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Examination of Damage Processes of Orthopaedic Orthosis

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Abstract

In my work, I examined a palmar forearm splint manufactured by a Hungarian medical device producer. Considering the test results that come from failure analysis, material composition analysis, hardness testing, macroscopic and microscopic examination, scanning electron microscopy and implemented on a product damaged under real conditions, I concluded that the medical device, returned by the customer, had broken prematurely due to improper use. The results of the fatigue test carried out as a physical simulation of the load show that the medical device can withstand more than 850 cycles of micromotion without any problems. Macrofractographic comparisons were performed between the fracture surfaces of the device returned by the users and those of that dismantled under laboratory conditions, thus confirming the validity of my measurement.

Keywords: *medical device, orthosis, failure analysis, validation, scanning electron microscopy.*

1. Introduction

Basically, orthoses (orthosis = A material, device or appliance that protects or fixes damaged parts of the musculoskeletal system, such as casts and splints.) have a long history in the literature.

Haarman describes a device to support hand function that can significantly improve the quality of life of patients with muscle weakness. The authors have developed a novel force transmission mechanism based on tape springs for use in hand orthosis. The actuator force is transmitted to the finger by a system consisting of a tape spring, two sliding blocks and one end-stop per finger. The tape spring allows bending in one direction and resists bending in the other direction. The new mechanism has been prototyped. The small profile (thickening effect) and the ability to transmit high forces make this mechanism suitable for manual orthoses [1].

Hansen points out that strokes often cause flexor hypertonia and weakness of finger extension. In this article, the authors detail the development of DigEx and MIDAS passive arm orthoses. They implemented a quick-change cam system that provides one-handed cam exchange. Belt pulleys and bearings were added to the tool to reduce friction caused by mechanical contact and material defects. Initial tests of the prototype were promising [2].

Gábor László investigated whether overnight immobilization as a monotherapy significantly improves clinical symptoms, hand functionality and patient quality of life in CMC joint arthrosis. An easy-to-fit wrist and glenohumeral joint orthosis with plaster-like circumferential stability (immobilization) at night was the only allowable therapy. The doctor interviewed the patients by telephone after the end of the study about any night-time complaints. None of the patients complained of night pain [3].

The purpose of the analysis I performed was to compare the fracture surface properties of a fractured orthosis received from the manufacturing company with a complaint and returned to the company with the fracture surface properties of a fractured device subjected to fatigue testing under laboratory conditions. This comparison may shed light on whether the patient wore their orthosis correctly and in accordance with the rules of use. In addition, I will determine whether the device meets the quality and durability expectations of the manufacturer and the current relevant medical technology regulations.

2. Examinotion of subortheses

2.1. An overview of the orthoses studied

Judging by the size of the palmar forearm tendon tested in this article, it is intended for children. The palmar forearm splint is used to immobilise or completely immobilise the wrist, hand and fingers after dislocation, surgery or casting. It may also be used as a substitute for a plaster cast. It is also used for the conservative treatment of tendonitis and degenerative lesions of the wrist, hand and fingers as a resting splint, as a post-operative rehabilitation period and as adjuvant therapy **[5]**.

The device under investigation is composed of the layers illustrated in **Figure 1**. First, the Al sheets of different thicknesses arriving in rolls are corrugated and then stamped to the specified shape. In many cases, several plates have to be riveted or stapled together to produce a suitable aluminium frame. In the assembly process, a layer of polyphom (cross-linked polyethylene foam) is placed on a layer of fabric, followed by the aluminium frame, another layer of polyphom and a final layer of fabric. This layered, flat frame is heat-formed and then cut out of the laminated, hybrid material using a die-cutter. Each flat frame is then individually perforated for better ventilation, sewn around the frame with a sewing machine and then bent to the required shape by hand or with the aid of suitable counter dies (tools). The straps are only put in place after bending and then packaged and shipped with patient information leaflets to orthopaedic shops worldwide.

2.2. Diagnostics by X-ray microscopy

AThe medical device was subjected to X-ray microscopy radiography to examine the deterioration of the metal parts of the orthoses used. The type of X-ray microscope used is DAGE XiDAT XD6600.

In all cases, measurements were made at a tube voltage of 140 kV and a power of 11 W.

It can be noted that, in addition to complaints regarding fractures and weakening in the flexio-extension direction at the wrist of the device, several unknown issues were found on the medical device. It can also be concluded that the perforations serve as stress collection points in many places, and the examples suggest that these perforations are the origin of the cracks. The X-ray images have given me an accurate picture of the alignment and number of layers within the orthoses.

The product, illustrated in **Figure 1** was assembled from two types of plate (thickness 0.2 mm and 1.1 mm) with rivet fixation. The thinner plate provides the bending onto the arm and the thicker plate is responsible for the actual fixing. The X-ray microscope image immediately showed that the product was broken at the height of the wrist, across its entire width. On the device investigated, the distinct fracture only affected the thicker reinforcement plate, which was 1.1 mm thick. The thin corrugated aluminium, 0.2 mm thick plate, was only partially broken under load, or in the case of the stressed device, not broken at all (**Figure2**).

From this property, it can be inferred that the thicker the reinforcing plate, the more rigid it behaves and therefore is less resistant to fatigue.

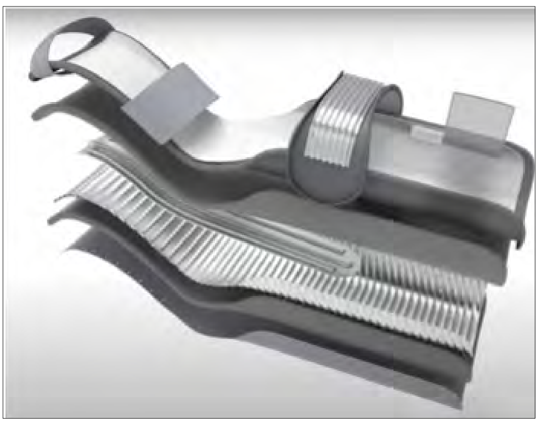

Figure 1. *Exploded view of the layers of the palmar forearm.* **[5]**

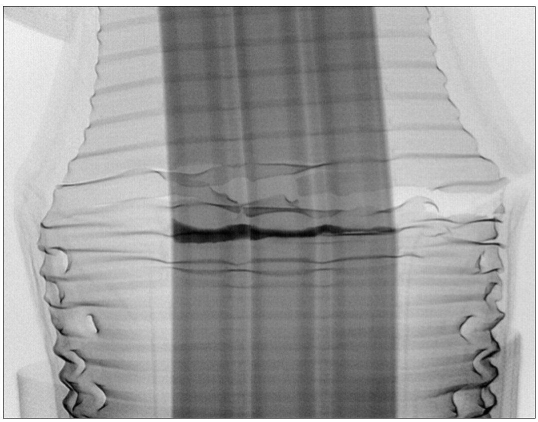

Figure 2. *X-ray of the fractured part of the wrists of the palmar forearm.*

A higher magnification image, examined with a stereomicroscope, shows that this fracture is not a pure fatigue fracture. In the second phase of the fracture, static rupture may have been involved in the fracture process.

2.3. Testing of corrugated aluminium reinforcing plate

To test the corrugated aluminium sheet in the orthoses, I made a resin embedded abrasive from a piece of factory corrugated aluminium strip, Lot: 76, 0.4 mm thick. The first striking observation I made was that even at low magnification it was possible to see that the profile of the corrugated aluminium sheet was not symmetrical, i.e. not sinusoidal.

The aluminium profile has unexpected indentations. Since this phenomenon is seen in the same part for all corrugations, I conclude that there is a bulge or a machining defect in the corrugating tool. The aluminium is 7-8 μm thinner in the chipped areas than in other areas (**Figure 3**). These spalls and thins act as stress accumulation sites. These areas are more likely to develop cracks and subsequent fractures. A small depression runs longitudinally along the bottom of the corrugations. This depression is present on all the corrugations, so I conclude that there is some kind of tooling defect along the entire length of the corrugator.

2.4. Description of the fatigue test

The small-cycle fatigue test demonstrates that the material part has undergone ductile deformation in the vicinity of the stress collection sites. At these locations, the stress exceeds the yield stress in each cycle. In such cases, typically the number of load cycles to failure is less than 10 000 **[6]**.

The fatigue test was performed using an INSTRON 8872 servo-hydraulic loading machine provided by the BME Biomechanical Research Centre, with the orthosis held in the device as shown in **Figure 4**. The machine has a maximum load capacity of 20000 N and a crosshead movement speed range of 0.001–1000 mm/min.

The fatigue test was carried out in two parts. Firstly, I loaded the device without quick-clamping, at a test frequency of 1 Hz, with a position control of 10 mm, for a duration of approximately 400 cycles. This method proved not to be suitable. The second method was the quick-clamp clamping method (**Figure 4**). In this case, I subjected the rail to a real load for about 1500 cycles at a frequency of 2 Hz, also with 10 mm position control. The evaluation was performed only for the test simulating the real load using the second clamping method. MATLAB 2021 (The MathWork, Inc., Massachusetts, USA) software was used to calculate the results and generate the graphs.

In all cases, the position varies by 10-10 mm both downward and upward at an offset of 15 mm. The measurement was performed for less than 800 seconds.

The force varies in a sinusoidal curve over time during fatigue and is repeated many times. In the initial stage, there was a gradual loss of elastic behaviour of the material and the damage to the aluminium stiffener plate - strain hardening, local thinning - which later gave rise to the cracks. Initially, a load of 120 N was required to move the

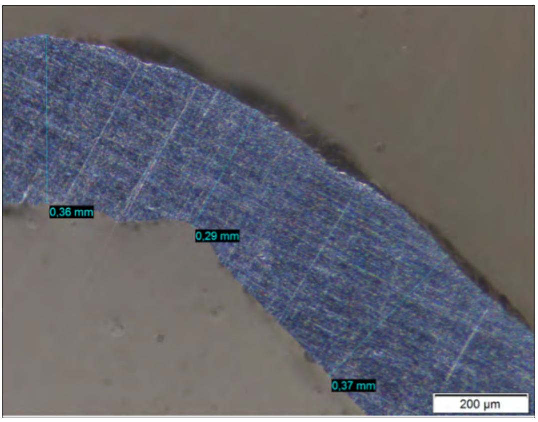

Figure 3. *Thickness values measured during the plate profile test.*

Figure 4. *The orthosis in the apparatus designed for fatigue testing.*

compression head by 10 mm. This was the resistive force exerted by the orthosis on the machine. After this, a long stretch of maximum resistance value of about 80 N and then the breaking phase begins. Full breakage occurs at the 850th cycle. Here the resistance curve was set to the maximum value of 40 N. This resistance is only due to the tissues in the hybrid structure.

Macrofractographic examination of the fracture surfaces was performed by stereomicroscopy. In the case of the fatigued device, we can say with certainty that the splint has suffered fatigue fracture. The resulting burr surfaces were compared with the surface of the investigated device.

In general, for both devices, the reinforcing aluminium plate is of uneven thickness. On the curved parts it is sometimes up to 0.3 mm thinner than on the straight ones. As I am testing an essentially uneven cross-section, several crack formation sites should be expected. Cracking, the irreversible movement of dislocations caused by cyclic movements, is the result of deformation and microcavitation. In such cases, the load is reduced and deformation may continue at other locations. However, the crack that is created propagates, i.e. the crack tip progresses. Crack initiation points are shown in Figure 5 a) for the fatigued and Figure 5 b) for the investigated rail. A crack with microscale extent will propagate if the adjacent crystallite is also in the correct position. Once the microcrack reaches a certain size, it becomes macroscale (macroscale is the range of extensions larger than about 1 mm). From then on, tensile stresses will control its propagation rather than shear stresses. The crack will mostly turn and propagate in a plane perpendicular to the maximum tensile stress. As the crack grows under the effect of cyclic loading, cyclicity in the form of regular grooves is also noticeable on the developed strut surface.

Both figures above clearly show semicircular grooves growing away from the crack initiation point. In the case of the fatigued device, the fatigue frequency was probably higher than in the case of the investigated rail, resulting in the formation of several grooves closer together. In the case of the investigated device, the grooves are spaced further apart.

Once the crack reaches a critical size, the propagation becomes unstable and the piece then breaks due to some static fracture. The pointed convexities that are visible in the circled part of Figure 5 b) have undergone plastic deformation in the compressive half-cycles, dulling down

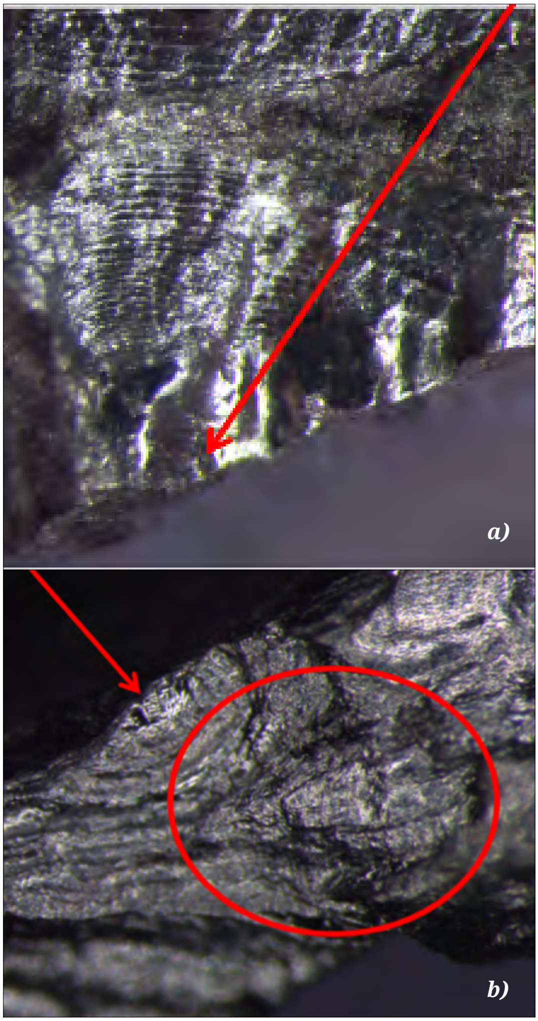

Figure 5. *(a) Crack initiation site on the proximal burst surface of the fatigued and the investigated (b) orthosis, marked with an arrow.*

and losing their original fractographic features. It is interesting to note that in the case of the fatigued tool, cracks were so densely formed as a result of the regular cyclicity that sometimes the semicircular grooves, starting from several directions, overlap. The resistance to fatigue can be improved by mechanical (rolling, spraying) or thermochemical hardening (nitriding) of the surface layer, or by surface coating (e.g. PVD). In the factory, the application of a polychromic coating to aluminium sheet is not considered as heat treatment.

2.5. Hardness testing of aluminium reinforcing plate

Hardness measurements can be used to determine the mechanical properties of the material as a good approximation and provide comparative data to tensile test data [4]. The measured data are approximate values of 40 HV. Proportionally deduced from the table in DIN EN ISO 18265:2004, a value of 40 HV corresponds to a tensile strength of approximately 125 MPa. This value is within the range of 105-145 MPa required in the technical certificate of the plate and the material is therefore suitable.

2.6. Scanning electron microscopy of aluminium stiffener plate

A scanning electron microscope is a device that scans the surface of a sample in a vacuum with a well-focused electron beam. Using secondary or back-scattered electrons from the sample or X-rays, the equipment can image the surface of the sample as set by modulating the signal from the sample with the light intensity of a cathode ray tube operating synchronously with the electron beam of the microscope. Using this technique, we can image the sample at a magnification of more than 16 000 times [7].

For my studies I used a ZEISS EVO MA10 scanning electron microscope. The machine was used in secondary electron detector mode, at a standard accelerating voltage of 20 kV, an anode current of 200 pA and a working distance of about 10 mm. From the images taken, it was found that there were no inclusions, foreign material, cracks or breaks in the plate. That is, the material of the plate can be considered homogeneous. The material of the stiffener plate was also examined by energy dispersive X-ray spectrometry (EDS).

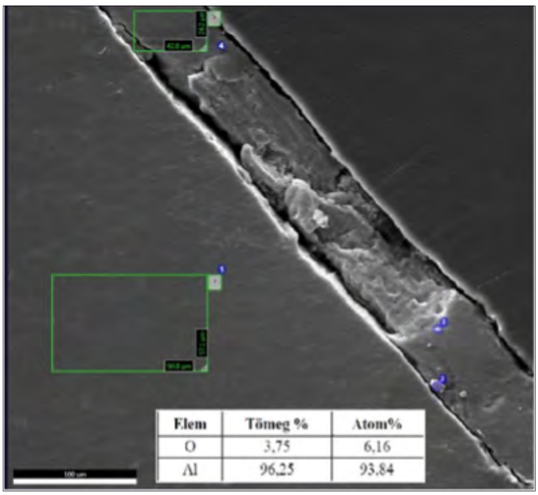

Figure 6. *Scanning electron microscope image of a part of the sample and the composition of the material measured by EDS in tabular form.*

The measurement proved that the plate contains only aluminium, since the oxygen peak can be considered as an artificial product caused by molecules adhering to the surface: in this case, too, it is found in the sample due to contact with air.

3. Conclusion

Examination of the stiffening plate of the hand orthoses tested on the basis of user complaints has also revealed characteristics that could be considered as manufacturing defects and certainly impair the resistance of the stiffening plate to fatigue. This discovery can be considered in the manufacturing development process.

Based on the hardness test, it can be stated that the tensile strength of the device meets the required specifications. Compliance with the requirements is also confirmed by the material composition measured by EDS. The damage to the tool subjected to the fatigue test proves that the faulty tool has suffered fatigue fracture due to micromovements. Based on the measured data, the device should not break after approximately two weeks of normal use. It can therefore be clearly established that the user did not comply with the conditions of use established to avoid overloading.

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