Mechanical Characteristics of Self-expandable Metallic Stents: In Vitro Study with Three Types of Stress

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Purpose: To obtain objective and comparable data for mechanical characteristics of self-expandable metallic stents widely used in the treatment of biliary obstruction.

Materials and Methods: The stents tested were the 6 and 8 mm-band Hanaro spiral stent, Gianturco-Rösch Z stent, Wallstent, Ultraflex stent, and Memotherm stent. Each was subjected to three types of load: point, area, and circular. We analyzed their mechanical characteristics (resistance force, expansile force, and elasticity) according to these three types of stress.

Results: With regard to point loads, the Memotherm stent showed the highest resistance force and expansile force. The 8 mm-band Hanaro stent showed the lowest resistance force and the Gianturco-Rösch Z stent and Ultraflex stent showed lower expansile force. With regard to area loads, the Ultraflex stent showed the highest resistance force. The 6 mm-band Hanaro stent, Gianturco-Rösch Z stent, and Ultraflex stent showed higher expansile force. The 8 mm-band Hanaro stent showed the lowest value in both resistance force and expansile force. For circular loads, the Memotherm stent showed the highest resistance force and the Ultraflex stent and Wallstent showed lower value. Under all types of stress, the Hanaro stent and Memotherm stent were completely elastic, and the Ultraflex stent and Wallstent showed a wide gap between resistance force and expansile force.

Conclusion: In clinical practice, awareness of the mechanical characteristics of each stent might help in choosing the one which is most suitable, according to type of biliary obstruction.

Index words: Stents and prostheses

Metallic stents have found a wide spectrum of applications in modern interventional radiology. To date, various types of metallic stents made of different materials have been designed to enhance clinical efficacy and are now widely used in the vascular, biliary, and gastrointestinal system (1 - 8).

The primary technical success of stent placement depends directly on the mechanical characteristics of the stent. These include resistance force, expansile force, and longitudinal flexibility. In a particular type of stent, these characteristics depend on the stent's construction and the nature of the materials used.

It is crucial to choose the most suitable stent, according to different types of obstruction, and is thus important to evaluate the mechanical characteristics of the metallic stent widely used. Only a few reports have described the mechanical characteristics of metallic stents (9 - 11). Thus, this study aimed to obtain objective and comparable data relating to the mechanical characteristics of widely used self-expandable metallic stents and to evaluate their suitability for the treatment of the different types of obstructions seen in clinical practice.
Materials and Methods

To evaluate their mechanical characteristics, six types of self-expandable stents were tested in vitro. These were the 6 and 8 mm-band Hanaro spiral stent (SooHo Medi-tech, Seoul, Korea), the Gianturco-Rösch Z stent (Cook, Bloomington, U. S. A.), the Wallstent (Schneider, Bulach, Switzerland), the Ultraflex stent (nitinol Strecker stent; Medi-tech/Boston Scientific, Natick, U. S. A.), and the Memotherm stent (Angiomed, Karlsruhe, Germany). To obtain objective data, stents designed for the biliary system were selected and the study was carried out in a standardized fashion. The stents used were 65 - 70 mm in length and 10 mm in diameter. For each type of stress, one stent of each design was tested.

For the measurement of strength, a method similar to that described by Flueckiger et al was used (9 - 11). Tests were performed at 35 - 37°C and three types of stress — point load, area load, and circular load — were applied to each stent (Fig. 1). Clinically these implied focal eccentric, diffuse eccentric, and concentric stenosis, respectively. Forces were measured with a microprocessor force gauge (EFG 250, Mecmesin, England).

Point load was applied using a rod with a round tip, 5 mm in diameter, and area load using a round plate 30 mm in diameter. We measured resistance and expansile forces under both these load conditions. Resistance forces were measured as stress was applied until the stents were compressed to 3 mm of their diameter, and expansile forces were recorded during subsequent relaxation. If the stent was distorted before the compressed distance reached 7 mm, no more stress was applied and relaxation was begun. The values of measured forces were plotted as applied force versus compressed distance. Circular loads were applied using a 30 mm-wide loop of nonelastic photographic film, with the loop wrapped around the center of the stent. One end of this was connected to a gauge which monitored force by applying increasing tension to the other end of the loop. Because it was technically impossible to monitor expansile force, only resistance force was measured under circular load. The values of measured forces were plotted as applied force versus the length of photographic film pulled. In all stents, forces were measured at the middle of their length. Additionally, in the case of the Gianturco-Rösch Z stent, point and area loads were applied at the connecting portion between stent bodies as well as at their center.

Results

In all stents, diameter of the stents decreased as force increased.

According to the results obtained for point and area load, all stents showed different values between resistance forces and expansile forces at the same diameter of compressed stent, and the values of resistance forces were higher than those of expansile forces. The ranges of force gap were different in each stent. We defined 'elasticity' of a stent as the gap between resistance force and expansile force (Fig. 2).

Point Loads

Resistance Force

At an indentation value of 3 mm, all stents showed similar resistance forces. Over this indentation, the Memotherm stent showed the highest resistance force, followed by the 6 mm-band Hanaro stent, the Wallstent, the Ultraflex stent, and the Gianturco-Rösch Z stent. The 8 mm-band Hanaro stent showed the lowest resistance force (Fig. 3A).

Expansile Force

During re-expansion to 7 mm of stent diameter, the Memotherm stent showed the highest expansile force, followed by the 6 mm-band Hanaro stent, the Wall-

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Fig. 1. Schematic drawing of the three types of stress; A. Point load. B. Area load, and C. Circular load.

Fig. 2. Force (newtons) versus compressed distance plot of the 6 mm-band Hanaro stent and the Wallstent subjected to area load. Elasticity is different in two stents. H6: 6 mm-band Hanaro stent. W: Wallstent.
Area Loads

Resistance Force

The Ultraflex stent, 6 mm-band Hanaro stent, and Gianturco-Rösch Z stent showed higher resistance forces than the Memotherm stent and 8 mm-band Hanaro stent (Fig. 5A). In the case of the Wallstent, the area load curve was interesting; at an indentation of 2 mm, its value was higher, but above that value, the curve reached a plateau. The Gianturco-Rösch Z stent showed no force difference between the middle of its body and the connecting portion under the area load.

Expansile force

The 6 mm-band Hanaro stent, Gianturco-Rösch Z stent, and Ultraflex stent demonstrated a higher expansile force than the Wallstent and 8 mm-band Hanaro stent (Fig. 5B).

The Hanaro stent, Memotherm stent, and Gianturco-Rösch Z stent showed good elasticity, but in the Ultraflex stent and Wallstent there was a wide gap between resistance force and expansile force (Fig. 2).

Circular Loads

Resistance force

At an indentation of over 2 mm, the Memotherm stent showed the highest resistance force, followed by the 6 mm-band Hanaro stent, Gianturco-Rösch Z stent, 8 mm-band Hanaro stent, Wallstent, and Ultraflex stent (Fig. 6).

Discussion

Metallic stents are now widely used to treat or palli-
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ate obstructions. To date, various types of metallic stents, made of different materials, have been designed (2-6). They are categorized into two groups, self-expandable and balloon-expandable. In biliary intervention, balloon-expandable metallic stents have now been largely abandoned; they need ballooning prior to stent placement and compared with self-expandable stents, have no benefit in long term patency (4, 8). In this study we therefore dealt with six self-expandable stents widely used in the biliary system.

The ideal stent would combine the virtues of simplicity of use, low introduction profile, radiopacity, proper mechanical characteristics, and high patency rate. The primary technical success of stent placement in many types of obstructive lesion depends directly on the mechanical characteristics of the stent. When choosing the type most appropriate to a particular clinical setting, awareness of the mechanical characteristics of each stent is thus important.

The mechanical characteristics of stents include expansile force, resistance force, elasticity, longitudinal flexibility, biocompatibility, and shortening. For each type of stent, these depend on the mode of construction, amount of mechanically effective mass of metal, and the mechanical characteristics of the metal such as plasticity, elasticity, and temperature dependence (9). During the early stage of making a metallic stent, stainless steel was used. The Wallstent, Gianturco-Rösch Z stent, and Hanaro stent are made of biocompatible stainless steel wires. To enhance expandability and elasticity, nitinol—a material with thermoelectric characteristics—has recently been used. It is used for the Memotherm stent and Ultraflex stent, for example.

The mechanical characteristics tested in vitro included expansile and resistance forces. Three types of load were applied to each stent, namely point, area, and circular, which under clinical conditions imply, respectively, focal eccentric, diffuse eccentric, and concentric stenosis.

The resistance force of a metallic stent is the strength to sustain its fully expanded state against an extrinsic growing mass. We experienced one hundred cases with metallic stent placement and in none of these was the stent compressed by a tumor (8). Furthermore, because all stents are designed to be inserted in their compressed state, resistance forces in the clinical situation are less important than expansile forces. Our results showed, fortunately, that the order of stents according to resistance force was similar to that according to expansile force.

Expansile force, on the other hand, is closely related to the primary effectiveness of stent placement; this is because it is closely related to the time that the stent takes to achieve effective luminal diameter against a surrounding tumor. According to our results, the 6 mm-band Hanaro stent showed higher resistance and
expandability under all types of stress. The Memotherm stent showed the highest expandability under point and circular load, though this was lower under area load. Conversely, the Ultraflex stent showed the highest expandable force under area load but a lower value under other loads. The Wallstent and Gianturco-Rösch Z stent showed somewhat lower expandability under all stresses. These results coincide with those of a study by Flueckiger et al (9). With regard to expandability itself, the Memotherm stent has an advantage in focal eccentric and concentric stenosis, the Ultraflex stent in diffuse eccentric stenosis, and the 6 mm-band Hanaro stent in all types of stenosis.

The Gianturco-Rösch Z stent showed uneven expandability along its length. As it has lower expansile force in areas of connections between individual stent bodies, in short-segment stenoses the exact placement of the Gianturco-Rösch Z stent is more difficult to control. This uneven expandability, however, has not been a problem in clinical use of the Gianturco-Rösch Z stent in longer stenoses.

In our study, the elasticity of six stents differed. The Hanaro stent and Memotherm stent were completely elastic, but the Ultraflex stent and Wallstent showed a wide gap between resistance force and expansile force. It is uncertain why the Ultraflex stent and Wallstent are less elastic, but their mode of construction appears to be related. Although the Ultraflex stent is made of nitinol wire, which has thermoelastic characteristics, it is knitted into a cylindrically shaped flexible mesh, which is not interconnected. We found that the configuration of the Ultraflex stent was easily distorted as stress increased, especially when a circular load was applied. When it expands from the compressed state, the vector of radial force is thus dispersed. Because of its design an eccentric load on the Wallstent causes concentric constriction over a considerable length. Accordingly, if an eccentric load is applied to this stent, it is unable to offer adequate mechanical resistance at precisely this segment (9).

Ideally, the diameter of a stent on insertion and the surface area when expanded should both be as small as possible. These two factors limit the mechanically effective mass of a metal, which could be expected to be of limited strength.

In this study we tested the mechanical characteristics of metallic stents in vitro, and the results obtained thus may not apply in clinical situations. When choosing the ideal stent in clinical practice, many factors other than these characteristics must be considered. One of these is the longitudinal flexibility of a stent, a feature which allows it to maintain its full diameter in the curved lumen. Though we did not test this feature in the present study, flexibility in general decreases as expandability increases; the former depends on the mode of stent’s construction. In other words, the inter-connection of mesh structures and construction of the stent influence the stent’s longitudinal flexibility.

Although the Ultraflex stent showed lower strength under point and circular loads, it has superior flexibility. It is constructed of mesh struts that are not fixed to one another, and this permits good longitudinal flexibility (5). The Wallstent is composed of 18 biocompatible stainless steel monofilaments, free to move over each other because the cross points between them are not soldered together. It is pliable and flexible in the longitudinal axis (9). In the case of the Gianturco-Rösch Z stent and Memotherm stent, however, each connecting portion is fixed, and this decreases their longitudinal flexibility.

Shortening of a stent in clinical application is another mechanical characteristic to be considered. The Hanaro stent, Memotherm stent, and Gianturco-Rösch Z stent shorten only minimally, and if, during deployment, this is the case—or there is no shortening—exact placement should be easy. In the case of the Wallstent and Ultraflex stent, however, shortening after placement is reported to be approximately 35–40% of the length of the unexpanded stent (5, 12). This could make proper positioning at the desired segment difficult, especially in cases involving hilar obstruction.

When choosing a stent, another important aspect is its design of construction. The Wallstent has sharp wires on both ends. Though such complications are rare, these may cause CBD ulceration, duodenal ulcerations when the stent is placed across the papilla for low CBD obstructions, or bleeding from duodenal mucosa. The Ultraflex stent, however, has soft looped ends which should not cause injury to the ductal or bowel mucosa (5).

In conclusion, the Memotherm stent showed the highest expandable force under both point and circular load. The Ultraflex stent showed the highest strength under area load. The 6 mm-band Hanaro stent showed favorable expansile force and superior elasticity under all types of stress. Under these conditions, the 8 mm-band Hanaro stent showed the lowest value. In clinical practice, these results may help in choosing the most suitable stent, according to the type of obstruction.

Acknowledgments: The authors thank SooHo Medi-tech for their technical assistance in measuring
the forces generated in stents during our experiments.

References


자기팽창성 금속스텐트의 물리적 성질:
3가지 부하에서의 실험 연구1

1 원자력병원 진단방사선과
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목 적: 담도폐쇄의 치료에 널리 사용되는 자기팽창성 금속스텐트의 물리적 성질을 객관적으로 비교한 자료를 얻는데 목적이 있다.

대상 및 방법: 실험에 사용된 스텐트는 6 mm-band와 8 mm-band 하나로 스텐트, Gianturco-Rösch Z stent, Wallstent, Ultraflex 스텐트, Memotherm 스텐트였다. 각 스텐트에 point load, area load, circular load 등 3가지 부하를 가하면서 각 부하에 따른 스텐트의 물리적 성질 (저항력, 팽창력, 탄성)을 측정하여 비교하였다.


결 론: 각 금속스텐트의 물리적 성질을 알고 있으면 임상에서 여러가지 종류의 담도협착에 따른 적절한 스텐트를 선택하는데 도움이 되리라 생각된다.