PUBLICLY AVAILABLE SPECIFICATION

ISO/PAS 7020

First edition
2023-05

Sizing parameters of surgical valve prostheses: Requirements regarding the application of ISO 5840-2

Désignation des dimensions des prothèses valvulaires chirurgicales: Exigences relatives à l'application de l'ISO 5840-2

Reference number
ISO/PAS 7020:2023(E)

Contents

Page

Foreword

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This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

0.1 General

In the past, inconsistencies have been reported with the labelling and instructions for use associated with sizing parameters and sizing procedures for surgical replacement heart valves, specifically, mechanical and stented bioprosthetic valves. These inconsistencies have led to confusion among some users about which size valve to implant in a particular patient and have also led to challenges in comparing results (published or otherwise) from one valve model to another. A solution to the problem can be achieved by providing more complete and accurate sizing information to the clinicians, which will ultimately benefit the patients.

ISO 5840-2 identifies a number of sizing parameters that are required in the labelling (including on the unit box, see ISO 5840-2:2021, 6.3.3, and instructions for use) to inform the selection of a surgical heart valve prosthesis to be implanted in a specific patient. However, no guidance is offered in ISO 5840-2 on how these parameters should be obtained.

0.2 Clinical rationale for additional sizing information

Successful valve replacement therapy requires that an adequate size surgical heart valve substitute is used, based on patient body size and the native valve annulus size. An understanding of valve sizing parameters and appropriate choice of size is critical to post-procedure success since a valve substitute that is too small for the patient can result in prosthesis-patient mismatch. For aortic valve replacements, severe mismatch has been reported in 5 % to 15 % of patients.[1] Severe prosthesis-patient mismatch leads to increased early, mid-term and late mortality, especially if the left ventricular ejection fraction (LVEF) is reduced.[2]-[5] In the mid-term, it causes a higher incidence of heart failure[5] and limits left ventricular mass regression.[5] In the long term, it can also contribute to accelerated structural valve degeneration (SVD).[6] Patients with severe prosthesis-patient mismatch can require replacement of the valve substitute with another having a larger effective orifice area (EOA). However, re-intervention has significant risk of mortality and morbidity.

The best approach to prosthesis-patient mismatch is prevention. This requires the surgeon to have clear and accurate information about the sizing parameters and EOA of each valve substitute.

A surgical heart valve substitute is described by a labelled size given by the manufacturer, which is assumed to be broadly consistent with the size of the patient native valve annulus for which the valve is intended. Literature reviews[1] and studies of haemodynamic function commonly compare valve substitutes by labelled size, but there can be major differences between the patient native valve annulus diameter and the labelled size of the valve substitute.[8]-[11] Intraoperative sizing is further complicated by the need for aortic supra-annular valves to fit within the aortic sinus. The disparity between labelled size and actual size means that echocardiographic or clinical comparisons based on labelled size can be misleading.

The issue of valve sizing is a complex problem and is being addressed in a stepwise fashion. The working group revising ISO 5840-2 proposed a first step toward greater transparency by requiring additional information be added to the unit box, namely, internal orifice diameter and effective orifice diameter. Although this information does not necessarily inform the surgeon on whether the valve would fit in the patient's annulus, it helps to estimate the internal orifice available for blood flow and thus indirectly the EOA. It is not feasible to use clinically measured EOA's since sizing information must be available before a surgical heart valve substitute is released for use in patients. Indeed, it can take a number of years to gather sufficient echocardiographic data to confirm the clinical EOAs. Furthermore, the use of echocardiographic data to help avoid prosthesis-patient mismatch has been criticized because of variability in the measurements obtained in vivo.[12] In vitro steady flow data have less variability and allow meaningful comparison of every design and size of surgical heart valve substitute under the same flow conditions. This information can be used by the surgeon to choose a specific valve substitute type and size based on more standardized parameters than labelled valve size. It is anticipated that further steps toward a standardised approach to sizing will be addressed in subsequent editions of ISO 5840-2.

This document provides further specifications to explain these two parameters (i.e. internal orifice diameter and effective orifice diameter) and other sizing parameters. This document also guides the manufacturer in selecting reproducible methods to obtain these parameters and the degree of accuracy required.

Sizing parameters of surgical valve prostheses: Requirements regarding the application of ISO 5840-2

1 Scope

This document describes in vitro methods of measurement of the sizing parameters for surgical valves (referring to mechanical and stented bioprosthetic valves only here and hereafter). It represents a consensus reached among manufacturers, independent bioengineers and clinicians, and is underpinned by interlaboratory studies.

This document relates to surgical heart valve prostheses and is intended to be used in conjunction with ISO 5840-1:2021 and ISO 5840-2:2021. Where noted, the requirements of this document clarify certain requirements of ISO 5840-1 and/or ISO 5840-2. Specific methodologies are included for flexible leaflet (bioprosthetic) and rigid (mechanical) valves. Sutureless valves, stentless valves and valved conduits are not included.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 5840-1:2021, *Cardiovascular implants — Cardiac valve prostheses — Part 1: General requirements*

ISO 5840-2:2021, *Cardiovascular implants — Cardiac valve prostheses — Part 2: Surgically implanted heart valve substitutes*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
effective orifice area
EOA
A_{eo}
orifice area that has been derived from flow and pressure or velocity data

Note 1 to entry: For in vitro testing, EOA is defined as:

$$A_{eo} = \frac{q_{V_{RMS}}}{51{,}6\sqrt{\frac{\Delta p}{\rho}}}$$

where

A_{eo} is the effective orifice area, expressed in cm^2;

$q_{V_{RMS}}$ is the root mean square forward flow, expressed in ml/s, during the positive differential pressure period;

Δp is the mean pressure difference, expressed in mmHg;

ρ is the density of the test fluid, expressed in g/cm^3.

3.2
external sewing ring diameter
ESRD
OD-SEWINGRING
outside diameter of the sewing ring at the largest point

Note 1 to entry: The external sewing ring diameter is expressed in millimetres.

Note 2 to entry: See Figure 1.

3.3
heart valve substitute
device used to replace the function of a native valve of the heart

3.4
inflow orifice diameter
ID-INFLOW
inflow internal orifice diameter
<flexible surgical heart valve> orifice diameter measured at inflow with a validated procedure

Note 1 to entry: See Figure 1.

Note 2 to entry: This definition clarifies the definition ISO 5840-2:2021, 3.5 for prosthesis minimum internal diameter for a flexible surgical heart valve.

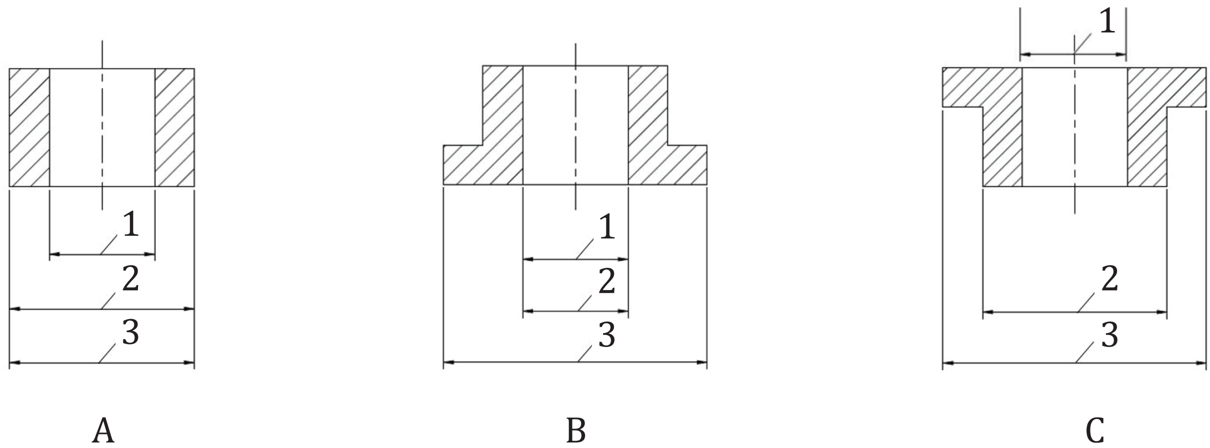
3.5
inflow orifice diameter
ID-INFLOW
inflow internal orifice diameter
<rigid surgical heart valve> inner diameter of the valve housing

Note 1 to entry: See Figure 1.

Note 2 to entry: This definition clarifies the definition ISO 5840-2:2021, 3.6 for prosthesis minimum internal diameter for a rigid surgical heart valve.

3.6
intra-annular
wholly or partially within the patient’s annulus

Note 1 to entry: See Figure 1.



Key

1 inflow orifice diameter

2 patient annulus diameter

3 external sewing ring diameter

A aortic/pulmonic intra-annular

B aortic/pulmonic supra-annular

C mitral/tricuspid intra-annular

NOTE This figure is a clarification of ISO 5840-2:2021, Figure 1.

Figure 1 — Designation of dimensions of surgical heart valve substitute sewing ring configurations

3.7
occluder
leaflet component that inhibits backflow

3.8
patient annulus diameter
PAD
diameter of the smallest flow area within the patient's valve annulus

Note 1 to entry: PAD is expressed in millimetres.

Note 2 to entry: See Figure 1.

3.9
effective orifice diameter
ID-EFFECTIVE
D_{eff}
prosthesis minimum internal diameter
diameter derived from hydrodynamic performance data measured with a standard validated procedure

Note 1 to entry: This definition clarifies the definition ISO 5840-2:2021, 3.5 for prosthesis minimum internal diameter.

Note 2 to entry: The effective orifice diameter, D_{eff}, is calculated from EOA data as

$$D_{eff} = 2\sqrt{\frac{A_{eo}}{\pi}}$$

where A_{eo} is the EOA derived from the steady flow pressure gradient.

3.10
supra-annular
wholly above the patient's annulus

Note 1 to entry: See Figure 1.

3.11
valve housing external diameter
OD-HOUSING
outer diameter of the structure that houses the prosthetic valve leaflets

3.12
valve size
designated valve size
manufacturer's designation of a surgical heart valve substitute which indicates the intended patient annulus diameter

Note 1 to entry: The valve size equals to the *patient annulus diameter* (3.9).

Note 2 to entry: This takes into consideration the manufacturer's recommended implant position relative to the annulus and the suture technique.

4 Abbreviated terms

EOA	effective orifice area
ESRD	external sewing ring diameter
ID-INFLOW	inflow orifice diameter
ID-EFFECTIVE	effective orifice diameter
LVEF	left ventricular ejection fraction
OD-HOUSING	outer diameter of housing or valve stent
OD-SEWINGRING	sewing ring external diameter
PAD	patient annulus diameter
SVD	structural valve deterioration

5 Information required for the outer container labelling

5.1 General

ISO 5840-2:2021, 6.3.3 specifies packaging, labelling and sterilization requirements for surgical heart valve prostheses. Most requirements are referenced to ISO 5840-2:2021, 6.3.3. However, ISO 5840-2 includes some additional labelling requirements to appear on the "outer container labelling … in diagrammatic and/or tabular form." The additional items required are:

— intended valve to be replaced;

— intended position in relation to the annulus;

— inflow orifice diameter (see 3.4 and 3.5);

— effective orifice diameter (see 3.9);

— external sewing ring diameter (see 3.2).

