides. In removing many of the drawbacks of existing technologies and significantly reducing costs, it is hoped that the technique may open up orthopaedic guidance so that a greater number of patients may benefit from a fully computer guided orthopaedic intervention.

The intellectual property disclosed in this paper is included within the subject material of International Patent Application No. PCT/GB2014/053304.

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DISCLOSURES

Mr Alastair Darwood and Professor Roger Emery are Technical Director and Clinical Director respectively of the company Prometheus Surgical ltd. (London, UK). Prometheus Surgical is the current owner of the intellectual property regarding the invention disclosed in the above paper.

ABSTRACT FOR BONE AND JOINT JOURNAL (BJJ)

MOULDING THE FURTURE OF PATIENT SPECIFIC INSTRUMENTATION – THE SHAPE OF THINGS TO COME

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Introduction: Optimal orthopaedic implant placement is a major contributing factor to the long term success of all common joint arthroplasty procedures. Devices such as 3D printed bespoke guides and orthopaedic robots are extensively described in the literature and have been shown to enhance prosthesis placement accuracy. These technologies have significant drawbacks such as logistical and temporal inefficiency, high cost, cumbersome nature and difficult theatre integration. A radically new disruptive technology for the rapid intraoperative production of patient specific instrumentation that obviates all disadvantages of current technologies is presented.

Method: An ex-vivo validation and accuracy study was carried out using the example of placing the glenoid component in a shoulder arthroplasty procedure.

The technology comprises a re-usable table side machine, bespoke software and a disposable element comprising a region of standard geometry and a body of mouldable material.

Anatomical data from 10 human scapulae CT scans was collected and in each case the optimal glenoid guidewire position was digitally planned and recorded.

The glenoids were isolated and concurrently 3D printed. In our control group, guide wires were manually inserted into 1 of each pair of unique glenoid models according to a surgeon's interpretation of the optimal position from the anatomy. The same surgeon used the guidance system and associated method to insert a guide wire into the second glenoid model of the pair.

Achieved accuracy compared to the pre-operative bespoke plan was measured in all glenoids in both the conventional group and the guided group.

Results: The technology was successfully able to intraoperatively produce sterile, patient specific guides according to a pre-operative plan in 5 minutes including device set up and planning, at a minimal cost. In the manual insertion group, average accuracy achieved was 6.8º and 1.58mm with respect to the plan compared to the guided group where an average of 0.74mm and 1.72 º was achieved.