Post-operatory evaluation on the effect of patient-specific 3D printed orthopaedic surgical guides

D 5.3.2

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G. Kraan	Surgeon	24-03-2022
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A.A. Zadpoor	Project coordinator	16-06-2022

History of Changes

Section, page number	Change made	Date

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Executive Summary

The purpose of this report is to set out the basis and present the results of the clinical evaluation study undertaken by Delft Hospital (RdGG) including post-operatory evaluation of the effect of patient-specific 3D printed orthopaedic surgical guides (Deliverable 5.3.2). This report specifically details 2 clinical trials to validate the clinical benefits of 3D printed surgical instruments (O 5.1)

The deadline for the finalised procedure is 31/03/2020 and MTL is responsible for delivering it, though the report is drafted in collaboration between 3DLP and RdGG.

The Author and Surgeon have been in contact with a medical 3D printing journal with the intention that this report will form the basis of a published article.

This report presents the post-operatory evaluation as follows:

1. Introduction
2. Collaboration between 3DLP and RdGG
3. Design and manufacture of surgical guides
4. Method
5. Results and analysis
6. Discussion
7. Future clinical and commercial viability

1 Introduction

Defining a 'surgical guide'

An orthopaedic surgical guide can be defined as a tool that has been custom designed and manufactured to fit an individual patient's specific anatomy during an operation, so that the surgeon may cut or bore the bone with greater precision than would normally be possible in non-guided surgery. The ideal location for the cut or bore is determined by the surgeon during their pre-surgical planning assessment, using a virtual 3-dimensional model to simulate the procedure.

The value of surgical guides in orthopaedics

Over the past years, 3D printing has become a more developed technology and has found its way into the field of medicine. In orthopaedics, it can be used to manufacture patient-specific instrumentation (PSI) that aims to improve surgical accuracy [1]. One of the applications of PSI is guidance during the procedures that require sawing or drilling in bone [2]–[4].

Additive manufacturing of patient-specific orthopaedic surgical guides can provide benefits to both patients and surgeons when employed. These include:

- Increased accuracy in drilling, cutting, and placement of implants
- Avoidance of additional surgeries which may be lengthier, riskier, or more traumatic for the patient and their overall recovery
- Reduced overall surgery time
- Reduced time under anaesthesia for the patient
- Reduced amount of patient blood loss during surgery
- Reduced risk of surgical complications
- Improved patient outcomes
- Improved patient recovery time

The widespread adoption of 3D technology to augment orthopaedic surgery would likely see these case-by-case benefits translate into larger healthcare improvement metrics for healthcare providers.

Establishing a standard manufacturing procedure

If medical 3D printing is to affirm itself as a critical component of modern orthopaedic surgery's clinical workflow and patient treatment, validated and accepted standards of its use must be established.

A standard manufacturing procedure helps push clinical adoption as strict guidance on design, manufacture and use of the technology, across the healthcare industry, would give clinicians

greater confidence in promised outcomes and better understanding of their vital role within the design of the guides for their patients.

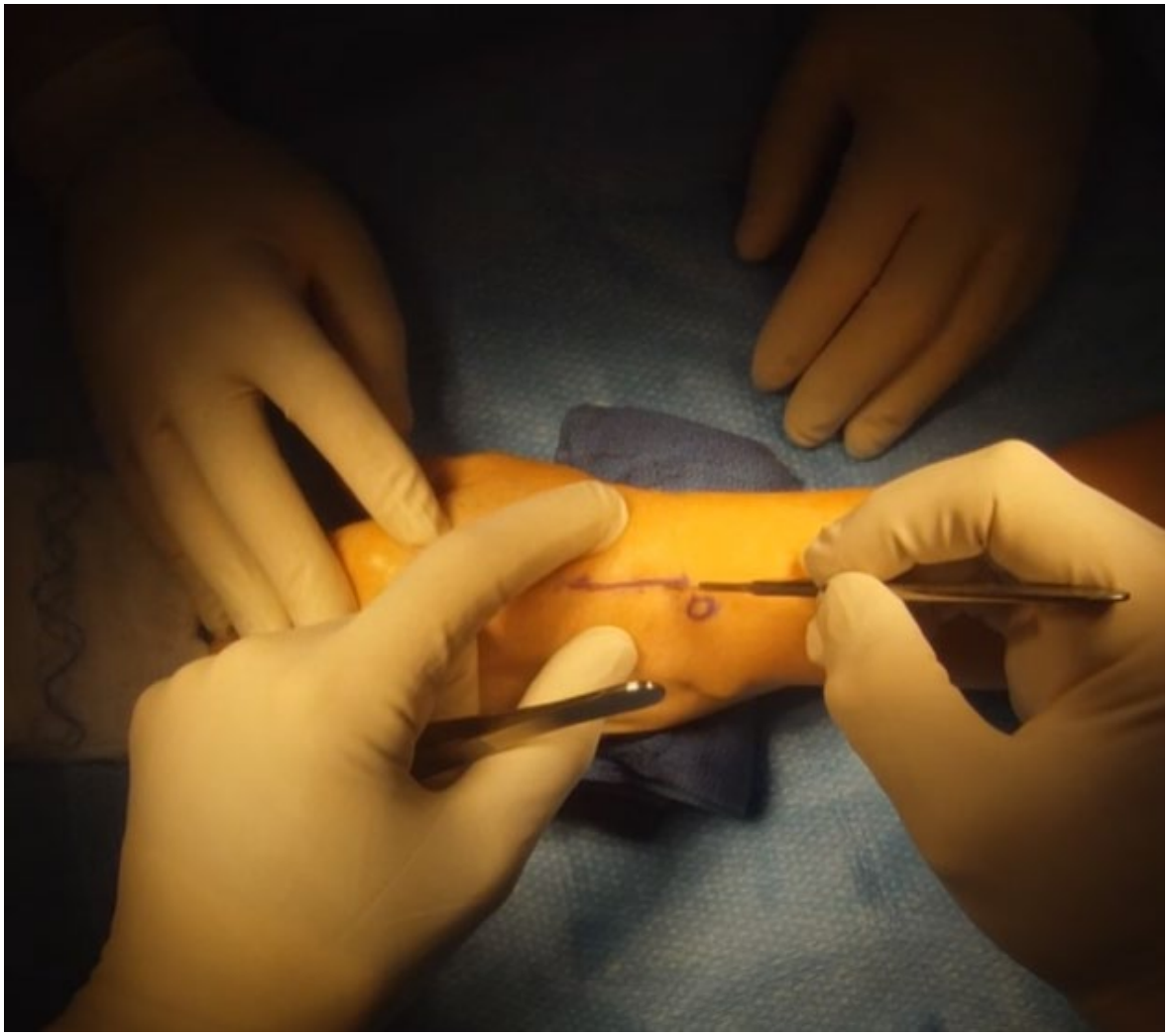
Given the range of orthopaedic surgical procedures, there are limits to the degree of specificity which can be built into a standard manufacturing procedure as each surgical procedure entails its own unique criteria of requirements.

As explored in Deliverable 5.3.1, we have established a working standard procedure which applies quality assurances and uniformity in approach to the design and manufacture of any orthopaedic patient-specific surgical guide.

The design and manufacture of the surgical guides used in the two clinical studies discussed in this report both adhere to the principles established and explained in more detail in Deliverable 5.3.1.

An overview of the Brunelli Procedure

For the purposes of this activity and a set of deliverables, 3D LifePrints and TU Delft focussed on an orthopaedic surgical guide which would assist with the successful execution of the Brunelli procedure, as described below:



- The procedure is used to correct instability in the wrist, such as where the patient has torn their scapholunate ligament
- A small hole is drilled through the scaphoid bone before tendon material from the flexor carpi radialis is pulled through and attached to nearby bones, tightening up wrist's range of movement
- Success depends heavily on the location and orientation of the hole in the scaphoid made during the operation
- Drill must pass through the center of the scaphoid and through the scaphoid tubercle
- Surgeons only have one chance to get it right due to the small size of the bone; more than one hole would lead to fatal damage to the bone (Figure 1).

Validating benefits with two clinical trials

In collaboration with 3D LifePrints, a new internal guide has been designed that attaches to both the palmar and dorsal side of the scaphoid, since incisions on both sides are needed for the procedure anyway. In these 2 clinical cadaveric studies, we used this new design on an embalmed specimen to assess the accuracy of the drilled tunnel.

The two clinical trials were carried out to measure the benefit from the use of an internal patient-specific guide (PSG) is the modified Brunelli procedure [5]. This surgery is performed to treat stage 4 scapholunate (SL) dissociation [6].

In a prior study an external PSG was designed that aids surgeons in drilling a tunnel through the scaphoid [7]. This design was tested, but the results were inconclusive, partly due to the use of surface scans instead of CT scans for designing and testing the PSG.

The results of the 2 clinical trials of the internal guide are contained in this report and the authors intend that the results will be published in a clinical journal.

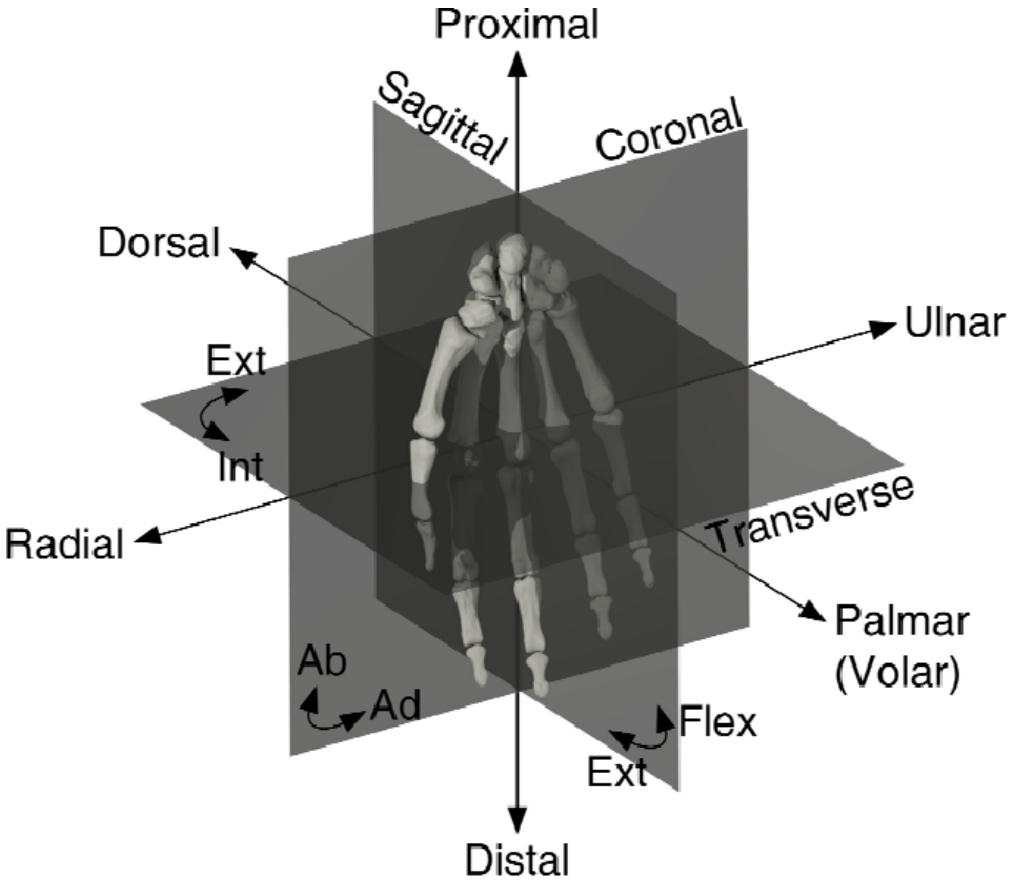


Fig. 1: Anatomical conventions for the hand, adapted from [10]

2 Collaboration between 3D LifePrints and TU Delft

For activity 5.3, biomedical engineers at 3D LifePrints, surgeons at Reinier de Graaf hospital and research staff at TU Delft, worked together to progress the development of a standardised procedure for the creation of orthopaedic surgical guides which could then be tested for validity,

This collaboration began in 2018. The following describes the collaboration as it relates to Deliverable 5.3.2, predated by the successful delivery of deliverable 5.3.1, which presented a standardized procedure for designing and manufacturing surgical guides.

Prototyping and testing history

In November 2020, at the Reinier Haga Orthopedic Center, a prototyping feedback session was held, in which three surgical guide prototypes were considered. Gerald Kraan, Ruud Deijkers, Karel Mirek, Mieke Schildmeijer, and Olivier Hiemstra were in attendance of the session.

All three were designed to aid in placing a K-wire through the center of the scaphoid according to a previously planned trajectory. The 3D printed devices all had two patient-specific faces contoured after the surface of the scaphoid on the dorsal and volar side. These two surfaces were connected with a C-shaped arm and a connecting mechanism. The three tested prototypes each employed a different connecting mechanism.

The prototypes were tested using a 3D printed phantom of the wrist consisting of the skeletal structure in hard nylon surrounded by silicon representing soft tissue. It was an unstructured session with all participants trying out the various guides. A summary of all comments and feedback is given below.

Experience per concept

Single hook:

- Connection not rigid enough

Dual hook:

+ Easy to apply
+ Most stable
+ K-wire was successfully placed in the planned trajectory (by resident, not specialist)
- Cannot be locked in the correct position

Click block:

+ When well attached, it provided the best support
- Too many parts (the connecting block could be fixed to one side?)
- Fell apart during use

General comments

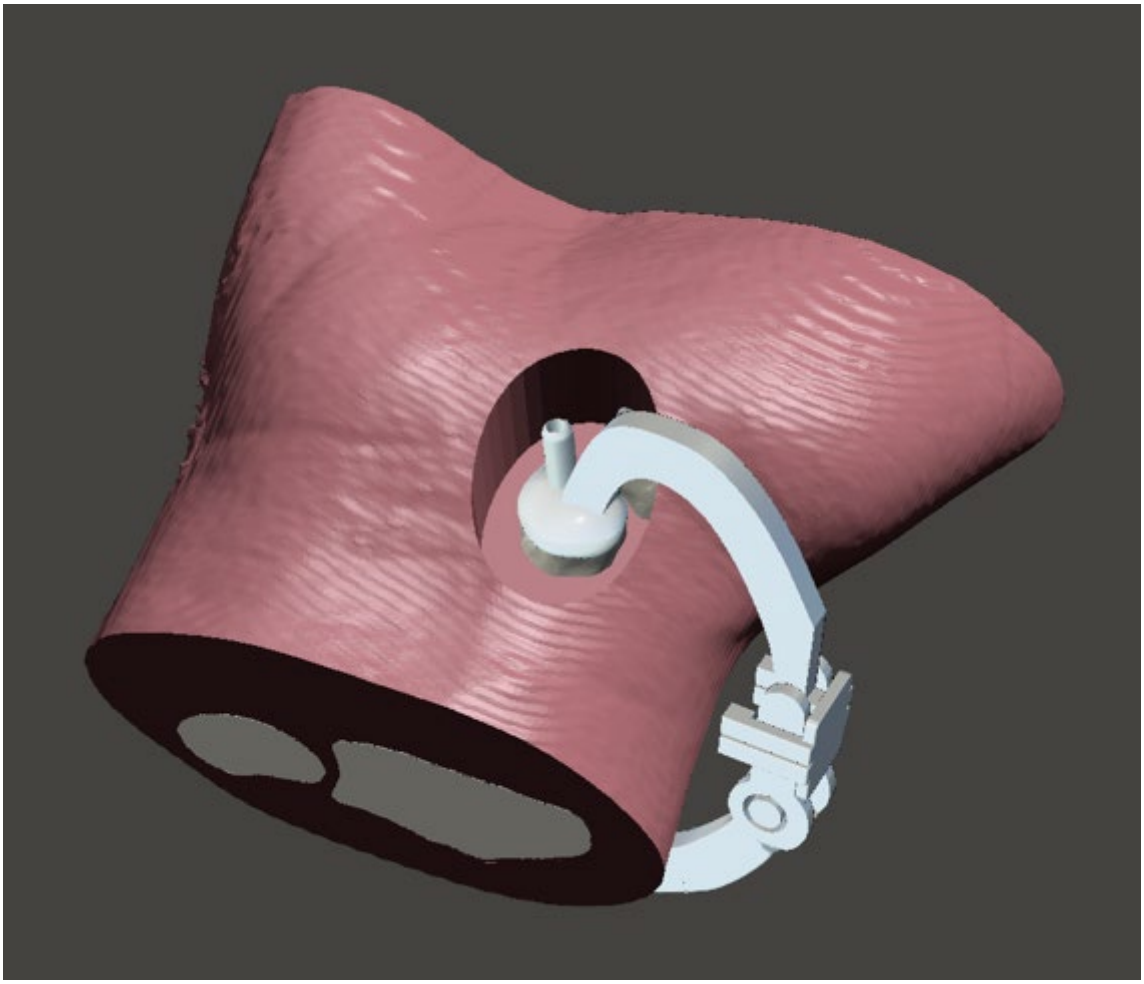
- Surgeons expressed the need for visual confirmation for confidence in correct placement, however view of the scaphoid is greatly reduced by the device.
- Silicon 'soft tissue' sometimes impeded the placement because it made contact with the C-arm. A larger C-arm was suggested.
- Surgeons strongly expressed the importance of stiffness of the device in all directions.
- Preferably the device could 'clamp' onto the bone so it does not require holding after correct placement.
- Idea: Metal C-arm (like Smith and Nephew micro vector) with custom 3D printed attachment blocks

Conclusion

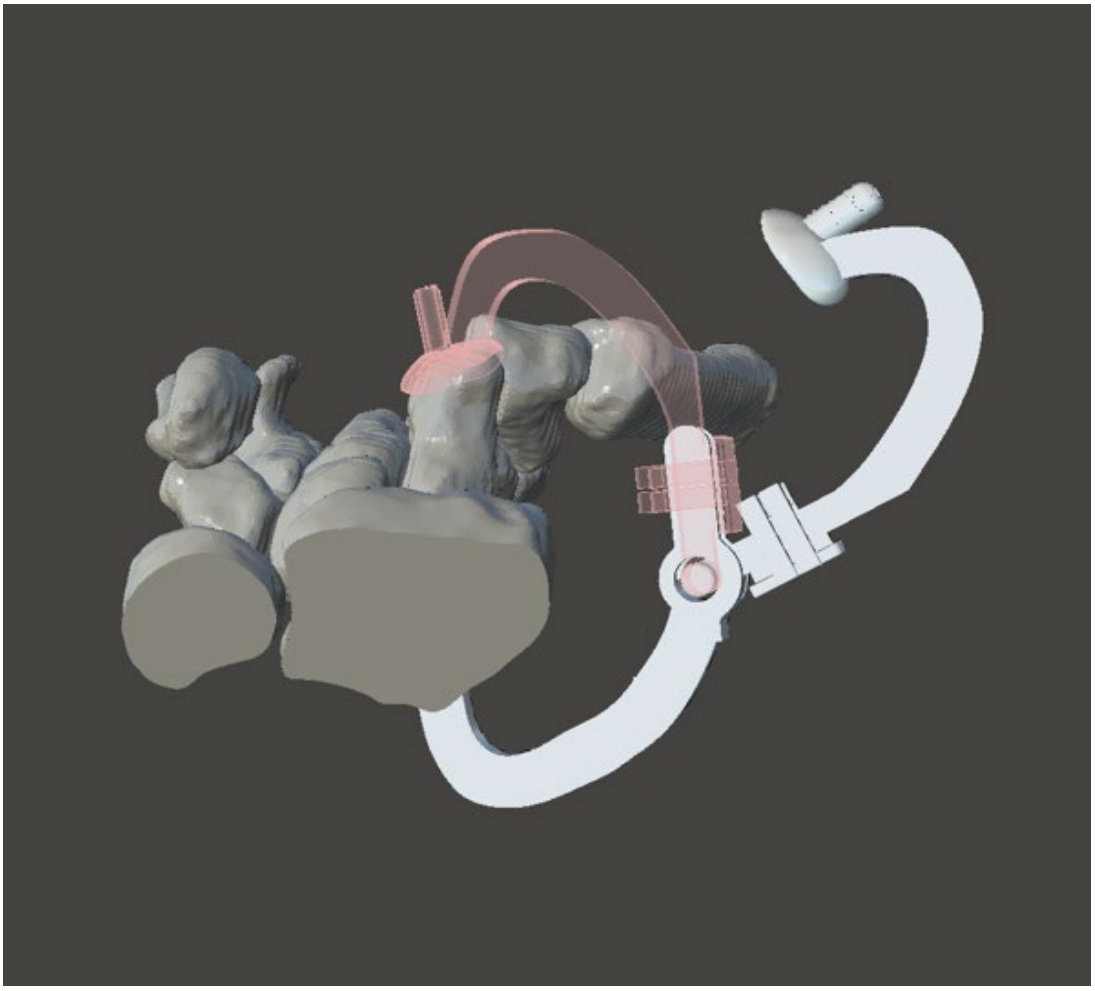
The concepts showed promise as a resident was able to place a k-wire in the planned trajectory. The dual hook concept worked the best because it was the easiest to apply, while still being stiff in most directions. Combining it with a method of fully locking the joint like in the 'click block' concept can achieve the benefits of both. Furthermore, the dimensions (and potentially the material) of the C-arm should be adjusted to increase the stiffness of the device, allowing better guidance as well as ensuring that the faces of the guide that contact the bone are correctly oriented with respect to each other.

Final design agreement

Upon receiving prototype feedback, 3D LifePrints took on board the recommendations from the surgeon's conclusions and settled on a final guide design concept. This was presented to TU Delft, and upon further testing, was deigned to be the optimum design to move forward with.



Final scaphoid surgical guide design showing bone and tissue anatomy



Final scaphoid surgical guide design on boney anatomy

Arranging clinical validation

Reinier de Graaf arranged for cadaveric specimens to be used for the two clinical trials which would test the accuracy, effectiveness, and ease of use of the final guide design.

Cadaveric imaging process

Reinier de Graaf took CT scans of the cadaveric specimens, storing them as Digital Imaging and Communications in Medicine (DICOM) files.

Imaging data sharing process

Reinier de Graaf transferred the DICOM files to 3D LifePrints so that the anatomy could be segmented and virtual planning of the surgery could take place, ultimately leading to the design and manufacture of the surgical guides required for the two clinical studies.

Imaging segmentation process

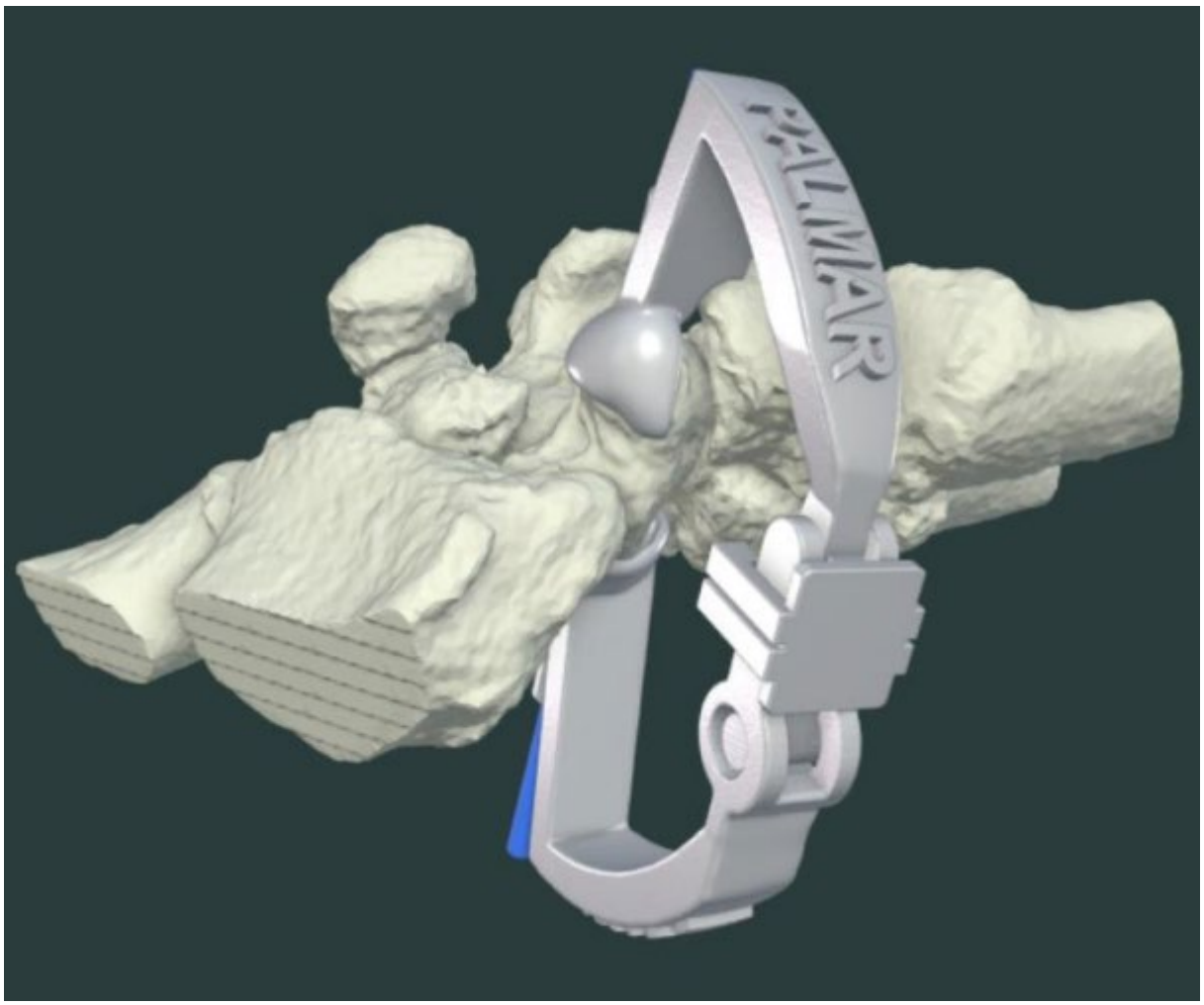
Upon receiving the scans, 3D LifePrints' used Synopsis Simpleware Medical ScanIP to segment the imagery and build a virtual model of the wrist and carpal bones.

Virtual surgery process

3D LifePrints' biomedical engineer and the lead surgeon at Reinier de Graaf conducted a virtual surgery to find the best location and axis for the drilling site within the scaphoid bones.

Once the optimum drilling planes were agreed with the surgeon, the biomedical engineer at 3D LifePrints began the design and manufacturing process for the surgical guides.

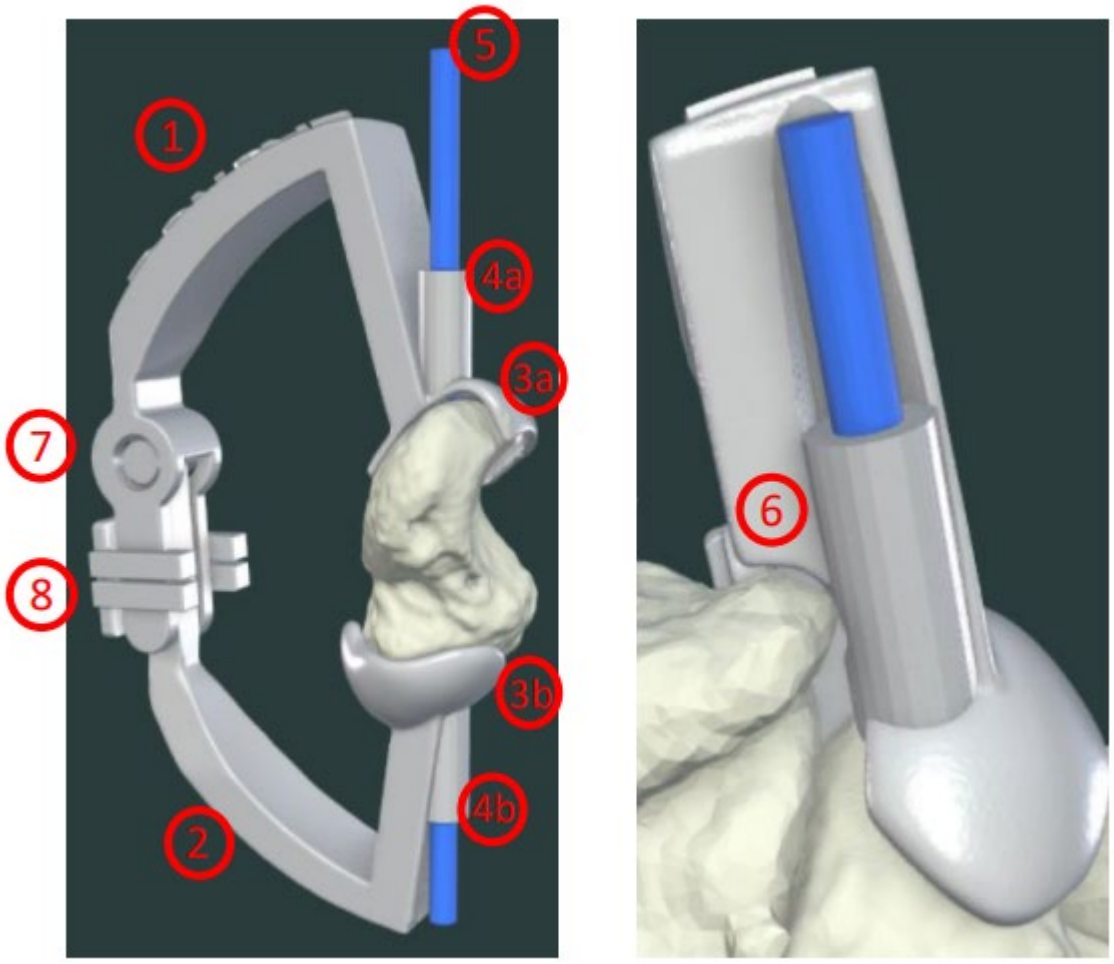
3 Design and manufacture of surgical guides



Design process

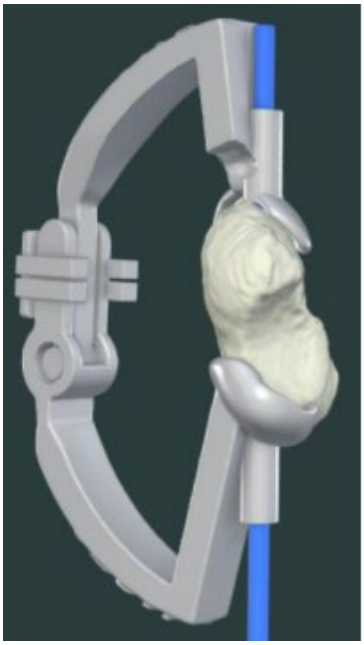
Clinical study 1 and 2

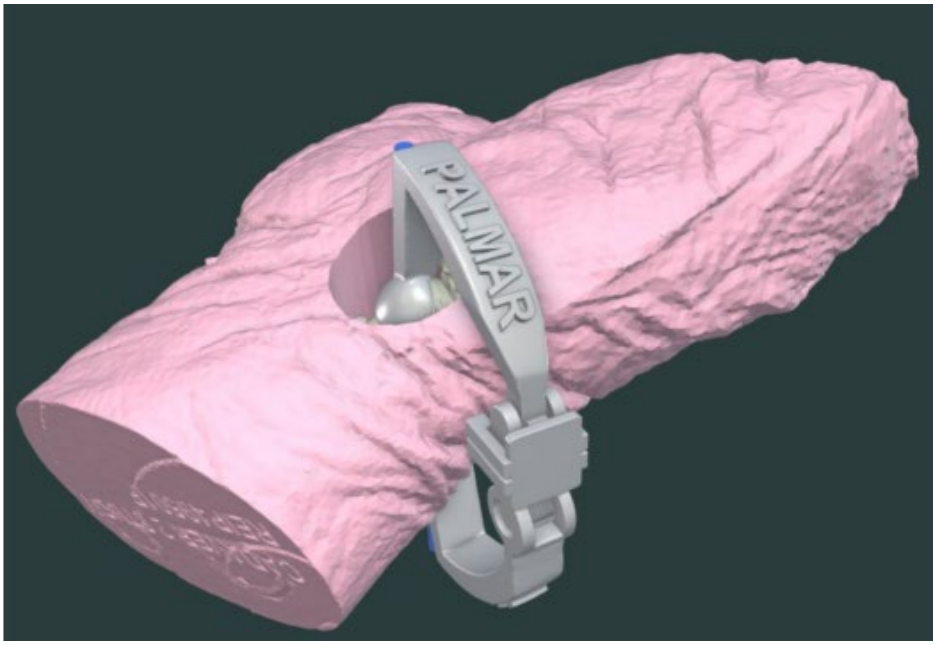
A design request was made to 3D LifePrints by Dr. Gerald Kraan, for the design and manufacture of a 3D-printed patient-specific drilling guide for the drilling of a cadaveric scaphoid.



- The guide was designed with dorsal (1) & palmar (ventral) (2) components & so facilitates the dorsal approach used for the procedure
- Guide contact surfaces (3a & 3b) are designed to rest on dorsal & palmer aspects of the scaphoid and incorporate drilling channels (4a & 4b) to define the planned drilling trajectory (5)
- A small sub-section of the palmar arm of the guide (6) is additionally designed to rest on the trapezium to aid correct positioning & therefore drilling accuracy
- The two guide arms pivot (7) & have a locking mechanism that clicks into place (8), to secure positions once correct placement on the scaphoid is achieved
- Soft tissue margins used to help define design
- Ventrodorsal patient specific drilling guide for the right scaphoid
- - 2x drilling channel locations (1x palmar & 1x dorsal) to accommodate up to 1.6mm kwires as per cadaveric study 1

This information was provided to Reinier de Graaf in the form of a design report. A design report was provided for the surgical guide in both clinical studies These were signed off by Gerald Kraan, at Reinier de Graaf, as per the standard procedure.





Manufacturing process

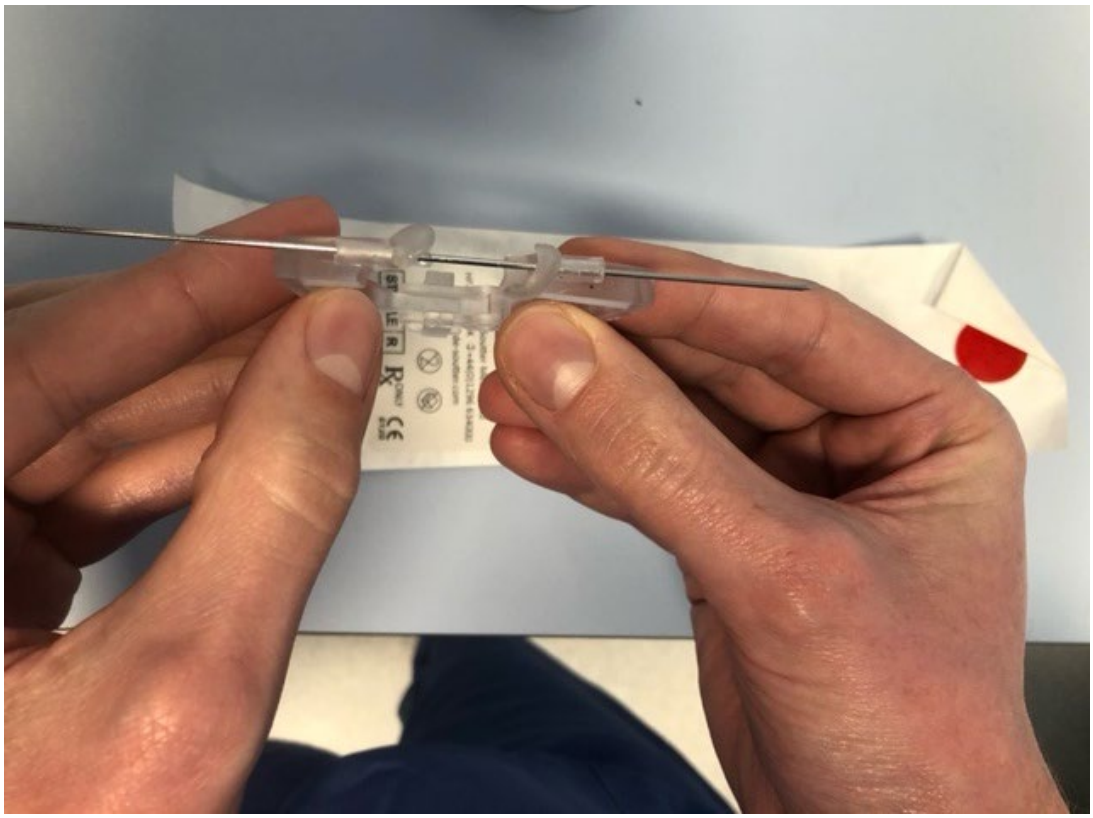
Clinical study 1

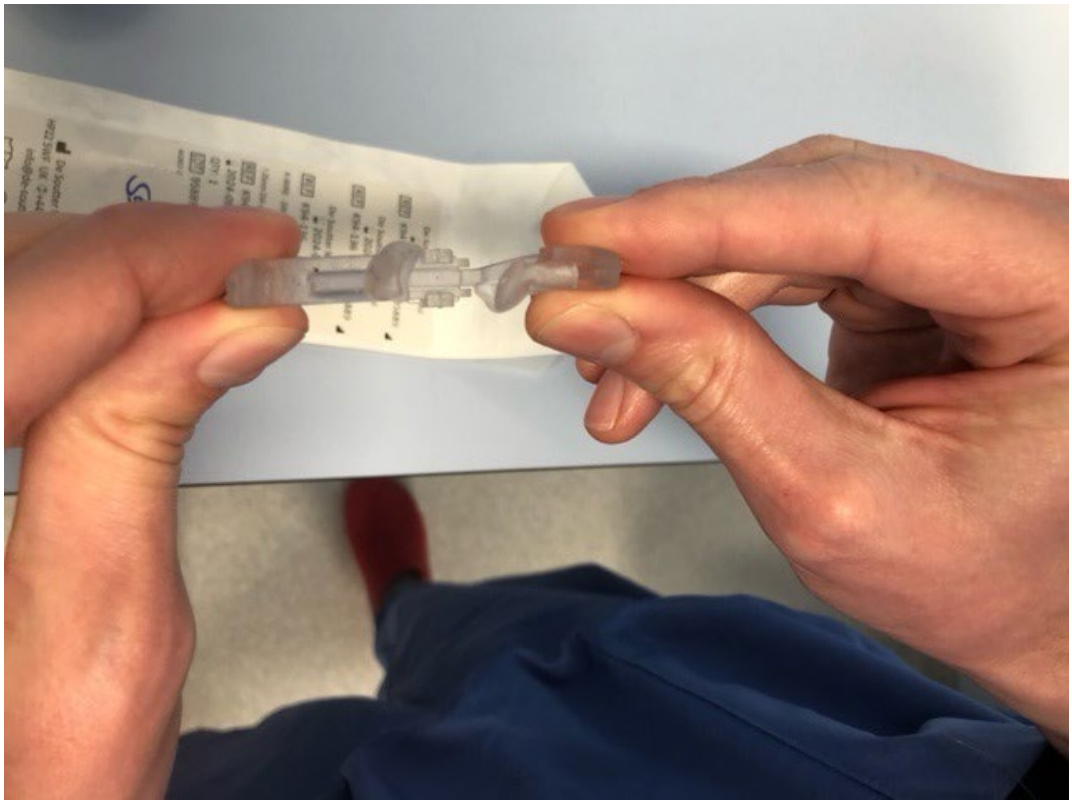
The digital file containing the guide design was sent to Oceanz (Ede, The Netherlands) to 3D-print and deliver the guide. Important to note is that this guide was printed in PA12 (polyamide) instead of the intended BioMed Clear resin.

Clinical study 2

For the second clinical study, 3D LifePrints were able to manufacture the surgical guide in BioMed Clear resin at their controlled environment printing facilities, located at their embedded hub in the Nuffield Orthopaedic Centre, Oxford, UK.

(For more information about both the design, manufacture, and post-processing procedures, please refer to the Deliverable 5.3.1 report)





The above pictures show the scaphoid Guide as manufactured in Bio-Med Clear

4 Evaluation Method

One specimen of the lower arm and hand is used, embalmed according to the AnubiFiX™ (AnubiFiX, Rotterdam, The Netherlands) method. Specimens embalmed according to this method retain most of their flexibility and plasticity [8]. This increases the reliability of the results, because it matches the bio-mechanical properties of a 'living' arm more closely than frozen cadavers. Also, in contrast to unembalmed specimens, these specimens can be used multiple times [9]. This is crucial, since the same specimen needs to be treated multiple times.

A preoperative CT scan was performed to determine the orientation of the scaphoid and the desired tunnel trajectory is derived.

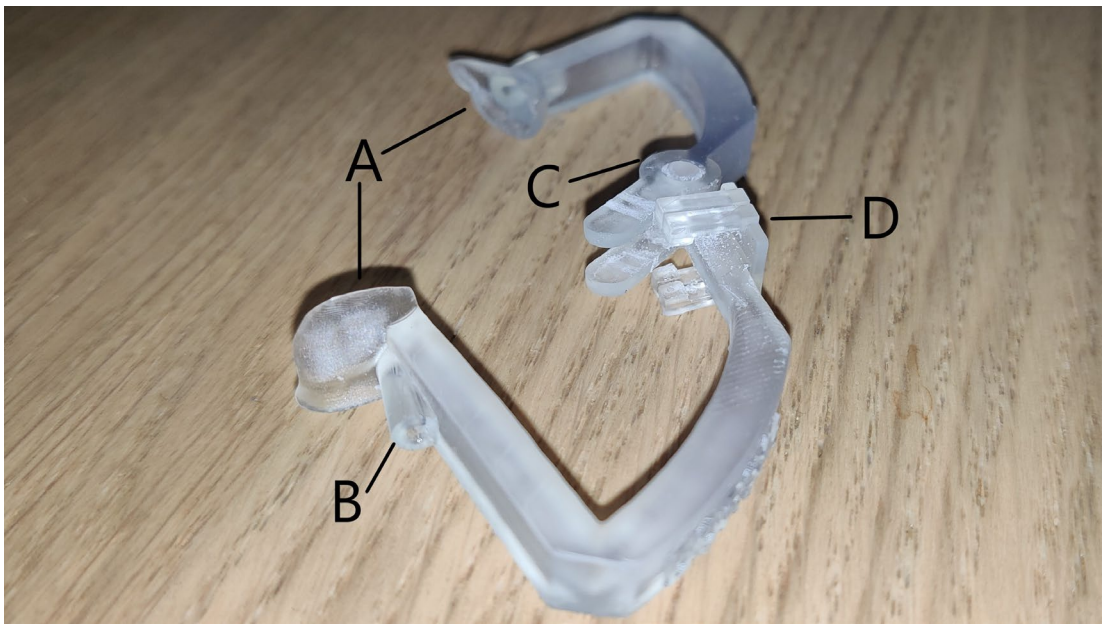


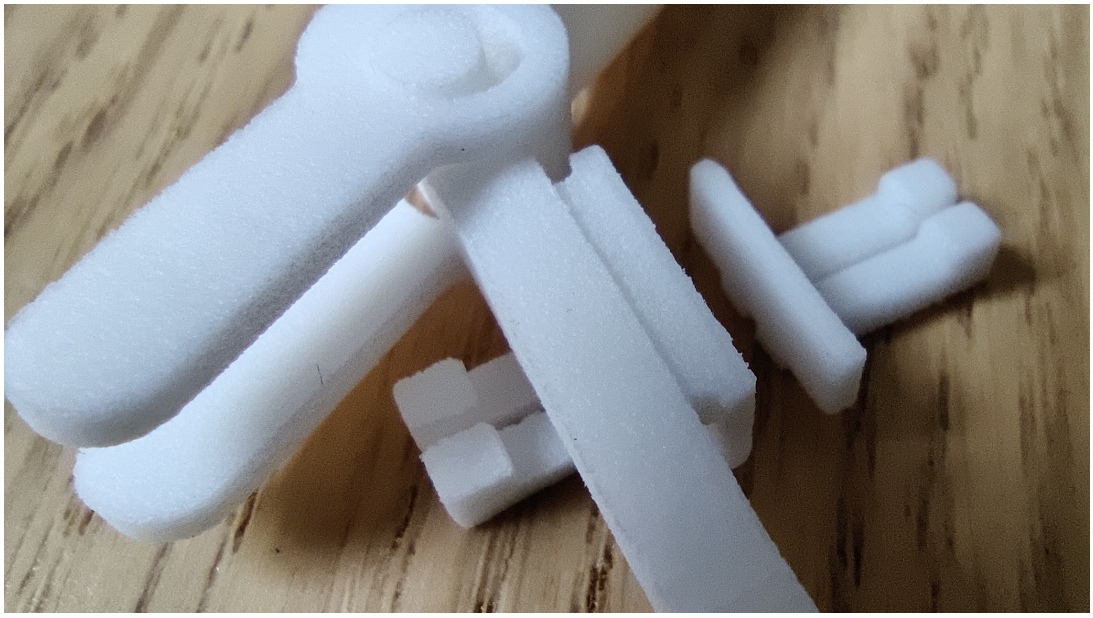
Fig. 2: 3D printed patient-specific guide. A: cups; B: guide cylinder; C: hinge; D: locking mechanism

This is used, along with the geometry of the scaphoid, to design the guide. The desired tunnel trajectory is also used to determine the drilling accuracy by comparing it to the achieved tunnel trajectory. The images that have been obtained from the CT scan were stored as Digital Imaging and Communications in Medicine (DICOM) files. The DICOM files were segmented and stored as STereoLithography (STL) files as well. Both DICOM and STL files were transferred to 3D LifePrints that designed and 3D printed the PSG in a biocompatible material (BioMed Clear Resin, Formlabs, Somerville, MA, USA). The new iteration of the design comprises two bent arms with a 'cup' on one side and are hinged together on the other side (Fig. 2). These cups follow the geometry of the scaphoid for a better fit. They also contain the guide cylinder where the Kirschner-wire (K-wire) is inserted into. The hinge can be locked to fix the guide on the scaphoid.

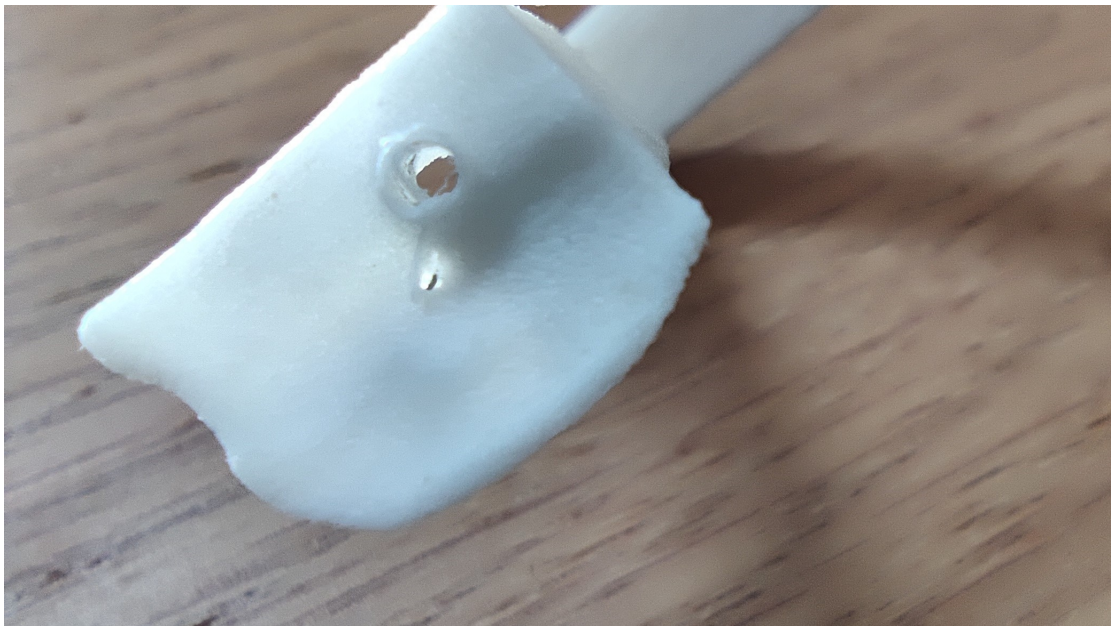
The first part of a Brunelli procedure, up to and including drilling a K-wire through the scaphoid, was performed on the specimen by an orthopaedic surgeon who is specialised in hand and wrist surgeries. Incisions were made on both palmar and dorsal side and underlying tissue had been moved aside using surgical retractors. The guide was placed on the exposed scaphoid. A 1.2mm

K-wire was placed in the guide cylinder and drilled through the scaphoid. Excess wire was bent sideways to prevent it from sticking out.

A postoperative CT scan was performed to determine the achieved tunnel trajectory. To assess its accuracy, it was compared to the desired trajectory that had been determined from the preoperative CT scan. Hiemstra [7] used a coordinate system with the desired trajectory as the z-axis and the origin halfway between the entry and exit point of the tunnel. A plane was spanned orthogonal to the z-axis and intersecting the origin. Two orthogonal planes are defined so that the coordinate system is slightly shifted from the anatomical coordinate system (Fig. 1). The angles between the desired and achieved trajectory were projected on the transverse and sagittal plane and were used as a measure of error. However, defining a set of orthogonal planes proved to be very difficult, since anatomical landmarks used to define the orthogonal planes are not exactly orthogonal to the desired trajectory. Also differences in hand position during preoperative and postoperative scans and between subjects will lead to inconsistent results. Therefore, a different approach is used without projecting the angle between the trajectories on the transverse and sagittal plane, resulting in a single angular difference α. For the translational difference, the Euclidean distance between the midpoint of both trajectories d is used. To compare the results to the maximum allowable errors as defined by Hiemstra, we will use the lower value for both the maximum allowable angular and translational difference. These are 11° for the angular difference and 1.3mm for the translational difference.



(a) Mechanical failure of the locking mechanism



(b) Drill hole due to misalignment of the guide cylinders

Fig. 3: PA12 guide that was used during surgery

Two clinical studies were conducted using the evaluation method described above. A notable difference is that the guide for the first study was not manufactured in the intended material due to technical issues. The guide in the second study was printed in BioMed Clear resin by 3D LifePrints, with some minor design improvements with lessons learned from the first study.

5 Results and analysis

Due to technical issues during the first clinical study, the guide could not be delivered in time. Oceanz (Ede, The Netherlands) 3D-printed and delivered the guide instead. Important to note is that this guide was printed in PA12 (polyamide) instead of the intended BioMed Clear resin.

During the surgery, part of the locking mechanism of the hinge broke off when unlocking the hinge, see Fig. 3a. The surgery was continued with the guide being locked in place manually. After inserting the K-wire into the guide cylinder on one side and drilling through the scaphoid, it should have passed through the guide cylinder on the other side. However, it was drilled through the cup instead, as can be seen in Fig. 3b. For the second clinical study, some minor design improvements were made to the guide and it was manufactured by 3D LifePrints in the intended material, BioMed Clear Resin.

The resulting angular error α is 13.783° in the first clinical study and 15.037 in the second. The translational error *d* is 1.5004 mm in the first clinical study and 1.4453 mm in the second. These results are also shown in Table 1 alongside the maximum allowable error, as defined in the Method. In both studies, the maximum allowable errors are exceeded, with a larger translational error in the first study and a larger rotational error in the second.

TABLE 1: Positional errors of the tunnel trajectory and maximum allowable error for α and d

Assessments	Study 1	Study 2	Maximum allowable error
α[°]	13.783	15.037	11
$d[mm]$	1.5004	1.4453	1.3

TABLE 2: summary of results in the table below for planned vs achieved drill trajectories in cadavers 1 & 2. 'entry' = dorsal, 'exit' = palmar/ventral.

Cadaver Study	3D Angular Difference (Degrees)	Translational Difference MidPoint (mm)	Translational Difference Entry Point (mm)	Translational Difference Exit Point (mm)
Study 1	13.783	1.5004	4.0997	2.3955
Study 2	15.037	1.4453	4.7031	3.3622

Statistical analysis method

For the differences in translational distances, we calculated these by plotting multiple coordinates at evenly spaced intervals along the lines of best fit and finding the coordinate closest to/intersecting the surface of the scaphoid for both the planned and achieved drill trajectories. We then used these 3D coordinates to calculate the difference in distances for planned/achieved 'entry' and 'exit' points.

6 Discussion

The results show that, in both studies, the positional error exceeds the maximum allowable error for both α and d. The results from the first study are not reliable however, since mechanical failure of the locking mechanism meant that we had to lock the hinge manually. This proved to be challenging due to the forces the surgeon exerted on the guide during drilling. Since the guide that has been used was manufactured out of a different material from intended, it is possible that the mechanical failure can be attributed to material properties. Oceanz PA12 has a Young's modulus of 1650 MPa [11], as opposed to 2080 MPa for BioMed Clear Resin [12]. With this difference in Young's modulus, 21% lower than intended, it is likely that the guide in BioMed Clear would not have failed. The locking mechanism of the original guide (delivered to us after the surgery) was repeatedly opened and closed without mechanical failure. This solidifies the assumption that the mechanical failure can be attributed to material properties.

Results from the second study, with the improved guide, show that the translational error is reduced compared to the first study. However, the rotational error has increased. As the material of the guide from the second study is stiffer, the problem could lie in the placement of the guide. Since this problem presented itself after the results from the second study were known, we were not able to address it. Setting up a protocol regarding the placement of the guide could lead to reduced positional errors, but the effect of such protocol will have to be evaluated in future studies.

Even though this guide is not attached onto the exterior of the hand, as was originally intended by Hiemstra, this is not considered a drawback. Incisions on both sides of the wrist have to be made in any case during a modified Brunelli procedure, since a strip of the flexor carpi radialis tendon has to be pulled through the scaphoid tunnel. Additionally, the guide is attached onto the scaphoid by making use of the geometry of the bone instead of anchoring it in the bone using pins, the former being less invasive than the latter. Another benefit of attaching the guide onto the bone surface instead of the skin surface is the elimination of inaccuracies caused by the flexible nature of the skin.

A shortcoming of this study is the way the maximum allowable errors are defined. These were originally projected onto two anatomical planes. However, the combination of two angles that are within the maximum values could still yield an inadequate trajectory, especially considering the complex bone morphology of the scaphoid. Using one value for angular error and one for translational error will be more reliable, as explained in section II. Due to time constraints, we converted the original maximum allowable errors by taking the ones with the lowest value, but this could still yield an inadequate trajectory. We recommend determining the maximum allowable errors again from the volume within the boundaries of acceptable drill placement, like Hiemstra, but this time expressing the maximum allowable errors as one angular error and one translational error in 3D. Even though certain combinations of rotation and translation could still yield an inadequate trajectory, it will be less likely to happen.

Furthermore, we recommend additional testing on specimens with the guide printed in the intended material, BioMed Clear Resin, and extra attention to guide placement for more reliable results. An estimate needs to be made of possible delay due to technical issues during manufacturing as well as increased shipping times due to Brexit to guarantee the timely delivery of the guides.

7 Future clinical and commercial viability

Continued cadaveric study

This guide is highly novel and requires further development. The 2 clinical trials on cadavers have shown that there is scope for further development of the concept and designs.

Live patient trials

Once the cadaveric trials are producing acceptable replicable results then the trials can move into use in humans on a case by case basis. In order to do so a full technical and regulatory pack will need to be created for the device in order for it to comply with the Medical Device Regulations.

Commercialisation

Upon the successful completion of human trials, both 3D LifePrints and TU Delft believe a commercial avenue for this type of surgical guide will be viable. This may involve Intellectual Property protection (if achievable) and then market launch.

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