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Patient-Specific Subvalvular Apparatuses Consisting of Chordae Tendineae and Papillary Muscles to Complete Mitral Valve Replicas

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***Abstract*— Mitral valve regurgitation is one of the most common heart valve diseases and mitral valve repair is the favored but challenging therapy. To improve preoperative understanding of mitral valve anatomy and enable preoperative simulation of mitral valve repair, patient-specific mitral valve replicas have been developed. However, most of these replicas are missing the subvalvular apparatus consisting of cords, the chordae tendineae, and papillary muscles. Hence, as they only represent incomplete anatomy, it is impossible to simulate the repair technique implantation of artificial chordae tendineae on them. To solve this problem, we developed patient-specific subvalvular apparatus replicas completing the mitral valve replicas. From 3D ultrasound images of hearts, the chordae tendineae were segmented and used to realize the subvalvular apparatus replicas which were 3D printed from soft material and integrated into the existing mitral valve replicas. The mitral valve replicas with subvalvular apparatus were assessed by an expert heart surgeon who rated them as realistic and successfully simulated mitral valve repair by implanting artificial chordae tendineae into them.**

***Index Terms*— subvalvular apparatus, chordae tendineae, papillary muscles, mitral valve replica**

I. Introduction

A. Anatomy and Function of the Mitral Valve

The mitral valve is one of the four heart valves. It is located between the left atrium and the left ventricle and consists of two leaflets. Below the mitral valve is its subvalvular apparatus consisting of cords, the chordae tendineae and two papillary muscles. The chordae tendineae connect the leaflets via the papillary muscles with the left ventricle. Fig. 1 shows a graphical representation of this anatomy. During diastole, when the heart relaxes, the mitral valve opens due to the decreasing pressure in the left ventricle and allows blood flow from the left atrium to the left ventricle. During systole, when the heart contracts, the mitral valve closes due to the increasing pressure in the left ventricle and prevents backflow to the left atrium. The blood is pumped into the body. The chordae tendineae prevent the mitral valve leaflets from prolapsing into the left atrium. Thereby the leaflets and the chordae tendineae form parachute-like structures.

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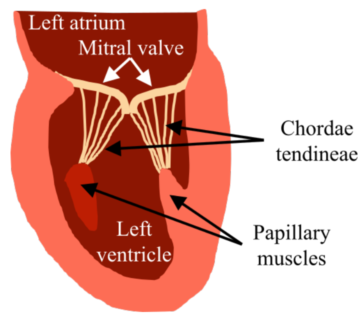

Fig. 1. Cross section of the heart showing the closed mitral valve and its subvalular apparatus consisting of chordae tendineae and papillary muscles.

B. Medical Problem

In mitral valve regurgitation, the mitral valve does not close completely, as shown in Fig. 2A. This causes a part of the blood to be pumped back into the left atrium instead of into the body during systole, which impairs the pumping function of the heart. Reasons for this can be a dilatation of the mitral valve, an excessive leaflet movement due to elongated or ruptured chordae tendineae or a restricted leaflet movement. Mitral valve regurgitation is one of the most common heart valve diseases [1], the prevalence is estimated at 1-2 % and rises depending on age up to more than 10 % for people over 75 years [2].

C. State of the Art and Research

The favored therapy for mitral valve regurgitation is mitral valve repair since it is superior to mitral valve replacement [3]. In this surgery, the mitral valve is treated so that it closes tightly again. Various repair techniques are available, for example the resection of a part of the mitral valve, the implantation of artificial chordae tendineae or the implantation of an

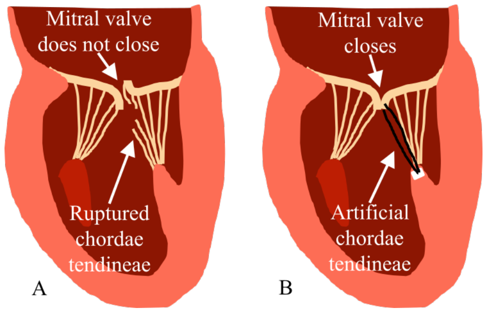

Fig. 2. A: Mitral valve regurgitation: The mitral valve does not close due to ruptured chordae tendineae. B: Mitral valve repair: Artificial chordae tendineae are implanted so that the mitral valve closes again.

annuloplasty ring. This article focuses on the repair technique implantation of artificial chordae tendineae, which is used in prolapsed mitral valve leaflets caused by elongated or ruptured chordae tendineae. Here the damaged chordae tendineae are replaced by artificial ones so that the prolapse is corrected, as shown in Fig. 2. The surgery is as follows: Preoperatively, the mitral valve is examined with ultrasound imaging. During surgery, the heart surgeon accesses the heart by opening the chest, bypasses the blood flow of the heart with a heart-lung machine, stops the heart and opens the left atrium to access the mitral valve. He inspects it and identifies the insertion points of the artificial chordae tendineae on the prolapsed leaflet and on a papillary muscle. The artificial chordae tendineae implants consists of usually four chordae tendineae loops connected by a pledge and two sutures with needles, as shown in Fig. 3, and are available with different loop lengths. The implant length is measured either preoperatively in ultrasound images or intraoperatively with a caliper by measuring from the tip of a papillary muscle to a not prolapsed part of the prolapsed leaflet. The heart surgeon first sutures the implant with the pledge to a papillary muscle head, then he sutures the loops to the prolapsed part of the leaflet and thereby pulls it downwards. This part no longer prolapses and the mitral valve closes tightly again.

To improve preoperative planning of mitral valve repair, patient-specific mitral valve replicas have been developed [4], [5]. Fig. 4 pictures an example. The realization requires 3D ultrasound images of the patient's heart from which the mitral valve is segmented. Based on the segmentation a casting mold is designed, 3D printed and used to cast the mitral valve replica from silicone. The mitral valve replicas are used by heart surgeons to plan the repair preoperatively by simulating it on the replica. This should enhance their knowledge and improve the outcome of the surgery.

Only few mitral valve replicas already have a subvalvular apparatus. For instance, the authors in [6] segmented mitral valves with subvalvular apparatus from CT images and 3D printed them. Mitral valve replicas with subvalvular apparatus that are used in a flow simulator were developed in the work presented by [7]. The authors segmented only mitral valves from ultrasound images, manufactured them from silicone and thereby added chordae tendineae with a synthetic distribution by integrating nylon strings into the replicas. Mitral valve replicas with subvalvular apparatus that are used for surgical training were developed in [8]. The authors segmented mitral valves and the position of the papillary muscle tips from ultrasound images, added synthetic papillary muscles and chordae tendineae and cast the mitral valve with chordae tendineae and papillary muscles in one part from silicone.

D. Drawbacks of the State of the Art and Research

The planning of mitral valve repair is challenging. Only ultrasound images of the mitral valve and its subvalvular apparatus are available to the heart surgeons preoperatively. However, they only obtain a complete and reliable understanding of the mitral valve and its subvalvular apparatus intraoperatively when they see the physical conditions and not just images of them. The heart is bloodless during the surgery so that the surgeon can operate. However, this makes the intraoperative inspection more complicated as the mitral valve and its subvalvular apparatus collapse without the supporting blood pressure. The repair must then be planned promptly based on the surgeon's insight and the ultrasound images.

When implanting artificial chordae tendineae, the most challenging part is measuring the correct implant length [9]. It is difficult to measure the distance between a papillary muscle and an unprolapsed part of the mitral valve leaflet at a collapsed mitral valve.

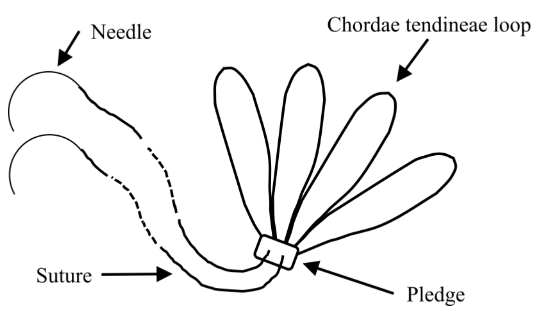

Fig. 3. Artificial chordae tendineae implant consisting of 4 chordae tendineae loops, a plege and sutures with needles.

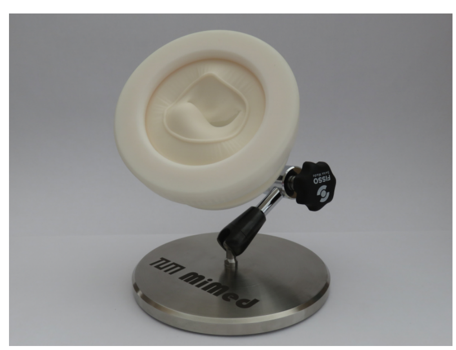

Fig. 4. Patient-specific mitral valve replica for preoperative planning of mitral valve repair. From 3D ultrasound images of the patient's heart the mitral valve is segmented and used to design a casting mold. With the 3D printed casting mold the mitral valve replica is cast from silicone.

Most mitral valve replicas are missing the subvalvular apparatus. Hence, as they only represent incomplete anatomy, it is impossible to simulate the implantation of artificial chordae tendineae. From the few replicas with subvalvular apparatus, only those from [8] seem to be suitable for the implantation of artificial chordae tendineae. However, their manufacturing method requires complex casting molds, they use synthetic papillary muscles and their chordae tendineae made of very soft silicone are supposed to be too elastic compared to natural chordae tendineae.

E. Research Goal and Expected Advantages

Our goal is to develop patient-specific subvalvular apparatus replicas consisting of chordae tendineae and papillary muscles for mitral valve replicas. Since we intend to use mitral valve replicas for patient-specific, preoperative planning of mitral valve repair, we want to model the anatomy of the patients' subvalvular apparatuses visible in the ultrasound images as accurately as possible. The subvalvular apparatus replicas should complete the mitral valve replicas and facilitate the preoperative understanding of their anatomy as it is easier to inspect a physical replica than to interpret ultrasound images. Furthermore, the subvalvular apparatus replicas should expand the planning possibilities by mitral valve repair with artificial chordae tendineae. For this purpose, it should be possible to measure the correct implant length and to implant artificial chordae tendineae.

For manufacturing the mitral valve replicas with subvalvular apparatus, we want to combine the technologies silicone casting and 3D printing to complement their advantages. The mitral valve replicas shall continue to be cast from silicone with 3D printed casting molds, giving them realistic haptics. The subvalvular apparatus replicas shall be 3D printed from soft material. This enables their complex geometry to be easily manufactured and the material properties are expected to be rational for a realistic implantation of artificial chordae tendineae. The design of the subvalvular apparatus replicas should be automatic to make it easy to use. For 3D printing, the same 3D printer as used for printing the casting molds for the mitral valve replicas should be used: A Formlabs Form 2 (Formlabs Inc., Sommerville, MA, USA).

II. MATERIALS AND METHODS

A. 3D Ultrasound Imaging and Segmentation of the Subvalvular Apparatuses

3D ultrasound images of the patients' mitral valves with subvalvular apparatus were taken using a Philips X8-2t transducer (Philips, Best, Netherlands) in transgastric view. The subvalvular apparatuses were segmented in systolic shape with the software 4D CARDIO-VIEW (TOMTEC Imaging Systems GmbH, Unterschleissheim, Germany). Distance measurements from the attachment point of the chordae tendineae at the mitral valves to their attachment point at the papillary muscles were performed for all visible chordae tendineae, as shown in Fig. 5. The measurements containing the coordinates of the attachment points were exported as a text file. The papillary muscles were not segmented but with the lower attachment points of the chordae tendineae surface points of them are known.

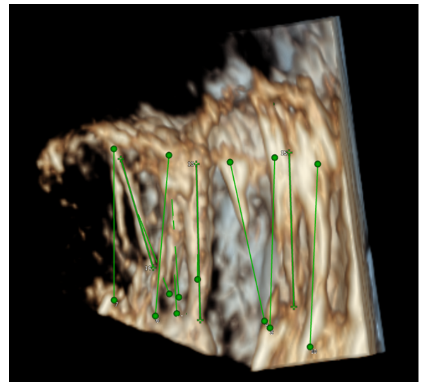

Fig. 5. Segmentation of the visible chordae tendineae from 3D ultrasound images by distance measurements from their attachment point at the mitral valves to their attachment point at the papillary muscles.

The mitral valves were segmented semi-automatically in systolic shape with the software 4D MV-ASSESMENT (TOMTEC Imaging Systems GmbH, Unterschleissheim, Germany) and exported in OBJ-format.

B. Concept of the Subvalvular Apparatus Replicas

Fig. 6 shows the concept of the subvalvular apparatus replicas completing the mitral valve replicas. They consist of chordae tendineae with papillary muscles at their lower end and clamping devices connecting them with the mitral valve replica at their upper end. A plate holds the subvalvular apparatus replicas together.

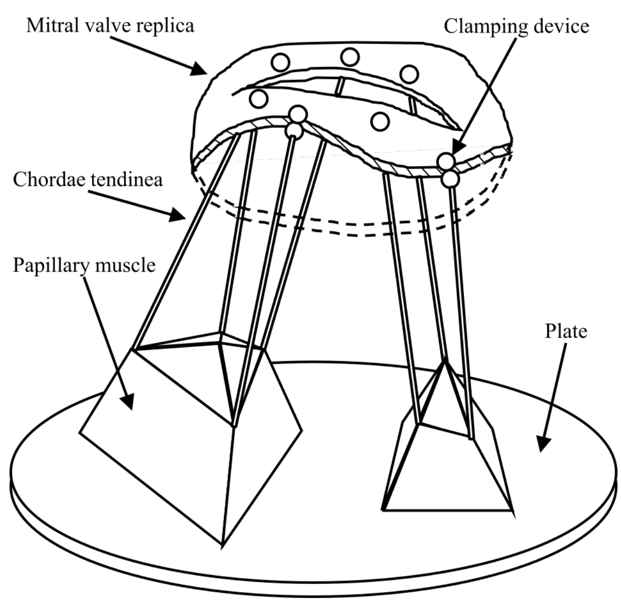

Fig. 6. Concept of the subvalvular apparatus replicas. They consist of chordae tendineae modeled by cylinders, papillary muscles modeled by polygons, clamping devices which connect the chordae tendineae with the mitral valve replica and a plate that holds the subvalvular apparatus together.

The chordae tendineae are modeled by cylinders with a diameter of 1 mm. Human chordae tendineae only have a diameter of approximately 0.4 mm [10], the diameter of the cylinders was chosen larger for reliable printability. The shape and size of human papillary muscles varies, their shape can be conical, flattop, truncated, bifurcated and trifurcated [11]. To model this variety in shape and size, two polygons are designed from the known attachment points of the chordae tendineae, which become wider downwards. The clamping devices attach the chordae tendineae to the mitral valve leaflets and consist of two overlapping spheres. The mitral valve leaflets therefore have corresponding recesses. A plate connects the papillary muscles and thereby holds the subvalvular apparatus replica together.

C. Design of the Subvalvular Apparatus Replicas

To realize the subvalvular apparatus replicas an automatic design process was implemented in the software MATLAB (The MathWorks Inc., Natick, Massachusetts, USA) using the SG-Library [12], a toolbox for creating and manipulating 3D printable surface models of geometric bodies consisting of vertices and facets. Fig. 7 shows the principle of the automatic design process.

The automatic design imports the segmented mitral valve (Blue in Fig. 7) and the chordae tendineae represented by their segmented points (Green crosses in Fig. 7). Due to the independent segmentation of chordae tendineae and mitral valve, the upper points of the chordae tendineae do not necessarily lie exactly on the mitral valve surface. Therefore, the automatic design calculates the intersection points (Black cross in Fig. 7) between the line through the segmented points of the chordae tendineae (Green dotted line in Fig. 7) and the lower mitral valve's surface and replaces the original upper points with them. It may happen that there is no intersection point, this situation occurs when the line through the segmented points of the chordae tendineae does not hit the mitral valve at all or passes through its opening. Then the automatic design selects the closest vertex of the lower mitral valve surface to the upper point of the chordae tenineae as new upper point. The boundary points of the mitral valve are excluded from this so that the new upper points do not lie on the boundary of the mitral valve. If two upper points of the chordae tendineae lie so close to each other that their clamping devices would overlap, the automatic design sorts one of them with its associated lower point out. For each pair of the refurbished points, the automatic design creates a cylinder (Red in Fig. 7) with diameter 1 mm and the distance between the points as length mimicing a chordae tendineae. For the design of the papillary muscles, the automatic design first sorts the lower points of the chordae tendineae into points for the right and left papillary muscle. It creates a contour from the points of each side, shifts it downwards and enlarges it. The automatic design meshes the original points and the points of the created contour, resulting in the two papillary muscles (Purple in Fig. 7). Spheres at the lower points of the chordae tendineae guarantee a good connection between the chordae tendineae and the papillary muscles. To hold the subvalvular apparatus together, the automatic design creates a flattened round plate (Grey in Fig. 7) connecting the papillary muscles. For the clamping devices the automatic design creates spheres (Orange in Fig. 7) with a diameter of 2 mm and positions them on a line normal to the mitral valve with a gap of 0.4 mm from the upper and lower mitral valve surface. This overlaps them by 0.2 mm and makes the lower sphere contain the upper end of the chordae tendineae. Finally the automatic design exports the subvalvular apparatus replicas as STL-file, an example is shown in Fig. 8.

Further the casting molds for manufacturing the mitral valve replicas and the fixture for holding the replicas were adapted. In the casting molds, the same spheres as in the clamping devices were integrated. Only their distance from the mitral valve surfaces was increased, so that they only touch instead of overlap. The spheres create recesses in the mitral valve replicas in which the clamping devices of the subvalvular

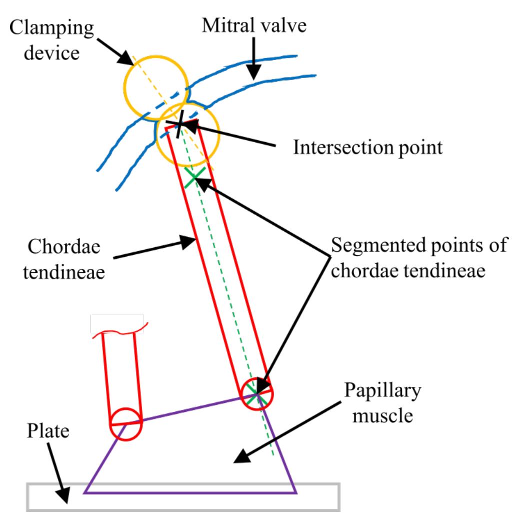

Fig. 7. Principle of the automatic design process illustrating the creation of the subvalvular apparatus replicas from the segmented chordae tendineae points.

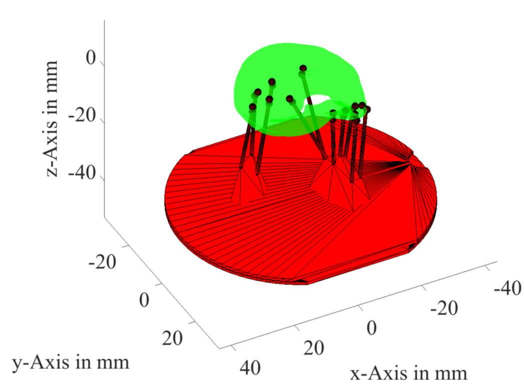

Fig. 8. Patient-specific subvalvular apparatus replica (red) with mitral valve (green).

apparatus replicas are inserted. The fixture was adapted so that the subvalvular apparatus replicas can be inserted with their flattened round plate.

D. Manufacturing of the Subvalvular Apparatus Replicas

The subvalvular apparatus replicas were 3D printed with a Formlabs Form 2 stereolithography 3D printer using soft Formlabs Elastic Resin with a shore hardness of 50 A. For printing first support structures without internal support structures were created automatically with the software Preform. Then three to five internal support structures were added manually to each chordae tendineae to ensure reliable printing. After printing, washing and postcuring, the support structures were removed with a wire cutter. In parallel, the mitral valve replicas and the fixture were manufactured as described in [4].

The mitral valve and the subvalvular apparatus replicas were inserted in the adapted fixture and the clamping devices of the subvalvular apparatus replicas were inserted in the corresponding recesses in the mitral valve replicas using forceps. Fig. 9 shows a resulting patient-specific mitral valve replica with subvalvular apparatus.

III. Results

Patient-specific mitral valve replicas with subvalvular apparatus were manufactured with the presented workflow for three patients with mitral valve regurgitation. An expert heart surgeon assessed them and performed mitral valve repair by implanting artificial chordae tendineae on two of them.

According to the surgeon's experience, the subvalvular apparatus replicas look very realistic and their haptics is somewhat realistic. He found that the correct artificial chordae tendineae implant length can be easily determined on the replicas. Since the replicas shows the mitral valves in their systolic shape, the distance between a papillary muscle and an unprolapsed part of the mitral valve leaflet is easier to measure than during a surgery on a collapsed mitral valve (Fig. 10). He was able to successfully implant artificial chordae tendineae into the mitral valve replicas with subvalvular apparatus to correct mitral valve regurgitation, as shown in Fig 10 and 11. Thus, the subvalvular apparatus replicas increase the usefulness of the mitral valve replicas for him. In the final stage of development of the subvalvular apparatus replicas, no real chordae tendineae implant was available. Therefore, the heart surgeon improvised and used a silicone tube as implant, as shown in Fig. 10. In an earlier stage where the subvalvular apparatus replicas consisted only of hemispheres, a real chordae tendineae implant was inserted, as shown in Fig. 11.

Fig. 9. Patient-specific mitral valve replica with the developed subvalular apparatus, top and side view.

Fig. 10. Patient-specific mitral valve replica with the developed subvalular apparatus after implanting a silicone tube (red arrows) as artificial chordae tendineae and annuloplasty to repair mitral valve regurgitation. Distances can be easiely measured on the replica.

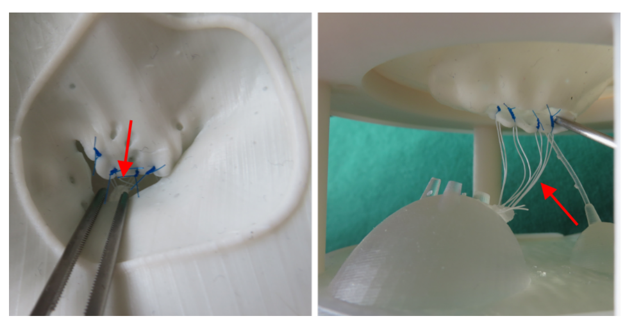

Fig. 11. Patient-specific mitral valve replica with an early stage subvalular apparatus after inserting an artificial chordea tendineae implant (red arrows).

IV. Discussion

We reached our goal to develop patient-specific subvalvular apparatus replicas consisting of chordae tendineae and papillary muscles to complete mitral valve replicas on which mitral valve repair by implanting artificial chordae tendineae can be realistically simulated. Now all common mitral valve repair techniques can be simulated on the replicas. We claim to have developed the most realistic subvalvular apparatus replicas as we only use patient-specific data and no synthetic data.

High-quality 3D ultrasound images are necessary for creating the replicas. In such ultrasound images, the correct implant length can also be directly measured. Nevertheless, the subvalvular apparatus replicas offer some significant advantages over ultrasound images for planning mitral valve repair according to the feedback of a heart surgeon. They facilitate the preoperative understanding of the subvalvular apparatus's anatomy. Heart surgeons can simply inspect the physical replicas and do not have to interpret ultrasound images on a screen. In addition, they can measure the length for the chordae tendineae implants on the replicas using their familiar methods from surgery and not software. Furthermore, mitral valve repair can be simulated preoperatively on the replicas. This can be helpful when planning complex and difficult cases. Compared to the patients' collapsed mitral valves during surgery, the replicas offer the advantage that they show the mitral valves in their systolic shape, the critical phase for leak tightness. This phase is normally only visible in the intangible ultrasound images.

The segmentation of the chordae tendineae from the 3D ultrasound images by distance measurements is a simple procedure. Thus, also surface points of the papillary muscle are known, from which their shape can be approximated. The distribution of the chordae tendineae over the mitral valve, shown in the top view in Fig. 9, illustrates that chordae tendineae are missing in some parts of the mitral valve. However, this does not limit the planning of mitral valve repair by implanting artificial chordae tendineae. Here, particularly the distance between the papillary muscle tips and the mitral valve is relevant. 3D printing makes it easy to manufacture the subvalvular apparatus replicas with the delicate chordae tendineae. Attention must be paid to generate enough support structures for the chordae tendineae, otherwise there is the risk that the print can fail. The material properties of the used soft material are rational for implanting artificial chordae tendinea and create a somewhat realistic haptics. The connection between the chordae tendineae and the mitral valve via the clamping devices is not very strong. It can detach when working on the mitral valve but can be restored afterwards.

With the presented workflow also subvalvular apparatus replicas with synthetic chordae tendineae distributions and papillary muscels for surgical training as in [7], [8] can be manufactured. Therefore, suitable coordinates have to be given as input for the automatic design.

For the future we plan to use the mitral valve replicas with subvalvular apparatus to preoperatively plan mitral valve repair by implanting artificial chordae tendineae. Subsequently, we want to operate the associated patients and evaluate whether we would insert the same implant length as planned on the replica.

V. Conclusion

In this article, patient-specific subvalvular apparatuses consisting of chordae tendineae and papillary muscles that complete the anatomy of mitral valve replicas were presented. From 3D ultrasound images of hearts, the subvalvular apparatuses were segmented by performing distance measurements for all visible chordae tendinea. From the measurements the subvalvular apparatus replicas were designed, 3D printed from soft material and integrated in existing mitral valve replicas. The assessment of the mitral valve replicas with subvalvular apparatus by an expert heart surgeon showed that mitral valve repair by implanting artificial chordae tendineae can be realistically simulated on the replicas. In future work, we want to investigate how much the preoperative planning of mitral valve repair can profit from its simulation on the replicas.

Acknowledgment

Michael Kruttschnitt developed the subvalvular apparatus replicas and wrote this article. Friederike Rehfuess assisted in the development. Klaus Tiemann took the ultrasound images. Niklas Hitschrich segmented the mitral valves and the subvalvular apparatuses. Ralf Sodian evaluated the subvalvular apparatus replicas and simulated mitral valve repair on them. Tim C. Lueth is the director of the Institute of Micro Technology and Medical Device Technology.

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