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Technical literature: orthopaedic technology

Integration of Additive Manufacturing Processes (3D Printing) in Orthopaedic Technology Fitting Routine

C. Kienzle, M. Schäfer, Special edition from: ORTHOPÄDIE TECHNIK 05/18, Verlag Orthopädie-Technik

Special edition from: ORTHOPÄDIE TECHNIK 05/18 –
Verlag Orthopädie-Technik, Dortmund

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The fabrication of orthopaedic devices using additive 3D printing processes opens up innovative options in various areas of orthopaedic technology, especially in the three-dimensional design and optimisation of components and in the not-to-be-underestimated user-friendly product properties regarding wearing comfort and device design. Setting up the digital process chain in device fabrication that is necessary for systematic implementation requires the integration of entirely new process steps compared with the workflows of traditional orthopaedic technology. The additive manufacturing product is not always better for the user than products made using traditional production and fitting methods. Thus, for each product, the actual potential for improvement for the user must be weighed against traditional fitting methods and standards in a cost-benefit analysis. The following case report describes the new additive manufacturing processes with respect to optimal user benefits and fitting quality and the challenges associated with the implementation of a new digital process chain in the fitting routine of O&P professionals based on the example of Pohlig GmbH.

Key Words: additive manufacturing, printed orthosis, 3D printing, 3D scanning, correction simulation

Introduction

Today you hardly have an option – everything is printed, and of course everything is much better, more functional, faster and cheaper than with traditional production methods. Is that really the case? This question has been asked repeatedly in the past ten years. At that time, it was assumed that every household would have its own 3D printer within five years and that we would print our own household objects. Nearly ten years filled with many positive and also negative experiences and advances show that some printer manufacturers and brands that counted on this trend have now quietly disappeared from the market.

There are thus other factors, not the least of which are of a processual nature, that may determine the success or failure of this innovative production method. The possibility of implementing a virtual component directly in reality appears to be too tempting [1]. Especially in the production of orthopaedic devices, i.e. medical devices, strict regulatory conditions must be met on the one hand – e.g. biocompatibility of the materials, properties for long-term use, risk analyses, fracture simulations and the required functionality – and on the other hand, the functional and therapeutic benefit, design and wearer comfort of the device are crucial factors for users (Fig. 1).

A product is not automatically better for a user of the device just because it is printed. On the contrary – in the media and in technical circles, there have been increasing reports of products such as three-dimensional printed prosthetic sockets whose wearing comfort and usability cannot compare with those of established devices. It is obvious that new additive manufacturing processes are frequently used to copy traditional design methods and make identical copies using 3D printing. But the attraction of 3D printing is not just the additive manufacturing process, but more the three-dimensional design possibilities of the products (Fig. 2).

It lends itself to the production of complex components and structures and can contribute in this way to a constructive improvement in the production of orthopaedic technology devices [2].

Rethinking and redesigning orthopaedic technology devices, especially adding useful new features for users, is a huge challenge in this context [3, 4]. Common additive printing methods must therefore first be tested and validated for the production of orthopaedic devices [1-6].

Selection of 3D printing production methods

The term „3D printing“ is often used in various contexts. It initially stood specifically for various rapid prototyping technologies [6]. This is a process for manufacturing three-dimensional objects by layering a certain material. In 3D printing, a distinction is made between metallic and non-metallic materials. Three-dimensional components can be produced layer by layer in additive manufacturing based on data sets using a CAD program.

The 3D printing process is increasingly used when complex components in small lot sizes are needed. Aside from prototype production, these production methods can now be used for many different applications to make high-quality finished products. Using different methods of post-processing, the strength, heat resistance, and appearance can be subsequently modified.

After various tests to check the printing quality, mechanical resistance to stress, accuracy of the components, and the required design options, in the authors‘ opinion and according to their experience in recent years, there are currently four additive processes that can potentially be used for producing orthopaedic devices:

Special edition from: ORTHOPÄDIE TECHNIK 05/18, Page 48 – 57

Fused Deposition Modelling (FDM)

In the FDM method, first a thin plastic cable (e.g. PLA, PC or ABS) is melted and applied in layers to the desired places through a nozzle. The material is then cured. Complex plastic models can be produced in this way, with or without supporting material. The FDM technique is well suited for prototyping and for creating components for testing good fits and 3D designs. However, in our opinion, it is not suitable for the production of definitive devices because of the low mechanical quality and grooved surface texture.

Continuous Liquid Interface Production (CLIP)

The CLIP method is a patented resin-based photopolymerisation process controlled by UV light and oxygen. In comparison with the other 3D printing methods described here, there is no visible layering and the production process is considerably faster. However, due to the currently available spatial parameters, the shapes and sizes of the products are limited. The materials SIL, RPU, FPU, EPU, UMA, EPX and CE can be used.

Multi Jet Fusion (MJF)

By applying powder and thermally conductive ink in layers and irradiating it with UV lamps, a precise homogeneous composite with a slightly rough, but precise surface is produced. At the time this article was printed, the experience in plastics was mainly with PA12 and only dark inks were available. The finished product is therefore grey in a best-case scenario, which is why the selection of colours is limited for the usual colouring processes. Currently, PA12 is available as a material.

Selective Laser Sintering (SLS)

With SLS, powder is built up in layers where the 3D shapes to be created are melted to a homogeneous composite in a high-temperature process with a laser system. With respect to the mechanical properties of the material, the quality of the composite and the colour options, this production method is predestined to be used for manufacturing orthopaedic devices. Commonly used materials are PA11, PA12, PA12CF, TPU and metals.

In addition to the still new MJF method, the long established and proven SLS method in particular is considered to be suitable for producing finished technical components from plastics such as PA11 and PA12 [3, 4, 7, 8, 13]. It allows a wide range of design options, provides mechanically high-quality 3D prints with a high degree of precision and already allows various finished orthopaedic products in the fields of prosthetics [7, 11, 13, 15] and orthotics [4, 8, 10, 12, 13] to be successfully produced. For the start of the fitting process, customised orthotic devices for the upper limb were especially suitable (Fig. 3). There are still clear limits today regarding the design of elastic guide and bedding zones and in the production of hollow volume-supporting structures such as prosthetic sockets. Although 3D printing of silicones and polyurethanes is qualitatively possibly today, it still does not have anywhere near the same versatility in application and cost-effectiveness of traditional production methods in orthopaedic technology [7].

In addition, the weight-bearing designs of jointed orthoses must be able to compete with lightweight, considerably more stable fibre-reinforced composites. In particular, a cost-benefit analysis must be taken into consideration. Fitting practice shows that the 3D printing process cited by many as the cheaper production method [14] is not always the more cost-effective alternative for customised devices – i.e. in the fabrication of unique devices for the respective patient depending on their indication – taking all steps of the process into consideration. The 3D printing devices are still expensive, so some specialised companies have started to outsource the services of SLS printing to external providers [14, 17, 18]. However, it must be taken into consideration that the service fabrication of customised devices – i.e. not of add-ons such as protectors for the devices – covers only one to two steps in the digital process chain and that the O&P professional is still responsible for the shape acquisition, the layout and the risk analysis of the finished product.

For all devices fabricated for individual patients, it should therefore be obligatory to conduct an evaluation and comprehensive testing in a risk analysis (see below: CAD-assisted design of orthopaedic devices) and assess the cost-benefit ratio before selecting a device produced by 3D printing.

Fig. 1 *WHO-Spiral-Printorthese® in SLS printing technique.*

Fig. 2 *3D design variations in orthotics.*

Fig. 3 Printorthesen® for the upper limb in SLS 3D printing.

Fig. 4 Orthosis design variation (L) and prosthesis protectors (R) in 3D printing.

Digital process chain in the OT workshop

Digitisation does not stop at orthopaedic technology workshops and it will be increasingly important for the trade to determine exactly where modern production methods and digitisation can enhance a traditional trade such as orthopaedic technology – and where not.

A distinction must be made between the fabrication of a customised device (Fig. 2) and the production of functional add-ons (Fig. 4) for protecting and optimising the design of devices and are thus not directly involved in the indication for a device. The implementation of digital processes should be viewed critically, especially for producing customised devices, because it poses perceptibly disruptive demands on implementation in an orthopaedic technology workshop. With a few exceptions, traditional production methods – e.g. plaster impressions, modelling with plaster and a number of other manual production processes – are replaced by digital shape acquisition and production methods. The digital process chain completely changes the workflows for fabricating customised devices in an OT workshop. Only the traditional fitting processes on the patient retain their similar pattern.

Users, on the other hand, can benefit considerably from some new processes when being fitted with a device, e.g. from shape acquisition without using plaster, reconstruction options and the simulation of corrections. The individual steps of an already implemented digital process chain are presented below (Fig. 5):

Digital shape acquisition in OT

The digital shape acquisition of the human body is usually conducted using a scanning system. Structured-light 3D scanning systems that provide reliable high-quality scans of the human body with 3D precision of up to 0.1 mm have proven valuable for this [6]. Unlike laser-based scanning systems, the structured-light scanners accommodate slight changes in position and deviation ranges during the scanning process. A body scan model in STL (standard triangulation language) format is produced. However, it was soon seen that the exclusively non-contact shape acquisition of the human body did not yield satisfactory results in the initial process of fabricating orthopaedic devices.

Plaster impressions are also made in final corrected positions. However, their disadvantage is that these positions can rarely be tested for function when the plaster impression is made. For this reason, in the authors‘ company, everything possible was done to remedy this deficit in order to improve the quality of the orthopaedically required, usually corrected final position at the time the shape was acquired.

As a result, an innovation called Simbrace® was patented. This is a simulation impression device that simulates corrections on the human body by adding corrective pads prior to the body scan (Fig. 6). Under guidance by the orthopaedic technician, users can conduct a functional test of the corrected position of the device to be fabricated during this process before the scan is made. This allows them to evaluate how much correction the patient tolerates and they can also check before shape acquisition whether the patient actually has a better functional outcome with a defined correction. This is a new and significant improvement compared with the traditional processes of fitting orthopaedic devices. This advance simulation can yield a considerable improvement in the final quality, both for orthoses for the torso and for the limbs.

Digital modelling

After the digital shape acquisition, the measurements and surface processing of the scanned body part are checked. Then the model is imported into the orthopaedic technology modelling software. Depending on the type of product, different workflows with the corresponding templates are created that can be arranged on the virtual body model. The modelling histories are made based on functional orthopaedic principles and are usually analogous to the familiar plaster modelling (Fig. 7). The decisive advantage over the traditional method of plaster modelling is that the base model can be returned to at every stage so all changes can be readily followed or reversed. After modelling, the model file is saved and transferred to the CAD design software for further processing.

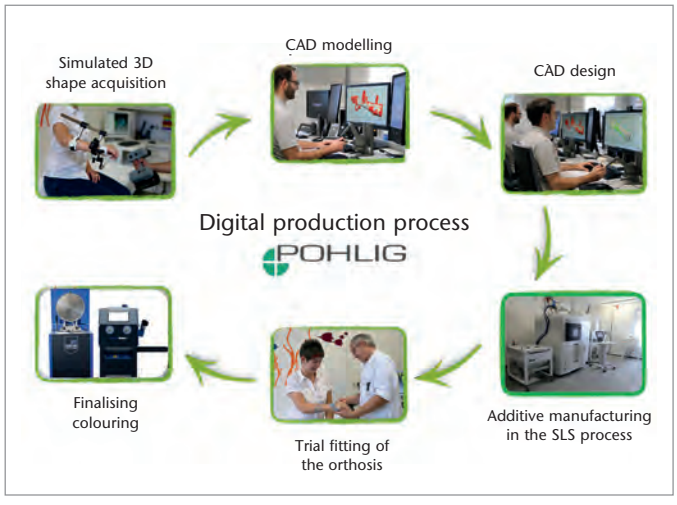


Fig. 5 Digital production process in orthopaedic technology.

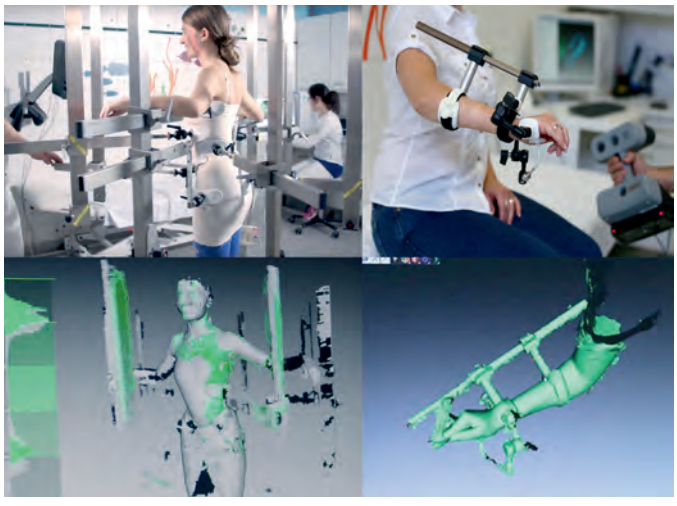


Fig. 6 Simbrace® correction simulation in trunk orthotics (L) and arm orthotics (R)..

CAD design of the orthopaedic device

Computer-aided design (CAD) plays a large role in three-dimensional printed products. Up to now, orthopaedic technology has focused strongly on material properties. Of course, there is no change when 3D printing materials are selected. When a device had to be designed to be more stable using traditional combinations of materials such as leather, metals, thermoplasts and fibre-reinforced materials, the cross section was usually increased. However, it was hardly possible to implement complex three-dimensional designs. The possibilities of CAD design allow traditional design principles – e.g. the specification of the acting force relationships taking the corrective 3-point design principle (Fig. 8) into consideration – as well as functional 3D structural elements to be integrated. In this way, the design of the device can be raised to a much more complex design level [3, 4, 7, 10, 11]. If these possibilities are utilised, this can lead not only to a considerable improvement of the functional properties of the device (e.g. breathing activity and increasing space by minimising the design or reducing the weight of the device), but can also improve acceptance.

When fabricating a customised device, experts in 3D design use state-of-the-art methods to check the device design. To accomplish this, target values must be defined and the corresponding design variants tested in advance. The cyclical testing of continual use properties and conducting maximum endurance tests (Fig. 9) that continue until component breakage are just as necessary as testing test bodies that allow later tests during production. The standard endurance values measured are imported as parameters along with the proportions into a structure simulation that is applied to the respective device using the finite elements method (FEM) (Fig. 10).

Additive manufacturing process

Customised orthopaedic devices are produced by 3D printing using a printing system for selective laser sintering (SLS) (Fig. 11). The powder base material is melted to a homogeneous composite by being applied to a construction platform in layers under the high temperatures of a CO_2 laser. The decisive factors for this system are the consistently high print quality, the homogeneity of the composite, the mechanical strength and the neutral colour of the print product.

Because an finished orthopaedic product is subject to continuous loads, polyamides in the qualities PA11, PA12 and TPAs are especially suitable for producing rigid and semi-rigid components for devices. Factors that affect the print quality are the quality of the STL file, the position of the object in the assembly space, the quality of the printing powder and the spatial continuous conditions of the printer station. The final result of a successful printing process in the SLS technique is a device workpiece made of the selected material (Fig. 12) that the O&P professional can use for an initial fitting after it is unpacked and cleaned.

Trial fitting of the orthopaedic device

The O&P professional then conducts the trial fitting of the 3D printed workpiece. First, the fit and therapeutic mechanical function of the device are checked. Modifications can be made to a limited extent by heating and reshaping specific parts. Conventional hot air tools are not suitable for this step because the non-specific heating bears a risk of destroying the composite material. The fit and volume can be influenced by integrating elastic pads (Fig. 13).

If the corrected result was thoroughly simulated and tested on the body in advance during digital shape acquisition (see above: Digital shape acquisition in OT), the required modifications are generally sufficient. However, even digital processes cannot do anything about indication-related changes in position and volume. In such cases, 3D printing must be repeated. The device should always be put through a continuous wearing and testing phase before finishing.

Colouring and finishing an orthopaedic device

After the successful trial fitting, the surface of the 3D printed workpiece is finished, compressed and refined (Fig. 14). This is a requirement for achieving a homogeneous colouring process and also for improving soil resistance and surface feel. After this, the colouring process is started. An approx. 0.2 mm thick layer of colour is applied to achieve the desired shade of the device and to enhance UV resistance and extend the service life. During finishing, pressure-relief gel pads can be attached to pressure zones and any closure mechanisms can be attached.

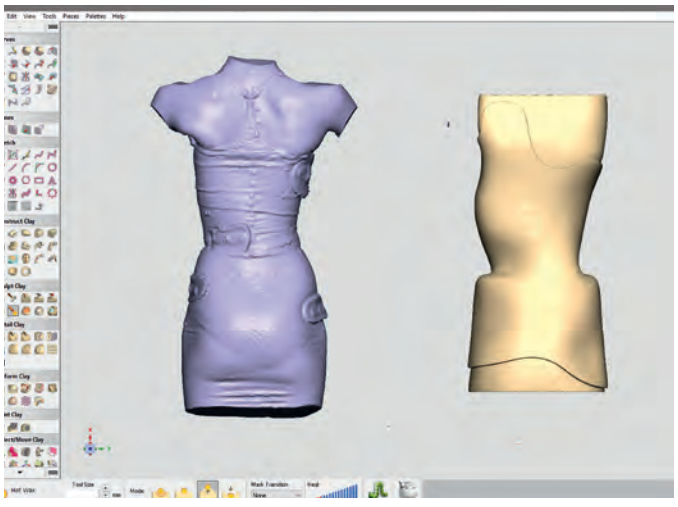
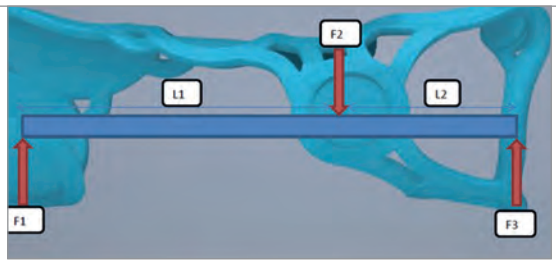


Fig. 7 3D trunk model for scoliosis treatment, before (L) and after (R) modelling.



Sum of all forces = 0

F1 - F2 + F3 = 0

Sum of all moments = 0 (at centre of pressure of F2)

F1*L1 - F3*L2 = 0

F2 is measured. L1 and L2 are determined by the patient's size / the design.

F1 = F2/(1+L1/L2)
F3 = F2 - F1

Fig. 8 Determining the loads occurring using the example of the WHO-Spiral-Printorthese®.

Initial results

3D printing was first tested in the authors' company using design studies in the major orthopaedic fields of orthoses for the upper and lower limbs and arm and leg prostheses (Fig. 15). A first workflow was successfully implemented for fitting spiral-shaped Unterarm-Printorthesen®.

As comparison with the traditional fabrication method, patients in a test series were fitted with conventional forearm-hand orthoses made with a conventional PE technique and with innovative orthoses produced in the 3D printing technique. The conventional orthosis was produced using the known production technique with a thermoplastic material – from the plaster impression to deep drawing to the trial fitting of the polyethylene orthosis. The new 3D printed orthoses were described completely digitally in the working method – from the simulated scan to digital modelling and design to completing the orthosis in an additive manufacturing process. The trial fitting of the orthosis was carried out in the usual manner, analogous with the traditional production technique.

The patients were surveyed after a wearing period of approx. six weeks using an expanded DASH/OPUS/CHEQ questionnaire. The documented data were then compared and analysed with respect to the two orthosis types.

A first comparison shows: The patients with the printed orthoses used the affected hand more often for bimanual activities, reported better tactile perception with greater wearing comfort, sweat noticeably less and experienced the active participation in the design (colour and design selection) and manufacturing process (scan technique) as clear improvements. Disadvantages were found to be the more difficult readjustment for changes in the situation and the longer manufacturing process.

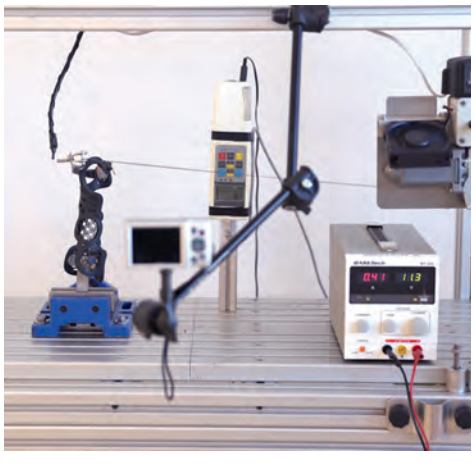


Fig. 9 Test setup for determining the continuous loading behaviour of the WHO-Spiral-Printorthesen®.

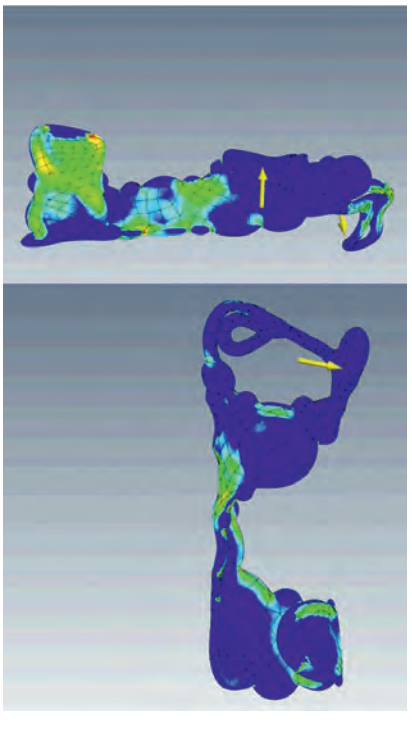


Fig. 10 FEM analysis for simulating and testing the structure of the CAD design.

Fig. 11 EOS SLS printer for producing customised orthopaedic devices.

Fig. 12 *Ready-to-try 3D printed workpiece made of polyamide after the printing process.*

Fig. 13 *Optimising wearing properties using integrated pads.*

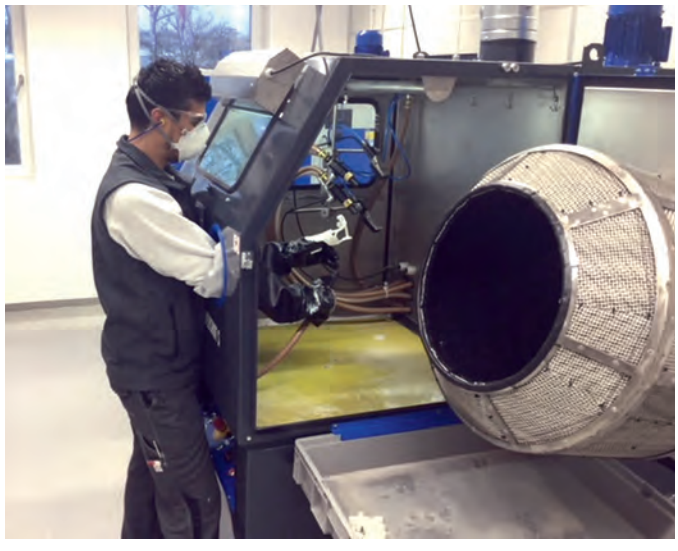


Fig. 14 *Final surface finishing before the colouring process.*

Conclusion

The results showed that the 3D printing technique is at the forefront of a development that will expand the treatment range of technical orthopaedics in many areas. The patients' expectations of the design of the device and of the wearing comfort should not be underestimated; the optimal fit and functionality of the device are naturally a minimum requirement. For the authors, the option of functional correction simulation in advance during shape acquisition is a significant improvement over the traditional methods of shape acquisition. In addition, the printing technique facilitates valuable design options that are superior to the traditional manual production methods in orthopaedic technology. Experience shows that the resulting innovative functional design has a perceptible effect on acceptance of the device.

Despite the enthusiasm for the new digital processes, it should not be forgotten that the technologies used also have gaps and cannot yet cover the entire range of orthopaedic devices for everyday use. Up to now, it is still not possible to implement comfortable materials, materials such as genuine leather that can absorb perspiration, or soft and elastic foam materials or to make adjustments and extensive modifications to the finished product and accommodate the high strength requirements for products subject to weights and shocks.

Modern digital 3D printing methods expand the range of orthopaedic technology treatment and can be a useful addition to the various everyday requirements for orthopaedic devices. However, this does not change the fact that for all devices produced using additive processes, the successful outcome for the patient is the ultimate goal. Orthopaedic technology is a trade that is less inclined to risks, so it is essential that the all stages of the production of the customised device be accompanied by an orthopaedic technician with ample experience in fitting devices.

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Fig. 15 *Pohlig 3D printing design studies on upper limb prosthetics.*

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