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SARAS

"Smart Autonomous Robotic Assistant Surgeon"

D2.1 – Patient specific based phantom models

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CI = Classified, information as referred to in Commission Decision 2001/844/EC.	
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D2.1 – Patient specific based phantom models
Version 1

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List of Acronyms

STL	Stereolithography (file format)
CAD	Computer Aided Design
aka	also known as
DICOM	Digital Imaging and Communications in Medicine (file format)

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1 Introduction

As deliverable D2.1 is of type DEM and as such is hardware, this document aims to accompany the hardware deliverable and to give some additional information. According to the overall project timeline, both the document as well as the hardware deliverable address the first application scenario, i.e. robot-assisted radical prostatectomy (RARP) surgery (see also schedule in Table 1). The document describes the different generations of the prostate phantom, discusses the achieved result in comparison with the requirements outlined in deliverable D7.1, and gives a short outlook over next iteration steps.

Month	Surgical Procedure	Platform
M12	RARP (Phantoms)	MULTIROBOT SURGERY platform
M24	RARP (Phantoms)	SOLO SURGERY platform
	LRN / LPN (Phantoms)	MULTIROBOT SURGERY platform
M36	LRN / LPN (Thiel Cadaver)	LAPARO SURGERY platform

Table 1: Schedule of Phantom Development

2 Phantoms for the RARP surgery

As already described in deliverable D7.1, the RARP phantom has to be based on a modular setup in order to create a reusable surgical training model with a replaceable, disposable internal module.

The RARP Platform mainly consists of a Pelvic Bone, Pelvic Floor Muscle, Rectum, Seminal Vesicles, Vas Deferens, Connective Tissue, Bladder, Urethra, and Prostate. The aforementioned components are all inserted in a rigid housing which simulates the (lower) abdomen. The rigid frame includes a 15cm band of a flexible synthetic skin layer which allows free trocar positioning according to the clinical specifications provided by partner OSR in D1.1 and D7.1.

2.1 3D Geometry

A workflow for transfer of medical data (in DICOM format) into 3D printable data (in STL format) has been established by using segmentation features of open-source software 3D Slicer for generation of anatomically correct geometry and post-processing of STL models from 3D Slicer (www.slicer.org) with AutoDesk Meshmixer (http://www.meshmixer.com/) and/or Materialise Magics (www.materialise.com/en/software/magics). Most of the components used for the RARP phantom, however, have been realized based on published 3D anatomical data (e.g. 3D Slicer database, NIH 3D Print Exchange) and own 3D design based on anatomic atlases.

2.2 Used Materials

The pelvic bone is made from polylactic acid (PLA) – soft tissue elements of the phantom are made from two-component silicone rubber (aka RTV (Room-Temperature-Vulcanizing) silicone) type SHA08 (for pelvic muscle and prostate) und SHA00 (for other elements), partly mixed with cellulose fibers and standard gel wax.

2.3 Production

The pelvic bone is being produced with a PLA filament printer available at ACMIT (see figure 1). Due to the size of the pelvic bone and the limited printing volume of the used printer, the bone is being printed in two parts which are being connected by means of standard epoxy glue.

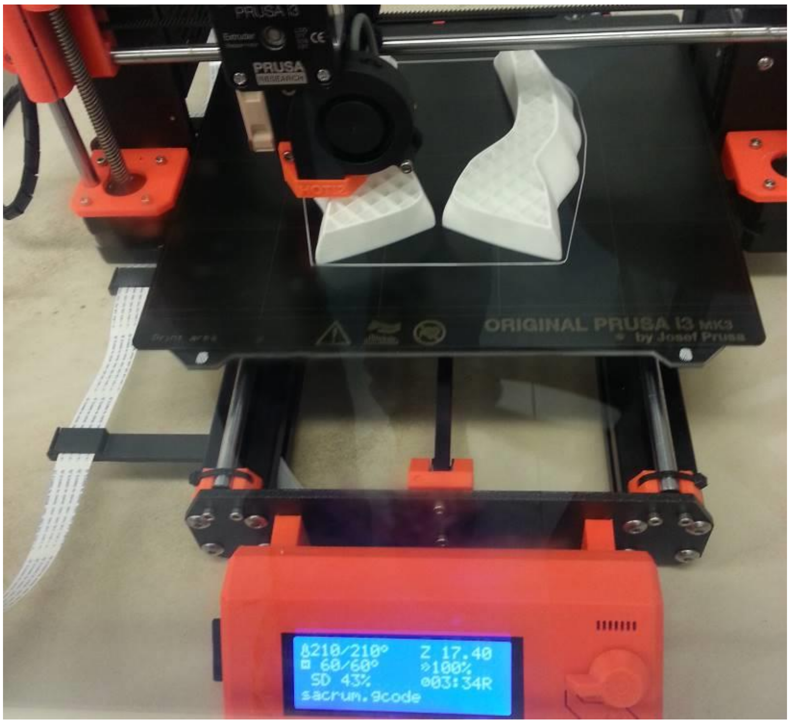

Figure 1: Printing the pelvic bone in two segments

All soft tissue elements are produced in a molding process – molds have been designed with SolidWorks CAD software using the part geometry from the particular STL files. Depending on the geometry, molds had to be separated into sub-elements. For the hollow elements (rectum, bladder) a wax core had to be manufactured, which creates the inner lumen of the element after dissolving (see figure 2). As this procedure is time consuming, difficult, and cumbersome an alternative production process of hollow silicone elements – i.e. 3D printing of silicone structures – is being investigated in the framework of WP2.

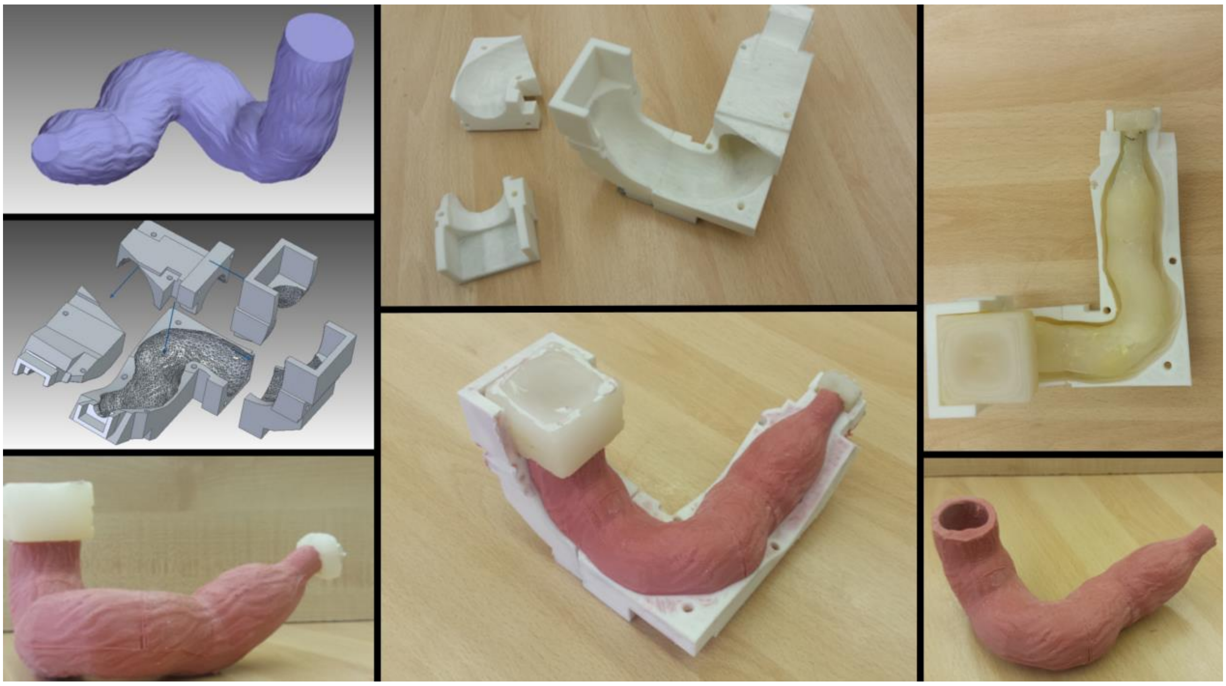

Figure 2: From STL to a silicone model applying a molding process – STL file of the rectum, CAD model of the mold, mold and wax core, final silicone model

2.4 Generations of the RARP Phantom

Following an iterative process, different generations of the RARP phantom have been developed and evaluated with the surgical partners.

2.4.1 RARP Phantom "Generation 1"

The starting point of the development was the "Generation 1" model, which already was partly available at start of the SARAS project (see figure 3). For this model, most of the elements were "hand-made" without molds and other manufacturing aids. The phantom mainly includes prostate, bladder and rectum – connective tissue is being simulated with loose cotton wool.

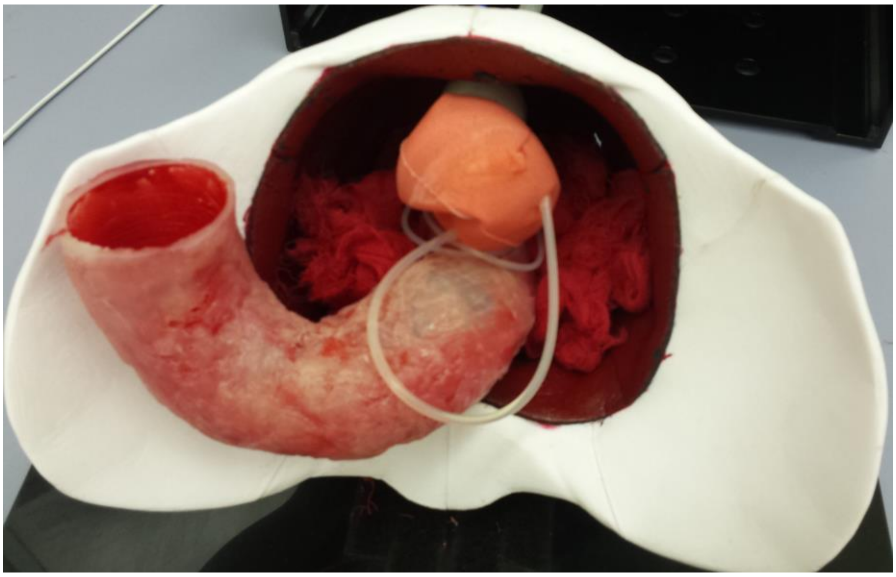

Figure 3: RARP phantom "Generation 1"

2.4.2 RARP Phantom "Generation 2"

Main advancement from the "Generation 1" model to "Generation 2" was to design and implement molds for all elements, in particular for the complex elements pelvic muscle and rectum (see figure 4).

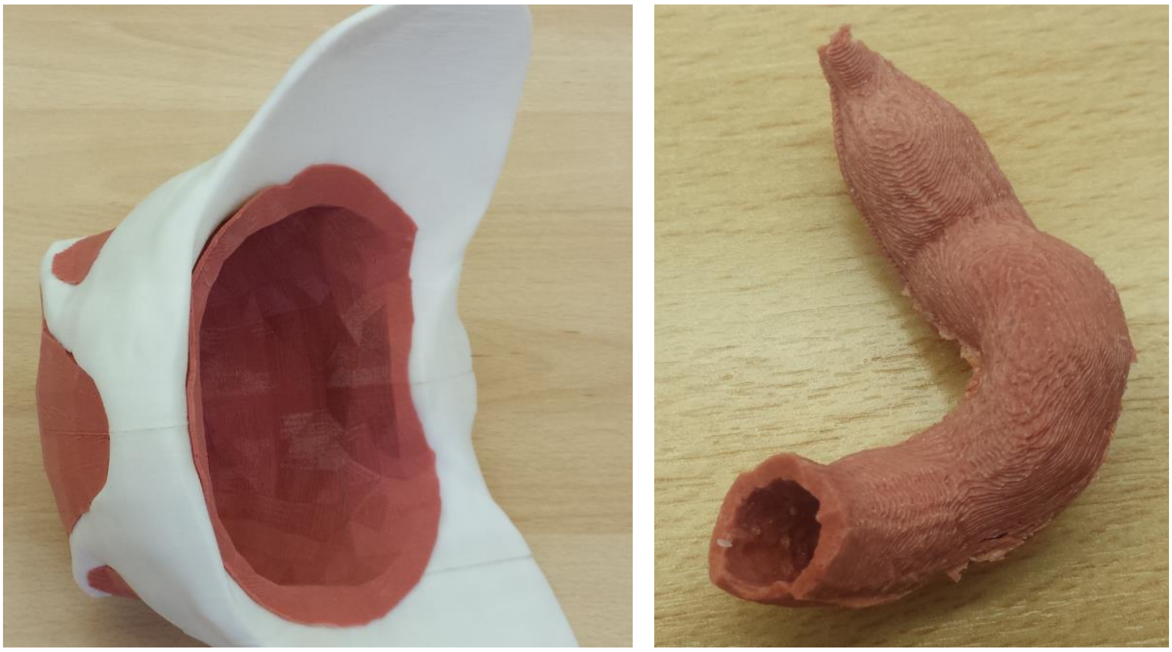

Figure 4: Selected components of RARP phantom "Generation 2"

2.4.3 RARP Phantom "Generation 3"

In a first hands-on evaluation of the "Generation 1" and "Generation 2" phantom together with clinical experts from partner ORS (Verona, 05.09.2018) some additional modifications for the phantom have been discussed, which later have been implemented in the version “Generation 3” (see figure 5). Main modifications have been as follows:

- Slight increase of size of pelvic bone (+15%)
- Slight increase of size of prostate (+30%)
- Decrease distance between bladder and prostate and realize as “soft flange”
- Reduce stiffness of rectum (should be collapsed and/or designed in a flat manner); remove last segment of rectum (i.e. make it shorter)
- Bladder, prostate, and seminal vesicles all should be embedded in soft tissue
- Optimize position of vas deference and ureters
- Create a replaceable element consisting of prostate-bladder-soft tissue


Figure 5: Phantom “Generation 3” with collapsed rectum, seminal vesicles, ureter and vas deference in anatomical correct position (left). Prostate+bladder enclosed in foam block (right).

2.4.4 RARP Phantom “Generation 4”

In a second hands-on evaluation of the “Generation 3” phantom together with clinical experts from partner ORS (Verona, 18.10.2018) some further modifications for the phantom have been discussed, which later have been implemented in the version “Generation 4”. Main modifications have been as follows:

- Less and softer tissue left and right of bladder/prostate
- Reduce stiffness of bladder (and/or collapse bladder)
- Reduce stiffness of “skin” for phantom box (i.e. abdominal wall simulation)
- Option for inclination of entire box (0 .. 30°; feet up) as well as of phantom inside of box (0 .. 30°; feet down)
- Box should be bigger in size, i.e. giving more room around phantom

Different options for the surrounding gel block have been investigated, with the final selection of a silicone+gel wax mixture.

Due to the reduced stiffness of the rectum (see requirements mentioned above) and the surrounding gel block, the aforementioned disposable block now also includes the rectum. Figure 6 shows the disposable block of the "Generation 4" phantom after dissection of the "connective tissue" around bladder and prostate.

Figure 6: Phantom "Generation 4" – after dissection of soft tissue around prostate and bladder

2.5 Evaluation

As already mentioned above, two hands-on evaluation rounds have been performed in order to optimize the RARP phantom. Meetings took place on 05.09.2018 and 18.10.2018, both in Verona/Italy at partner UNIVR. Besides of evaluation of the phantom in its actual configuration, the two meetings also have been successfully used for a first investigation of optimal placement of the robot arms (see figure 8).

Figure 7: Hands-on evaluation of the phantom with clinical experts and discussion of desired modifications

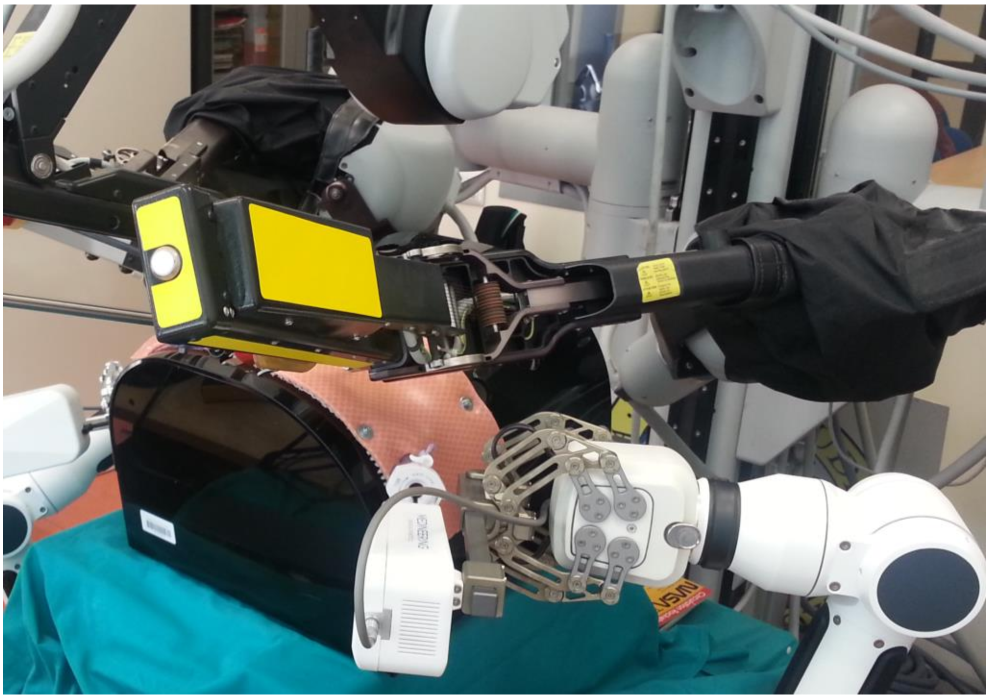

Figure 8: Placement of robot arms around RARP phantom "Generation 3"

2.6 Requirements vs Realized Features

In the following, the requirements for the RARP phantom outlined in D1.1 and D7.1 are being investigated with respect to their fulfilment.

Requirement	Mechanical properties?	Anatomical Fidelity?	Disposable	Realized Feature
Peritoneum Frame made of Perspex or similar; cover with skin simulation	NO	YES	NO	Basic frame of acrylic glass with 15cm band of fiber-reinforced silicone as skin simulation
Muscle of the pelvic floor 3D printed together with pelvic bone; material TBD	NO	NO	NO	Casted structure made of silicone; glued into 3D printed pelvic bone
Rectum Silicone; casted (for first versions) or 3D printed	APPROX	APPROX	NO	Casted silicone object (planned for later phases: 3D printed silicone object) Part of the disposable block
Seminal vesicle Silicone; casted	APPROX	YES	YES	Casted silicone object
Endopelvic fascia Soft cast filler material such as polyacrylamide or alternative hydrogel with fine mesh i.e. cotton wool	APPROX	NO	NO	Simulated by soft tissue block around bladder and prostate Part of the disposable block

Connective tissue simulated by cotton wool for first prototype version(s)	APPROX	NO	NO	Simulated by soft tissue block around bladder and prostate Part of the disposable block
Bladder Silicone; casted (for first versions) or 3D printed	APPROX	YES	YES	Casted silicone object (planned for later phases: 3D printed silicone object)
Urethra Silicone tube; cut into size	APPROX	APPROX	YES	Silicone tube from prostate towards Bulbar Urethra; no silicone tube between prostate and bladder, but “soft flange”
Prostate Silicone, casted	APPROX	YES	YES	Casted silicone object
Vas Deference **Ureter** not planned originally				Silicone tubes with different size (and color) in anatomically correct (approx.) position

Table 2: Requirements vs realized features

2.7 Further aspects, iterative phantom optimisation

Depending on the experiences during the first robotic experiments with the RARP phantom, additional modifications may be considered. Beside of such further optimisation cycles, future extensions of the phantom may include:

- Shape of the Peritoneum:
  The current (quasi-cylindric) shape of the peritoneum will be changed to a more realistic one for later versions of the phantom.
- Texture on the surface of the organs for helping 3D reconstruction:
  Texture to prostate and bladder is already being applied by adding a mix of cotton fiber and gel wax. Based on experiences and feedback, these texture elements may be modified and/or color elements (by using coloured cotton fibers, for example) may be included.
- Dorsal Venous Complex and Neurovascular bundle:
  Simulation of these structures is planned as an option in later versions of the RARP phantom.
- Bleeding functionality:
  Simulation of bleeding will be added on demand. This functionality, however, might be more applicable for the upcoming renal phantom.