Design for Additive Manufacture of Fine Medical Instrumentation—DragonFlex Case Study

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The recently popularized domain of additive manufacturing (AM) has much to offer to medical device development, especially to the growing field of minimally invasive surgery (MIS). With the advancements in AM materials, one could soon envision materializing not only the proofs of concept but also the final clinically approved instruments. DragonFlex—the world's first AM steerable MIS instrument prototype—was recently devised with the aim to follow this vision. Apart from the medical device design restrictions, several limitations of AM materials and processes had to be considered. The aim of this paper is to present these insights to those opting for this means of manufacture, serving as a helpful design and material guide. Over the course of its development, DragonFlex has gone through four design generations so far, each differing in the AM material and process used. Due to being a prototype of a MIS instrument of miniature dimensions, the printing processes were limited to stereolithography (SLA), as to achieve the best possible precision and accuracy. Each SLA process and material brought along specific advantages and disadvantages affecting the final printout quality, which needed to be compensated for either at the design stage, during, or after printing itself. The four DragonFlex generations were printed using the following SLA techniques and materials in this order: polymer jetting from Objet VeroBlue™; SLA Digital Light Processing™ (DLP) method from EnvisionTEC® NanoCure RCP30 and R5; conventional SLA from 3D Systems Accura® 60; and DLP based SLA process from a ceramic composite. The material choice and the printing orientation were found to influence the final printout accuracy and integrity of thin features, as well as material's postproduction behavior. The polymeric VeroBlue™ proved structurally sound, although suffering from undermined accuracy and requiring postprocessing, hence recommended for prototyping of upscaled designs of looser manufacturing tolerances or overdimensioned experimental setups. The NanoCure materials are capable of reaching the best accuracy requiring almost no postprocessing, thus ideal for prototyping small intricate features. Yet their mechanical functionality is undermined due to the high brittleness of RCP30 and high flexibility of R5. The transparent Accura® 60 was found to lose its strength and appeal due to high photosensitivity. Finally, the ceramic composite shows the best potential for medical use due to its biocompatibility and superior mechanical properties, yet one has to compensate for the material shrinkage already at the design stage. [DOI: 10.1115/1.4030997]

Keywords: DragonFlex, minimally invasive surgery, steerable instruments, additive manufacturing, SLA

1 Introduction

1.1 MIS and Steerable Instruments. MIS is an increasingly growing surgical field, as in comparison with open surgery the incisions made are minimal and lead to shorter hospital stay and recovery time of the patient [1–5]. One or several small incisions are made in the skin, e.g., in the abdominal wall in laparoscopy, in order to accommodate trocars. These serve as portals with airtight seals used for the inflation of the body cavity with carbon dioxide to create a working space for the surgeon, and for the insertion of surgical instruments. Due to the limited site access, the traditional surgical instruments for open surgery cannot be used in the MIS procedures. Hence, specialized long and slender minimally invasive surgical instruments have been developed, which generally feature either a fully rigid or a steerable tip (Fig. 1(*a*)) [6,7].

The rigid MIS instruments consist of a handle, a rigid shaft, and a tip, and their motion is restricted to four degrees-of-freedom (DOF): axial sliding, axial rotation, and pivoting in two perpendicular planes around the incision point (Fig. 1(*b*)) [8]. Since the incision acts like a fulcrum, the motion of the rigid instruments is limited and so is the surgeon's approach to the tissue [2,7]. Therefore, traditional rigid designs of the MIS instruments were enriched with a steerable tip, enabling two additional DOF using one or more joints (Fig. 1(*c*)) [9]. The steerable tip not only expands the instrument's workspace but also enables the surgeon to reach behind obstacles [7,10].

1.2 DragonFlex Design. DragonFlex, a 5 mm wide steerable MIS instrument prototype (Fig. 2(*a*)), was recently designed at TU Delft with the vision of presenting a simple handheld MRI compatible instrument featuring a steerable cable-driven joint

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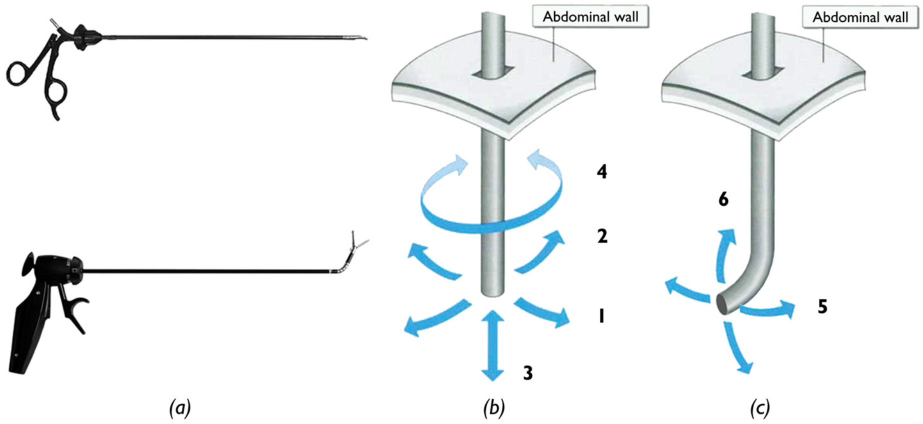

Fig. 1 (*a*) Rigid [6] and steerable [7] laparoscopic instruments; (*b*) rigid instrument DOF [8]; and (*c*) additional steerable tip DOF [9]

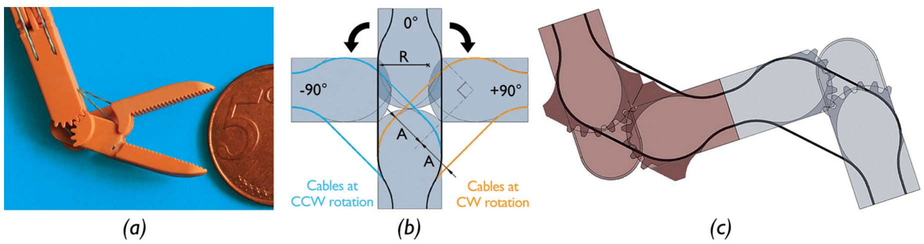

Fig. 2 (*a*) Real-scale 5 mm wide DragonFlex prototype tip. (*b*) Combined with the cable guiding profiles of radius *R*, the rolling joint equalizes the cable moment arms *A*. (*c*) Section through the basic modular parallelogram construction of DragonFlex joints (bent 90 deg). Adapted from Ref. [9].

construction free from fatigue, while attaining high bending stiffness for surgery [9,11,12]. DragonFlex's tip DOF include ± 90 deg joint articulation in two perpendicular planes and grasper actuation with a maximum grasper opening angle of 180 deg.

Compared to the other state-of-the-art steerable MIS instruments, DragonFlex maximizes the bending diameter of the joint-driving cables to a theoretical limit of 1.5 times the instrument width (valid for two mutually rotatable joint components per rotational DOF). The large cable bending diameter was achieved by devising specialized cable guiding profiles with a large radius R (Fig. 2(*b*)) surpassing the capabilities of a regular pulley, embedded for instance in da Vinci's EndoWrist (Intuitive Surgical, Sunnyvale, CA) [9,13–15]. The cable bending radius maximization theoretically leads to decreased cable fatigue, thereby increasing the instrument's lifespan.

Figure 2(*b*) shows DragonFlex's geared rolling joint design which equalizes the cable moment arms A and thus the forces in both steering cables. As seen in the prior work [11,12], together with the tight guidance, supporting the driving cables at all times, the fully actuated rolling joints minimize the joint play and therefore exhibit high bending stiffness, i.e., bending resistance to external loading. The rolling joints are arranged in a repetitive parallelogram configuration (Fig. 2(*c*)) enabling intuitive handling of the overall construction [10].

1.3 AM of DragonFlex—Potential and Challenges. In spite of the innovative aspect of the steerable MIS instrument design combining simplicity, stiffness, and resilience, its manufacturability via conventional machining or injection molding seemed doubtful. Although potentially achievable to some extent, such as milling of the miniature gears and protrusions, the complications would arise with the accurate manufacture of the curved cable holes in each rolling joint component while maintaining the design unchanged and compact.

Nonetheless, with the advances of AM technology [16–21], in particular SLA, DragonFlex design was generated quickly and relatively inexpensively, as compared to being machined at the same level of detail. As a matter of fact, DragonFlex is the world's first additive manufactured steerable MIS instrument prototype, and as such consists only of seven structurally rigid components and two looped cables steering the joints and holding the entire construction together. Thanks to AM, the entire design was printed in its original form featuring stacked hinge-less construction of rolling joints, only requiring the alignment of the individual components and fitting and tensioning of the steering cables, thereby considerably simplifying the assembly.

To put everything in perspective, by minimizing the number of essential structural components, the seven-piece DragonFlex design enables control of all seven steerable MIS instrument DOF. More specifically, its four-piece 5 mm wide tip provides the same 3DOF as the 8 mm wide EndoWrist, which consists of more than ten parts including miniature rivets and pulleys.

While the AM provided immediate means of materializing and verifying the design of DragonFlex, the next steps bringing the prototype closer to the final medical product will require further developments in the field of biocompatible AM materials and a close collaboration between designers and AM professionals. Ultimately, to facilitate the adoption of the AM materials in the surgical field, the key qualities of the current golden standard—surgical stainless steel—will have to be met, i.e., superior mechanical properties, biocompatibility, and preferably even sterilizability.

(a) (b)

Fig. 3 (*a*) Upscaled Objet VeroBlue™ DragonFlex I prototype demonstrating tip opening and pivoting in 2DOF. (*b*) Close-up picture highlighting the striking size difference between the 5 mm and 15 mm wide prototype tips. Adapted from Ref. [9].

On top of the prior work [9,11] focusing mainly on design and geometry, the authors would like to present their insights and experience with the use of a variety of promising AM materials, the related design changes and the required manufacturing adjustments leading to the current fourth generation of DragonFlex. The aim here is to present the design development as a helpful example and a design guide for those starting to investigate this field of manufacturing for their challenging designs, while pinpointing particular dos and don'ts related to certain materials and design features. Apart from the advantages, each DragonFlex prototype is discussed with respect to the most striking material drawbacks; however, these can be generally valid to other materials as well to a greater or lesser extent.

2 DragonFlex Prototype Development

2.1 DragonFlex I. The first DragonFlex prototype was printed as a part of a feasibility study, therefore upscaled and via readily accessible means. The 15 mm wide prototype, i.e., three times the original scale (Fig. 3), was produced by one of the most affordable SLA methods—polymer printing or jetting [22]—from a resinlike Objet VeroBlue™ RGD840 material [23], printed at TU Delft at 100 μm voxel resolution, using Objet Eden260V™ 3D printer [24]. The design was printed simply to verify its envisioned functionality, and hence the medical use requirement did not influence the material choice yet.

2.1.1 Printout Accuracy Versus Material Choice. As such the VeroBlue™ material, similarly to others from Vero family in the PolyJet™ series, offers very good mechanical properties as seen in Table 1. The material is rather strong, stiff, and hard, as well as relatively flexible, which adds to its toughness and overall robustness. Therefore, to date, the manufactured prototype has lasted for several years of frequent demonstrations, including a few small drops, with no visibly adverse effects.

On the other hand, even though the Objet Eden260V™ 3D printer is theoretically capable of achieving 16 μm layer thickness and 42 μm printing resolution depending on the material used, its printing accuracy ranges within 20–85 μm for features smaller than 50 mm and reaches up to 200 μm for larger ones. Therefore, while the precision figures may appear optimistic, the final printout can suffer from undermined accuracy and will need postprocessing, such as filing and polishing. This is especially relevant to delicate features and tight tolerances which are difficult to achieve due to the printout error being simply too large with respect to the printing resolution. Furthermore, even if the designer would try to compensate for the printing accuracy by modifying the feature's dimensions, the question then remains whether to add or remove material as the error can count both ways. Rather than spending too much time on the postproduction, the easier alternative is to create larger clearances, even 100 μm for a loose fit.

Fig. 4 Upscaled DragonFlex I joint component made from Objet VeroBlue™ showing the wear of the outermost sticky coating and some sign of oxidization

2.1.2 Postproduction—Coating Issue. Another aspect adding to the inaccuracy issue is the fact that the Vero material family uses a gel-like support material, in which all the printed objects are completely embedded and which also fills all the hollow features. The majority of the supporting material can be removed relatively effortlessly, by breaking off most of its parts and using a water jet on the remainders. Nevertheless, even when dried out, the printout is left with a layer of initially invisible coating that will remain sticky and influence the mechanical functionality, unless polished off in the first place, or removed later by component wear. Naturally, as the main advantage of AM is producing objects of intricate and difficult-to-access features, the topic of polishing can start to pose an issue, as in the example of DragonFlex's gear teeth, grooves, slots, and corners. Hence, after failing to access such hard-to-reach features and subjecting the object to contact and friction, the outermost sticky coating will eventually start to wear off, as illustrated in Fig. 4, and require perpetual cleaning in order to attain some esthetical value and maintain smooth contact surfaces. Last but not least, as far as the esthetics is concerned, since the material used is a photopolymer, it will

Table 1 Additive manufactured material properties from datasheets and literature [23,25,26,28,29,32,33]

Additive manufactured material	Tensile strength (MPa)	Elongation at break (%)	Modulus of elasticity (MPa)	Flexural strength (MPa)	Flexural modulus (MPa)	Hardness (Shore D)	Biocompatibility
Objet VeroBlue™ RGD840	50–60	15–25	2000–3000	60–70	1900–2500	83–86	No
EnvisionTEC® NanoCure RCP30	46	2.5	4890	102	3860	93.1	No
EnvisionTEC® NanoCure R5	31–39	11–25	1245–1510	40–45	1190–1383	81	No
3D Systems Accura® 60	58–68	5–13	2690–3100	87–101	2700–3000	86	No
Alumina–zirconia composite	~330	N/A	N/A	~350–650	N/A	N/A	Yes

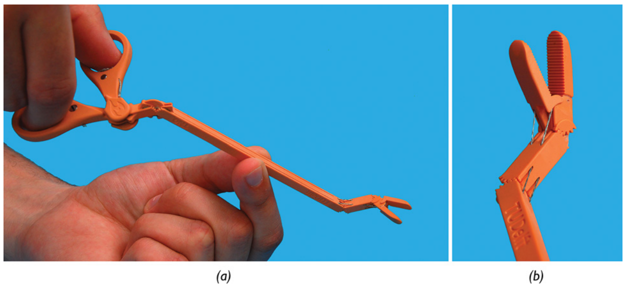

Fig. 5 (*a*) Real-scale DragonFlex II prototype made from EnvisionTEC® NanoCure RCP30. (*b*) Close-up on the tip showing cable-driven joints and grasper. Adapted from Ref. [9].

oxidize after some time or an excessive exposure to ultraviolet (UV) light, as demonstrated by the yellow–green patchy regions (see online version for color) on the joint component in Fig. 4.

2.2 DragonFlex II. After proving the design feasibility and functionality of the upscaled prototype, the second generation of DragonFlex was printed already in real scale, i.e., 5 mm width (Fig. 5). Due to the limited accuracy of the previous material and the printing process, a different, more accurate yet financially demanding method was chosen. DragonFlex II was produced by the Dutch Organization for Applied Scientific Research—TNO (Eindhoven, The Netherlands) using the SLA DLP method [17], from a ceramic-filled epoxy resin EnvisionTEC® NanoCure RCP30 [25,26], and printed by Perfactory® 3 SXGA+ Mini Multi Lens rapid prototype manufacturing system [27] at 30 μm resolution and 50 μm layer thickness. Even though the accuracy data are unavailable, this particular printer can achieve voxel resolution as low as 16 μm and the printout quality is visibly superior and needs very little polishing, if any.

2.2.1 Printout Integrity Versus Printing Orientation. Due to the ceramic content, NanoCure RCP30 is a very stiff and hard material; however, due to a very small elongation at break, it lacks toughness and suffers from brittleness. Similarly to the VeroBlue™ material, NanoCure RCP30 is not biocompatible either. The issue of brittleness is further aggravated, since in the case of AM materials one has to consider the printout anisotropy due to their layered formation.

Compared to DragonFlex I, the most obvious design change in DragonFlex II was the handle geometry and the fixation of the cables, which will be elaborated on in Sec. 2.2.2. However, the less visible yet important change occurred on the inside, more specifically in the instrument shaft. At the handle side, the shaft was split and introduced an inner rod and a slot accommodating a compression spring intended for cable tensioning (Fig. 6(*a*)), the lack of which allowed cable slack in DragonFlex I.

Since the best resolution can be achieved within the printing layer, rather than along the printing direction, the individual DragonFlex components were printed such that the cable hole cross section was as smooth as possible—each printed layer representing the component's and the hole's cross section, rather than their longitudinal section. Hence, referring back to the printout anisotropy, when excessively loaded along the printed layer, the resulting shear forces and inferior layer-to-layer adhesion will result in component breakage, as seen in Fig. 6(*b*). Therefore, there is an obvious drawback between precision and resilience, which has to be considered already at the design stage or, if possible, compensated for when determining the component's printing orientation.

One could also compensate for the inferior properties of one material by using a different one. As in the case of DragonFlex II, the broken rod component was reprinted from a material similar to the ceramic-filled epoxy resin, however, without the ceramic content (Fig. 7(*a*)). The substitution material is called EnvisionTEC® NanoCure R5 [28], printed in the same quality by the same printer, and it represents a relatively strong and hard polymer with high flexibility, therefore resistant and tough. For some applications or geometries the material may be too flexible, but another advantage is its transparency which enabled visualizing the cable channels for the sake of assembly and demonstration.

2.2.2 Postproduction—Creep Issue. As can be seen in Fig. 7(*a*), the instrument handle made from the NanoCure RCP30 was replaced by the one from NanoCure R5 material as well—the reason for that being the change made to the cable fixation between the first and the second prototype generation. DragonFlex I has the cables guided partially through the handle and then secured in between two washers by a bolt, which proved difficult to handle. Therefore, and also for esthetical reasons, in DragonFlex II the cables and their fastening mechanisms were brought inside the handle, leaving only cable ends outside for easier tensioning. The cables here were supposed to be clamped between a smooth custom-made bolt and the rest of the handle material, the two of which were designed to have an interference fit. Initially, the fastening mechanism proved to work successfully, nevertheless, the NanoCure RCP30 was found to suffer from creep, which enabled bolt loosening after some time (Fig. 7(*b*)). Hence, rather than redesigning the handle, the easier choice was opting for a more creep-resistant material.

2.3 DragonFlex III. The most noticeable design change occurred in the third prototype generation (Fig. 8), where an innovative solution for cable-slack reduction [11] was implemented, thereby eliminating the need for the cable-tensioning spring and the inner rod that only introduced stress concentrations. Furthermore, the cable fixation was incorporated completely inside the handle and redesigned as a bolt-and-wheel mechanism, or a sort

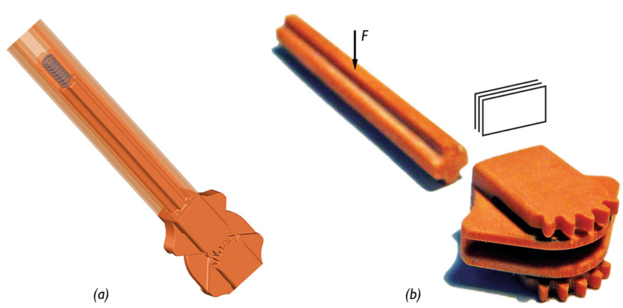

Fig. 6 (*a*) Inner rod and slot in DragonFlex II accommodating a compression spring for cable tensioning. (Reproduced with permission from Jelínek et al. [11]. Copyright 2015 by Informa Healthcare). (*b*) Breakage of the inner rod due to force *F* applied along the printed layers, demonstrating the importance of choosing an optimal printing orientation.

Fig. 7 (*a*) Replacement of several NanoCure RCP30 DragonFlex II components by the more flexible and creep-resistant NanoCure R5 alternative. (*b*) The location of the loosened cable-fixing bolt, originally having an interference fit with the handle, due to permanent radial expansion of the hole.

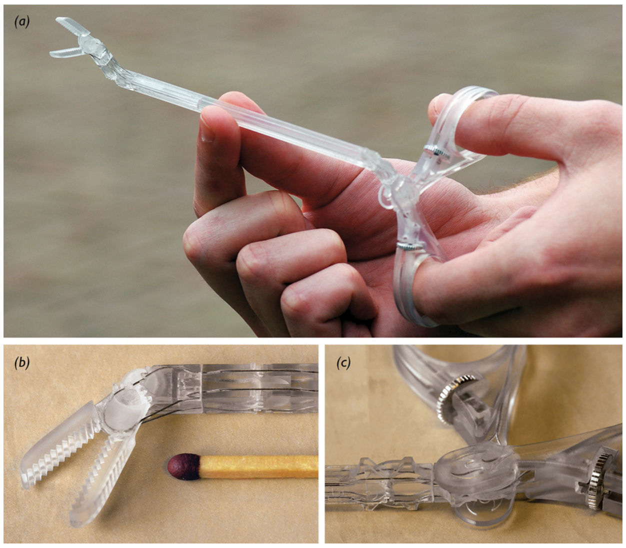

Fig. 8 **(*a*) Real-scale DragonFlex III prototype made from 3D Systems Accura® 60 and featuring (*b*) an innovative solution for cable-slack reduction and (*c*) a bolt-and-wheel mechanism for easy cable tensioning and fixation. (Reproduced with permission from Jelínek et al. [11]. Copyright 2015 by Informa Healthcare).**

of a turnbuckle (Fig. 8(*c*)), providing both cable tensioning and fixation functions. Even though the cable fixation was redesigned to be independent form the material's ability to perfectly retain its original shape, the third prototype was printed from a different material—one that would combine the strengths of both NanoCure RCP30 and NanoCure R5, and which would be a step closer to the clinical application. DragonFlex III is made from a clear polymer 3D Systems Accura® 60 [29] and it was printed by PROFORM AG (Marly, Switzerland) using 3D Systems Viper si2™ SLA® System [30]. The material as such is very strong, hard, and moderately stiff and should be tougher than NanoCure RCP30 in theory. In spite of not being biocompatible, Accura® 60 is used for the prototyping and manufacture of some medical products.

2.3.1 Printout Accuracy Versus Printing Orientation. The Viper si2™ printer provides relatively inferior printing resolution of 75 μm and 15 μm accuracy already in the high resolution mode, yet this should be compensated for by the alleged 2.5 μm layer thickness with 7.6 μm accuracy. Nevertheless, the practice has shown that the layer thickness in the final printout is much larger, as in fact it was the main reason why grasper flaps of DragonFlex III had to be removed in order to provide any grasper functionality, as seen in Figs. 8 and 9(*b*). More specifically, as shown in Fig. 9(*a*), the layers in DragonFlex III grasper run longitudinally parallel to the flaps, as opposed to the layers in DragonFlex II grasper where they run cross-sectionally. Although the intention was to make the grasper flaps stronger in bending, this printing orientation only created inaccuracies, which could not have been compensated for by postproduction due to material brittleness. However, a more apparent peculiarity of DragonFlex III graspers is the warpage of their flaps. Once again this is related to the particular printing orientation, due to which the shear stresses arising between the layers while curing manifested themselves by causing the bending and warpage of the long and thin features. Although mentioned as an alternative in Sec. 2.2.1, sometimes compensating between the precision and the resilience by adjusting the printing orientation is difficult to achieve and may even be counterproductive when not solved already at the design stage.

2.3.2 Postproduction—Curing Issue. Unfortunately, compared to the VeroBlue™ material in DragonFlex I, Accura® 60 is even more photosensitive, which does not add to its esthetical value as it yellows quite rapidly (Fig. 9(*b*)). This way even the initially attractive property of this clear transparent polymer loses its appeal, as the surfaces do not oxidize uniformly and the different hues of yellow can be easily distinguished. On top of esthetics, the curing or oxidization process has another negative impact on the photosensitive material properties, in particular brittleness. It was discovered on several printouts that as soon as they turned yellow, their impact resistance was severely diminished and so the long and thin features broke off almost automatically when subjected to any lateral load (Fig. 9(*b*)).

2.4 DragonFlex IV—Work in Progress. As the issues of cable slack, tensioning and fixation have been solved over the three prototype generations; the latest DragonFlex IV prototype design has remained virtually unchanged so far, compared to DragonFlex III. Hence, the time has come to focus on the final medical application of the device and search for suitable biocompatible materials. Even though there are several polymeric biocompatible AM materials available on the market, they suffer from inferior mechanical properties compared to their nonbiocompatible AM counterparts. Nevertheless, as ceramics are known to solve the issues of cytotoxicity, hemocompatibility, and thus biocompatibility [31], a choice has been made to print the latest DragonFlex prototype from an alumina–zirconia composite [32,33]. Even though most of the material data are still unavailable as seen in Table 1, the AM ceramic composite is likely to be extremely strong and hard as compared to the other AM materials discussed so far, according to the literature. The superior material properties have been already observed on several DragonFlex component printouts manufactured by ADMATEC Europe BV (Moergestel, The Netherlands) at 40 μm resolution and 30 μm layer thickness using a DLP based SLA process called ADMAFLEX technology and custom-made printers. Yet, since dealing with a purely ceramic material, the question of brittleness remains

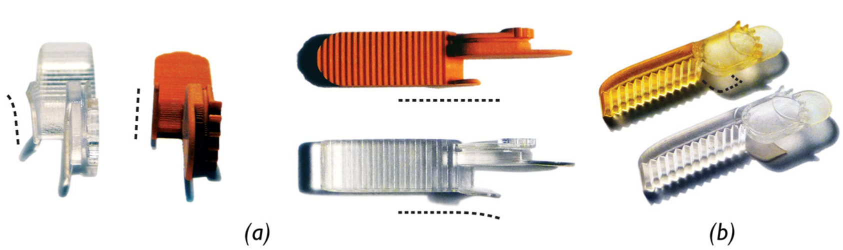

Fig. 9 **(*a*) Comparison of DragonFlex II and III grasper printouts showing the effect of material choice and printing orientation on the warpage of grasper flaps (curved dashed lines). (*b*) Old and new Accura® 60 grasper halves showing the impact of material's photosensitivity on its appearance (the new darker grasper on top gained a yellow hue) and increased brittleness (missing broken flap marked by a dashed contour).**

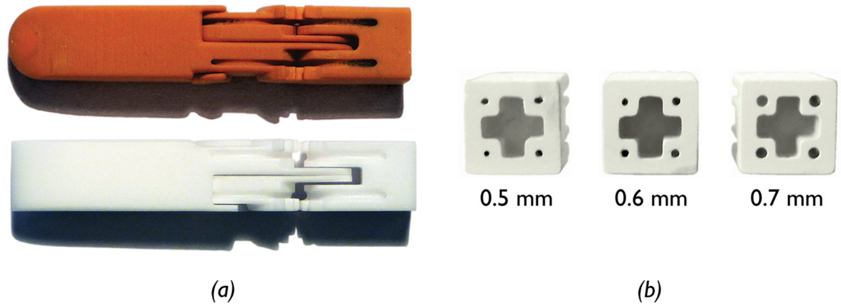

Fig. 10 (*a*) Comparison of DragonFlex II and IV grasper printouts demonstrating the shrinkage of solid long and thin features (grasper flaps) made from the alumina–zirconia composite. (*b*) The effect of sintering on hollow long and thin features (cable holes) shrinking to 0.36, 0.39, and 0.58 mm in diameter from the designed 0.5, 0.6, and 0.7 mm, respectively.

to be investigated, and so does the material's potential to compensate for it by its considerably superior strength and hardness.

2.4.1 Promising Material Properties Versus Thin Features. On top of the material's superior resilience, another advantage of using ceramics for medical device manufacture is their high melting point, which is at least an order of magnitude higher than that of the most heat-resistant polymeric AM materials. This is a vital aspect since, unless designed to be disposable, each surgical instrument has to be resterilized in an autoclave before another use, which subjects it to more than 130 °C that would melt most of the AM materials available nowadays.

Despite the very promising material properties of the alumina–zirconia composite, just like other materials, even this one suffers from a visible drawback. Due to the debinding and sintering processes, which follow directly after printing, the material hardens, becomes denser, and dimensionally more compact. While relatively negligible when producing larger solid objects, the shrinkage becomes an issue when printing long and thin features, whether solid or hollow.

As seen in Fig. 10(*a*), even though designed with a zero tolerance, the grasper flaps of DragonFlex IV appear visibly thinner than the ones of DragonFlex II, creating a large clearance, which in this particular design configuration is problematic. The issue of shrinkage was also observed in DragonFlex III on the grasper's outermost flap at the joint interface (Fig. 9(*a*)). Of course this issue can be solved already at the design stage, by optimizing the geometry of the long and thin features so that the final printout dimensions match the intended ones. Naturally, this may prove to be an iterative trial-and-error process requiring the expertise of AM professionals.

As shown in Fig. 10(*b*), the shrinkage affects also hollow long and thin features, such as cable channels. As in the previous 5 mm wide DragonFlex prototypes, the cable holes were designed to be 0.4 mm in diameter. Nevertheless, due to some of the holes being closed up when sintered, three more printouts were made of cable hole diameters being 0.5, 0.6, and 0.7 mm. Once measured, all the holes were found to experience a considerable shrinkage (17–35%) and in order to achieve the Ø0.4 mm holes, they had to be designed Ø0.6 mm (Table 2).

Table 2 Demonstration of the alumina–zirconia material shrinkage due to debinding and sintering

Designed hole Ø (mm)	Real hole Ø Range (mm)	Real hole Ø Mean (mm)	Shrinkage (%)
0.5	0.27–0.46	0.36	28
0.6	0.34–0.42	0.39	35
0.7	0.56–0.60	0.58	17

3 Discussion

3.1 Summary and Alternatives. To best summarize the presented insights on the use of several AM materials, one should always bear in mind the one paradoxical limit to this technology stemming from its layer building nature. As shown, even with the best AM materials nowadays, it is difficult to combine sufficient precision and accuracy with ideal material properties due to their anisotropy. Therefore, if the intention from the very beginning is to manufacture one's prototype by AM, one should always consider the limitations of these processes already at the design stage and ideally in consultation with AM professionals in order to attain time- and cost-efficiency—these include printing orientation, printout accuracy and integrity, design of long and thin features, as well as material behavior postproduction.

To dedicate a few summarizing words to the AM materials trialed specifically for the manufacture of DragonFlex prototypes, several recommendations are given as to their final use. Due to the accuracy reasons, the more affordable polymer jetted materials, such as Objet Vero family, proved to be practical for convenient and immediate prototyping of upscaled designs and overdimensioned experimental setups, provided they do not require tight manufacturing tolerances [12]. The EnvisionTEC® NanoCure materials are capable of providing the best accuracy requiring very little or no postprocessing, ideal for verifying the designs and functionality of small intricate features. Yet for real long-lasting mechanical functionality, these materials may prove either too brittle or too flexible. The 3D Systems Accura® 60 material is very appealing due to being clear, transparent, and rather strong; however, these advantages can easily turn into weaknesses if overexposed to UV light. Last but not least, the alumina–zirconia composite shows the best potential for medical use due to its biocompatibility and very likely superior material properties. However, one has to compensate for the material shrinkage already at the design stage, and other potential material drawbacks are still to be investigated.

As mentioned earlier, despite being the best option when it comes to precision and accuracy, the SLA materials generally lack superior mechanical properties and biocompatibility, both of which are important for medical device manufacture. Nevertheless, potential alternatives exist either in the form of material postprocessing or the use of different AM technology. The former option involves gold plating of SLA materials, which can potentially enhance their resilience and introduce biocompatibility. The latter alternative involves opting for techniques such as fused deposition modeling (FDM) or selective laser sintering (SLS). With FDM one can achieve very sturdy real-ABS-like printouts, while SLS is a known AM method for the production of metal prototypes that should provide biocompatibility by default, although not MRI compatible. Nevertheless, both of these techniques suffer from an undermined manufacturing precision compared to SLA and require considerable postprocessing, thereby elevating the final costs.

3.2 Vision for the Future. An attractive developing field of AM is printing in simultaneous combination of different material groups [17–19,21], currently being commercialized by companies such as EoPlex, Inc. (San Jose, CA) and named 3D high volume print forming (3DHVPF™) [34]. Printing plastics, ceramics, and metals simultaneously could open far-reaching opportunities especially in the medical device development, since apart from a fast and relatively inexpensive assembly-free production; one could integrate complex mechanical functionality with electronic circuits. In MIS, this could be especially beneficial for the production of devices which are conventionally very problematic in terms of sealing, such as a steerable MIS bipolar forceps. One particularly desirable aspect of an assembly-free AM would be the manufacture of cable-driven MIS devices already with the cables embedded—whether incorporated and positioned along the printing process, or printed as such.

Another anticipatable aspect of the AM concerning the future of medical instrument manufacture would logically be a demise of the manufacturing facilities as such. Equipped with the AM technologies of the future, hospitals could readily manufacture their equipment in-house after being supplied with virtual, medically approved tool designs—straight from the designer to the clinician. Likewise, this notion could be easily extrapolated to almost any industry and product, even food, which is closer to reality than one might expect, as any AM specialist could readily verify [35].

4 Conclusions

This work presents practical design insights and hands-on experience with the use of several SLA materials and processes for the production of the world's first AM steerable MIS instrument prototype—DragonFlex. Particular dos and don'ts related to the layer building AM processes are discussed over four prototype generations, including considerations for the printing orientation, printout accuracy and integrity, design of long and thin features, as well as material behavior postproduction. Since dealing with a medical device development, the issues of biocompatibility and sterilization enrich the discussion, together with the vision for the future of AM in the medical field. In conclusion, so far the most promising material for the presented DragonFlex prototype is SLA alumna–zirconia composite satisfying the demanding medical device design criteria including resilience, biocompatibility, resterilization, and even MRI compatibility. Yet, as with other SLA materials one has to take into consideration the drawbacks of this particular material and the printing process, and compensate for them already at the design stage in close collaboration with AM professionals.

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