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A model for in vitro evaluation of overlapping connections between devices used in the endovascular repair of popliteal aneurysms.

Short Title: Evaluation of overlapping connections

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ABSTRACT

This work proposes a new methodology to investigate the potential for disconnection (Type III endoleak) of pairs of overlapped endoprostheses in a popliteal model vessel after a cyclic physiologic load, for three different overlap lengths. A multiaxial fatigue accelerated testing was designed to mimic the physiological loads and movements to which the peripheral arteries are submitted during gait. The experiment design was based on principles from technical standards ASTM F2477-07 and ASTM F2942-13. Migration and disconnection were monitored by DIC (Digital Image Correlation) for three different overlap lengths (20, 30 and 40mm). The testing method proposed in this work was efficient to provide a simulated environment to evaluate the influence of gait biomechanics on overlapped endoprosthesis disconnection. Obtained results demonstrated minimal or absence of relevant migration between the endoprosthesis, range -0.06 to 0,34 millimeters. The proposed methodology was verified as a valuable tool to investigate the influence of the biomechanical environment which the devices are subjected to on the migration of overlapped endoprosthesis. It may become a new alternative to study the pre-clinical *in vitro* performance of single endoprosthesis or multiple connected devices with different overlapped regions.

Keywords: popliteal artery, aneurysm, endovascular procedures, endoleak, mechanical testing

1. Introduction

The popliteal artery (PA) is the continuation of the femoral artery below the adductor hiatus. This vascular segment is exposed to a complex biomechanical demand due to its position behind the knee. PA undergoes cyclic extension, shortening, flexion, torsion, external compression as well as diametral changes during daily activities. [1–5] Therefore, due to its complex biomechanics PA is affected by a unique set of pathologic conditions including atherosclerosis, arterial embolus, trauma, popliteal artery entrapment syndrome, cystic adventitial disease and popliteal artery aneurysm (PAA). The later (PAA) is a common type of peripheral aneurysm and is associated with occlusion of vascular flow due to thromboembolic episodes, in which the amputation rate may be as high as 20% in non-operated patients.[6] Surgical treatment of PAA is indicated when its diameter is greater than 25 millimeters [7]. The procedure consists of open surgery and reconstruction of arterial flow with autologous saphenous vein or artificial graft. [8]

Endovascular popliteal aneurysm repair (EVPAR) is a feasible, minimally invasive treatment option in anatomically suitable cases and high anesthetic-surgical risk patients. [9] This procedure consists of the insertion of a stentgraft through a remote arterial site followed by proximal and distal fixation, resulting in patency of endoluminal flow with absence of endoleaks.[10] However, the difference of caliber between the proximal and the distal arteries complicates the treatment since the diameter and length of the endoprosthesis cannot be customized. An alternative to overcome this problem is the overlap of endovascular prostheses, which is observed in 70% of EVPAR. [11,12]

Overlapping consists of the connection of the ends of two stents or endoprostheses to compatibilize the diameter between the proximal and the distal arteries as well as increasing the length of the treated area. The connection of the ends of the two devices is achieved by overlapping of the two devices. It is recommended that the smaller caliber endoprosthesis is initially installed and then a larger caliber endoprosthesis is placed inside the smaller one, in order to guarantee the sealing and the fixation, with an overlap of at least 10 millimeters. [13] This strategy implies an increase in the radial force on the internal endoprosthesis and minimizes the risk of disconnection. As the overlapping area presents different physical characteristics comparing to devices alone, the behavior of overlapped devices *in vivo* as well as its interaction with the surrounding environment is difficult to predict, particularly in a diseased artery. [14]

Structural failures and disconnections of devices implanted in these regions due to cyclic deformations have been reported.[14] Migration and disconnections are complications seen in 8-14% of patients.[12,15] Intraoperative considerations might influence outcomes after EVPAR including the access type, number of devices, oversizing and overlapping. Considering the extension of overlapping area in EVPAR, it is known that it may range from ten to forty millimeters, however, there are no studies investigating how this variation may influence device disconnections and failures. [16]

The Gore Viabahn Endoprosthesis (W. L. Gore & Associates, Flagstaff, Arizona) has been widely used in patients submitted to EVPAR. The Viabahn features a contoured, instead of a straight, proximal edge to prevent infoldings in case of oversizing and is available in long lengths reducing the number of overlapping zones.[11] Moreover, this device is flexible while maintaining good radial force, making it potentially useful for popliteal artery applications, where there is substantial vessel motion. [17] The manufacturer recommends overlapped length of connected endoprothesis to be at least twenty millimeters. [13]

Despite the advances in knowledge of PA anatomy and physiology, PAA pathology, and its biomechanical environment, little is known about how overlapping zones of endoprosthesis can be evaluated *in vitro* to investigate or prevent disconnection *in vivo*. Studies have been made based on medical images and finite element analysis (FEA). Medical images usually reveal only the effect of the surgery without providing more details on how the overlap influences the performance of the device. On the other hand, FEA data have elucidated the type of interactions during overlapping process and stent failure[18]. The present paper proposes a new method to study the disconnection (Type III endoleak) of pairs of overlapped endovascular endoprosthesis in a popliteal model vessel after cyclic physiologic load, for three different overlap lengths.

2. Materials and Methods

Institutional Review Board was not required because this research was not conducted on human subjects.

2.1 Simulated peripheral arterial aneurysm model and endovascular endoprosthesis implantation

Silicone-based simulated models (Figure 1) of peripheral arterial aneurysm were designed using Computer Aided Design (Solid Works) and Finite element Analysis. The models were manufactured via injection molding, using an aluminum cast, with an inner diameter of 4.4 mm. To evaluate the mechanical behavior of the peripheral arterial aneurysm model, the manufactured artificial aneurysms were filled with Phosphated Buffered Saline (PBS) and maintained at 37 °C with pressure flow ranging from 80 mmHg to 160 mmHg at the physiological frequency of 1.2 Hz, according ASTM F2477 - Annex 1. They showed compliance (8.5%) and diametral distension (2.8%) similar to the natural popliteal artery.[4] The model vessel was created with an inner diameter of 4.4 mm, and when combined with a stent of 5 mm nominal diameter, there is an oversizing of 13,6%. In the center of the model there is a dilatation simulating an aneurysm of 40 mm extension, where the internal diameter of the model reaches 8 mm. The tubing diameter was designed considering an appropriate oversizing between the smaller and larger endovascular prostheses, in which the minimum difference between these devices is 1.0 mm. This strategy causes an increase of the radial force of the smaller prosthesis and a lower risk of disconnection. A labeled device diameter of 5 mm is recommended for a vessel of 4.0 to 4.7 mm.[13] Similarly, a labeled device of 6 mm is recommended for a vessel of 4.8 to 6.6 mm diameter, for instance. This difference was not taken into account, as the aim was to investigate disconnection rather than to evaluate the proximal and distal neck interactions. The effect over implant joint due to aneurysm diameter is not relevant once there is no contact with it. All that is necessary is to choose a diameter large enough to avoid contact between implant and tubing. Two Viabahn endoprosthesis were inserted on the artificial peripheral arterial and connected one to another at the central point of the aneurysm model. Through the upper opening of MAPS fixture a 300 mm long guide wire was installed through the entire aneurysm model. Then a Gore VIABAHN® endoprosthesis (5 mm x 100 mm) delivery system was introduced. The endoprosthesis was released according to the manufacturer's instructions. The delivery system was removed and a second endoprosthesis (6 mm x 100 mm) was introduced using the same guide wire. Continuous manual measurements were taken to control the length of the overlapped region. Three groups with four samples each (n = 4) according to overlapping distance were produced (G1 = 20 mm, G2 = 30 mm, and G3 = 40 mm). The midpoint of the overlapped segment remained at the center of the aneurysm of the silicone model. All endoprostheses were inserted by a senior vascular surgeon, according to the manufacturer's instructions.

Figure 1. a) Dimensions in millimeters of the model vessel in silicone simulating peripheral arterial aneurysm. b) Computer aided Finite Element Analysis of the model.

2.2 Testing set-up

The silicone aneurysm models were attached to a Bose MAPS (Multiaxial Peripheral System, Electroforce Systems Group, Eden Prairie, Minnesota). Pre-tensioning was not performed to minimize the possibility of premature endoprosthesis disconnection. The manufactured models were then filled with Phosphated Buffered Saline (PBS) and maintained at 37 °C.

2.3 Multiaxial Fatigue Testing

The multiaxial fatigue testing was designed to mimic the PA's physiological loads and movements. The biomechanical environment was based on parameters from technical standards ASTM F2477-07 (*Standard Test Methods for in vitro Pulsatile Durability Testing of Vascular Stents*)[19] and ASTM F2942-13 (*Standard Guide for in vitro Axial, Bending, and Torsional Durability Testing of Vascular Stents*)[20] simulating the worst-case scenario. The sets were submitted to the cyclic loading of 76 million pulsating cycles at a frequency of 24 Hz, (to simulate the diametral distension imposed on the popliteal artery with pulsatile flow). The mechanical load on the model and endoprosthesis simulated knee flexion during gait activities (65 °) with flexion peaks (135 °), related to larger flexions (such as lifting objects or bathing).[21] The knee flexion simulated load reproduced the walking condition of 6 million cycles (approximately six years gait)[22] with peak angles at the frequency of 10 times every 24 hours. The knee torsion load (which simulated the tibia axial rotation torsion in relation to femur, screw-home movement, and torsion in the popliteal artery) was defined as 30 °.[23] So, the setup for loads was: elongation (14.2%), flexion (58.0 mm, curve radius of 24 mm) and torsion (30°) in the frequency of 1 Hz (Figure 2). The intent was to simulate the mechanical loading of the first two years in the patient using this prostheses combination. The phosphate buffered saline was changed weekly to assure camera visibility and image capture quality.

(a) (b)

Figure 2. Eight silicon aneurysm models with two overlapped endoprostheses inside it. (a) Equipment setup at rest and (b) cyclic forces acting on endoprosthesis sets: (1) Elongation (14.2%); (2) Flexion (curve radius of 24 mm); (3) Torsion (30 °); (4) External compression; in the frequency of 1 Hz.

2.4 Migration evaluation

To measure the eventual displacement of the endoprosthesis within the aneurysm model submitted to multiaxial fatigue testing, a DIC (Digital Image Correlation) system was used. Displacements were measured by changes in pixels in a digital image and allowed for characterization of material behavior and structure response to external loads[24]. This methodology has been previously used to evaluate the displacement forces of stent grafts.[25] The monitoring system was composed of 4 cameras with resolution of 1280 × 960 pixels controlled by a computer used to register the test and create a digital image. Each position in the digital image array contains information about the color of the image in that position, and corresponds to the smallest element of the image (called a pixel). The images of the present study were in greyscale represented by a 1280 × 960 matrix (corresponding to the resolution of the optical sensor of the camera used). Each element represents a pixel with a value between 0 (black) and 255 (white). Each camera took images of two adjacent samples at each scheduled time point (Figure 3a). In order to enable the distance measurement from the images captured by the cameras, a scale with high accuracy (1 ± 0.001 mm) (EDMUND OPTICS INC.) was used, where 1 pixel corresponded to a distance of 0.05 mm. (Figure 3b). The error associated with the scale is 0.001 mm every 1 mm. The monitoring system performed the visual recording of the behavior for each of the specimens. Throughout the test, at every 3600 flexion cycles, corresponding to one hour of testing, the machine paused for 30 seconds, during which images were made and stored digitally.

Figure 3. (a) Samples image made by camera 1, monitoring samples 1 and 2 (b) Precision scale used to match the actual distance (mm) to the distance in the image (pixels).

The images taken during the experiment allowed the analysis of connection between devices throughout the duration of the mechanical test by monitoring the vertical distance between pairs of points in the images. One point was located in the upper endoprosthesis and another point was located in the inferior endoprosthesis. It was assumed that only the vertical displacement of endoprosthesis is relevant to evaluate the likelihood of disconnection. The initial procedure for measuring the detachment of a pair of endoprosthesis was based on the monitoring of manually labeled homologous points. The stitches were scored in pairs so that one of the pair points was part of the upper endoprosthesis and the other pair point was part of the lower endoprosthesis. The choice of starting points was arbitrary. However, low repeatability was observed along the initial experiments. Therefore, another strategy was proposed. It consisted primarily of a code written in MATLAB software, and its purpose was to aid the marking of homologous points in test images. The markers identification is a semi-automatic process in which an area was selected manually enclosing the fiducial marker in each endoprosthesis. Then, the algorithm finds the darkest point in these areas and measures the distance between them. To minimize errors an illumination system was assembled and maintained at the same position and light intensity. The accuracy is associated with a specific pixel within the selected area (1 pixel is equivalent to 0.05 mm). (Figure 4)

Figure 4. Measurement of vertical distance (in pixels) between a pair of homologous points. Each target point is located in each endoprosthesis and is determined semi-automatically (red lines) (see text for details).

At the end of this procedure for all images of a test body, distance values between the two pairs of homologous points were taken throughout the test. Each measurement was performed five times and the mean value was considered representative of the displacement. The resolution of the experiment was 0.01 mm.

2.5 Tensile Testing

After multiaxial fatigue testing end, the silicone aneurysm models with the endoprosthesis in its interior were removed from the fatigue test machine. Then each silicone aneurysm model was sectioned without damaging the set of endoprosthesis. The tensile testing was performed on the set of endoprosthesis until disconnection. It was used a universal testing machine (EMIC Universal, Instron Brasil Equipamentos Científicos LTDA, São José dos Pinhais, Paraná, Brazil) operating with a load cell of 20 N and displacement control for a test speed of 0.4 mm/sec.

2.6 Statistical Analysis

The vertical displacement was defined as the mean of the distance variation of homologous points. Data were graphically described as mean. Variance Analysis for Repeated Measures was used to study the difference between groups. The level of statistical significance was 95%.

3. RESULTS

The results of migration measurements of samples tested in the assay are shown in Table 1 (range -0.06 to 0,34 millimeters). There was no difference between the time periods evaluated (p 0.087), however, differences were verified between groups. The group with overlap of 20 mm had a higher migration than the group with a 40 mm overlap. (p 0.034). The 30 mm group presented no difference in relation to the group with 20 or 40 mm of overlap (p 0.125 or 0.620, respectively). There were no visible disconnections or breaks from endoprosthesis sets in the aneurysm model at the end of the predefined number of loading cycles. All samples completed all cyclic loading for cardiac cycles and gait simulation without connection failure.

Table 1. Displacement between endoprosthesis during the multiaxial fatigue test with three different overlapped lengths.

	20-millimeter overlap				30-millimeter overlap				40-millimeter overlap			
Sample	1	2	3	4	1	2	3	4	1	2	3	4
Test progression	migration (mm)				migration (mm)				migration (mm)			
0%	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
25%	-0.06	-0.02	0.05	0.10	-0.06	0.04	-0.01	0.00	-0.02	-0.05	0.08	0.04
50%	-0.06	-0.02	0.01	0.11	-0.04	0.06	0.02	0.00	-0.03	0.03	0.08	-0.03
75%	0.06	0.39	*	0.11	-0.06	0.03	0.01	-0.05	-0.02	0.00	0.11	-0.02
100%	0.11	0.38	*	0.10	-0.06	0.04	-0.01	-0.04	-0.06	0.00	0.09	-0.02

*The silicone tube of the aneurysm model of test sample number (3) in the 20 mm overlap group ruptured with 3.78×10^7 cycles, approximately half the total cycles of the assay.

To evaluate the disconnection ultimate load for the overlapped endoprosthesis, tensile tests were performed in samples with 30- and 40- mm overlap, as demonstrated in Figure 5. The end of each line represents tension required for devices' disconnection. According to Table 2, the tension required for disconnection of the stents was higher for samples with 40 mm overlapping.

Figure 5. Tensile test results of 30 mm (black) or 40 mm (dashed line) overlapping endoprosthesis sets.

Table 2. Tension for disconnection of endoprosthesis with 30 or 40 mm overlapping after fatigue test.

	30 mm	40 mm	p
Tension (N)	7.85 ± 1.28	10.25 ± 0.56	0.014

4. Discussion

It is relevant to evaluate new devices despite premarketing testing and validate data of established devices in different clinical contexts.[10] Interaction of two or more endoprosthesis in the complex biomechanics of the knee deserves attention, because long-term patency rate is not equivalent to open surgery.[15,26] The current study proposes a new methodology for experimental evaluation of stents and endoprosthesis, which allows the evaluation of not only the mechanical performance of these devices, but also the behavior of overlapped endoprosthesis under *in vitro* conditions that simulate the biomechanical environment faced *in vivo*. The absence of disconnection between the different groups demonstrates good results in terms of performance of investigated devices. Furthermore, it demonstrates that when overlaps higher than 20 mm are used, the risk of disconnection might be reduced.

Device failure is a multifactorial event. It can be related to error of indication for the device (technical details such as size, length, overlapping, oversize) or related to the failure of the device, all resulting in endoleaks or occlusion. The specific mechanisms behind stent failures have not been understood completely, however, previous studies demonstrated that long stented segments with multiple overlapping regions are more likely to fail. The explanation for this behavior is based on the increase of axial stiffness of the stent segment. An *in vitro* evaluation of six different modern self-expandable stents tested long term fatigue after repetitive deformation (5%) and bending (48°) during 10 million cycles at 7 Hz. Results demonstrated a variable ability of withstanding chronic deformations and fractures of Nitinol wires were dependent on the type of deformations. [27] Another study evaluated 12 different devices used in peripheral occlusive artery disease and compared force-strain behavior, stiffness, and geometrical shape under each deformation mode (axial and radial compression, axial tension, bending, and torsion). It is unknown which of these deformation modes has the greater clinical impact. None of the 12 stents demonstrated superior characteristics under all deformation modes.[28] The experiment proposed in the present work was focused on a physiologic approach, combining elongation, bending, torsion and compression in the same test. Furthermore, previous studies have used straight silicon tubes as a model vessel whereas the present model represented an aneurysmatic artery, simulating loss of contact of the endoprothesis with the arterial wall. As it was expected, force required to detach devices was greater to uncouple pairs with longer length of overlap.

The goal of this study is to investigate device disconnection. Fracture might also occur. Hence, this was also monitored along the mechanical test but not detected. . In occlusive arterial disease, fracture of Nitinol bare stents is strongly associated to long term occlusion of arterial flow.[29] Fractures of nitinol endoprosthesis after EVPAR surprisingly were not associated to loss of patency, but were found mostly in overlapped zones.[15,30] However, the reason why endoprosthesis are more prone to better outcomes in occlusive diseases is yet to be explained.[31] Although it is not the most common complication of EVPAR, disconnection between overlapped endovascular devices do occur[30] and may be underreported.[32] The consequence of disconnection of overlapped endoprosthesis is aneurysm sac pressurization and a secondary procedure is indicated as soon as possible.

Another originality of our study is the evaluation of different overlap extensions. Freedom from migration is key to the durability of endovascular procedures.[33] It may lead to endoleaks and secondary procedures. In this study, clinically significant migration or disconnection was not verified in devices evaluated. Moreover, dislocation of the entire set within the vessel was not verified, probably due to the oversize of the device relatively to the model vessel. Unfortunately, there is no standardized definition of migration limits in EVPAR, but studies in aortic repair migration have defined it as significative when greater than 10 mm.[10]

There is no gold standard durability and fatigue assessment that adequately predicts the clinical performance of therapies for peripheral artery disease [34] making comparison of results a difficult task. Different subjects of study and different methods of evaluation of normal artery deformations during daily activities have resulted in a problematic range of normal values. Values used in this study are between the range reported in the literature, however, which load is adequate to simulate every required conformational change is not yet standardized. The developed methodology is able to model in an accelerated approach to the mechanical environment of the first two years in the patient using this prostheses combination. Considering moderate movement limitations or chronic disease, the patient will carry out on an average of 4250 steps per day, approximately 3 steps per minute.[35] Therefore, the selected pulsatile cycles and gait cycles frequencies were 24 Hz and 1 Hz, respectively. So, 76 million pulsatile cycles and 3.1 million gait cycles were performed simultaneously during 37 days using these input frequencies. Laboratory studies are useful to promote insights or new concepts into medical devices and disease, and method standardization is the first step to acquire reliable results as well as for proper comparison in interlaboratory evaluations. Since endoprosthesis connection failure occurs in 10-12% of EVPAR,[11,12] further research is necessary using the proposed methodology but varying not only the overlapping range but also the number of connected devices.

The ideal scenario would be the conduction of a large prospective randomized trial on overlap distances in EVPAR, to determine the ideal overlap length, if any, but huge difficulties need to be overcome to accomplish such a task. For the moment, published case series and anecdotal cases are the best possible evidence in decision making in regards to overlap length. In the manufacturer IFU, an overlap of 20 mm appears to be a safe start to minimize the risk of disconnections.

According to our data, there is no difference in the occurrence of disconnection in devices when longer overlapping lengths are used, so it seems that deliberate increase of the overlapped area would not be associated to decreased risk of middle or long-term complications (Type III endoleak).

Conclusion

This work proposed a new methodology to evaluate the mechanical performance of overlapped endoprosthesis submitted to simulated gait conditions. The connected devices were submitted to the diametral distension, tension, flexion and compression during 6 million cycles, which represents approximately six years gait. Three different overlap lengths were evaluated, 20, 30 and 40mm, however, minimal or absence of migration was verified in the tested devices. The proposed methodology was verified as a valuable tool to investigate the migration of overlapped endoprostheses. It may become a new alternative to evaluate the *in vitro* performance of single endoprosthesis or multiple connected devices with different overlapped regions.

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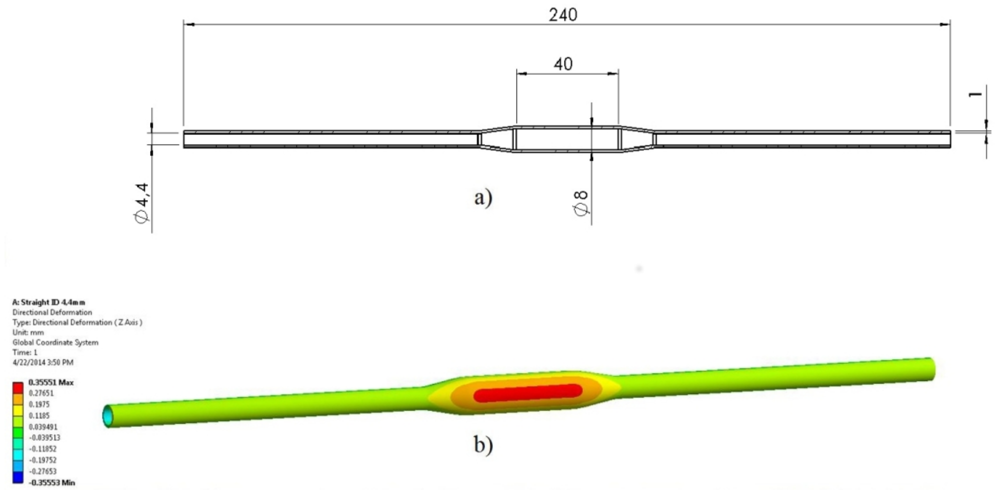

Figure 1. a) Dimensions in millimeters of the model vessel in silicone simulating peripheral arterial aneurysm. b) Computer aided Finite Element Analysis of the model.

128x69mm (300 x 300 DPI)

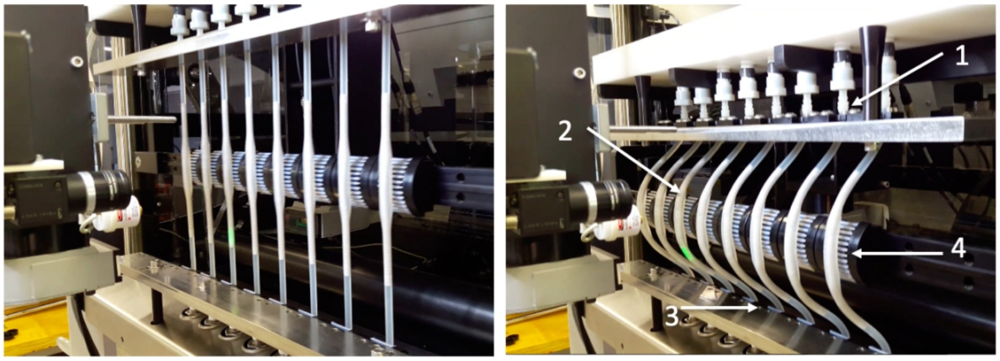

Figure 2. Eight silicon aneurysm models with two overlapped endoprostheses inside it. (a) Equipment setup at rest and (b) cyclic forces acting on endoprosthesis sets: (1) Elongation (14.2%); (2) Flexion (curve radius of 24 mm); (3) Torsion (30 °); (4) External compression; in the frequency of 0.5 Hz.

107x38mm (300 x 300 DPI)

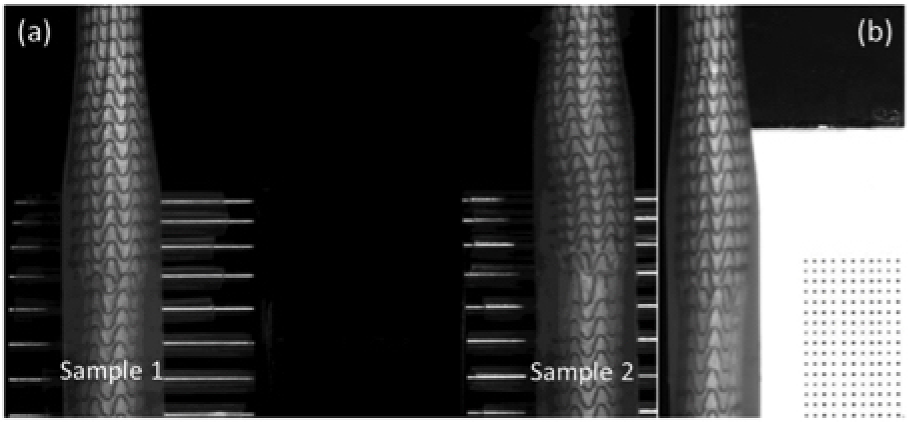

Figure 3. (a) Samples image made by camera 1, monitoring samples 1 and 2 (b) Precision scale used to match the actual distance (mm) to the distance in the image (pixels).

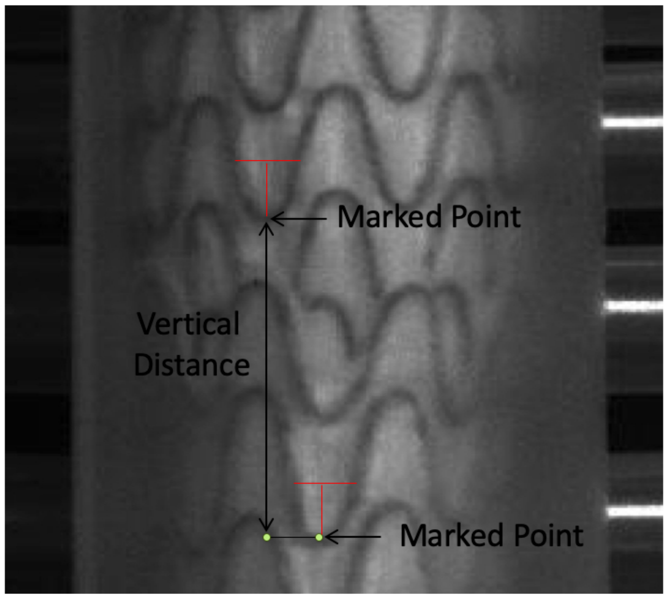

Figure 4. Measurement of vertical distance (in pixels) between a pair of homologous points. Each target point is located in each endoprosthesis and is determined semi-automatically (red lines) (see text for details).

90x98mm (300 x 300 DPI)

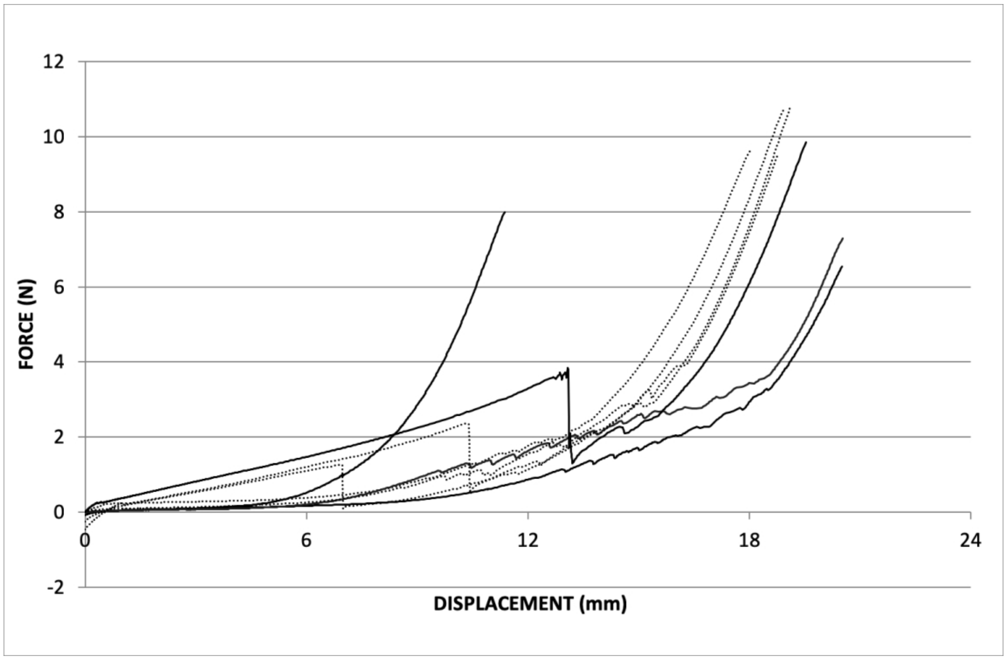

Figure 5. Tensile test results of 30 mm (black) or 40 mm (dashed line) overlapping endoprosthesis sets.

129x84mm (300 x 300 DPI)