

## **New egzoluminal circular surgical stapler**

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The study presents the design, prototype version and preliminary results of in vivo testing of the egzoluminal circular surgical stapler for “end-to-end” anastomosis of bowels after the resection, where staples are put outside the intestinal lumen, and walls of the intestinal tube directly contact the intestinal mucous membrane. The adopted idea of an “end-to-end” intestinal anastomosis as well as a strong need for a device that would be re-usable have determined its specific design. The device is characterised by a kinematic mode of operation, different from the operating mode of commonly used staplers, and hence by a specific combination of the individual components. The in vivo tests, successfully conducted on animals, have proved that this method of anastomosis as well as the device used for its practical performance are fully applicable in clinical practice, as best shown by patent application No. P 386369.

*Key words: extraluminal circular stapler, mucous membrane, intestinal anastomosis, sterilisation*

### **1. Introduction**

The intraluminal circular staplers used currently are equipped with heads that are placed in the lumen of the bowel, the borders of which are folded to the inside. Staplers of this design are an excellent tool for the anastomosis of an intestinal section of the alimentary tract, especially its rectal part [1]. The application of intraluminal surgical staplers in the anastomosis of the remaining intestinal part of the alimentary tract is theoretically possible but not fully consistent with the well-known Halstead’s principle of surgical art [2]–[5].

The egzoluminal circular surgical stapler described in this study has been assigned for use in surgical anastomoses, especially in an “end-to-end”

intestinal anastomosis performed in practically all sections of the alimentary tract, where patency of the bowels is obtained by extraluminal folding (folding to the outside) the borders of the bowel sections that are to be put together. Similar to intraluminal staplers, also in this case, metal staples are used for the anastomosis.

### **2. Materials and methods**

The main task of the designed versatile circular surgical stapler is to perform an “end-to-end” interintestinal anastomosis at each and every arbitrarily chosen section of the bowels, proceeding in accordance with the Halstead’s principle of medical art (figure 1).

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The said principle is fully satisfied using the newly designed stapler, where borders of the bowels are folded in the direction opposite to the intestinal lumen. This means the situation reverse to that faced in a traditional method using standard circular surgical staplers. The method itself forces the use of split elements (head, anvil and cartridge holding the staples). The split design enables complete removal of all components of the circular surgical stapler from the patient's abdominal cavity after the anastomosis has been completed.

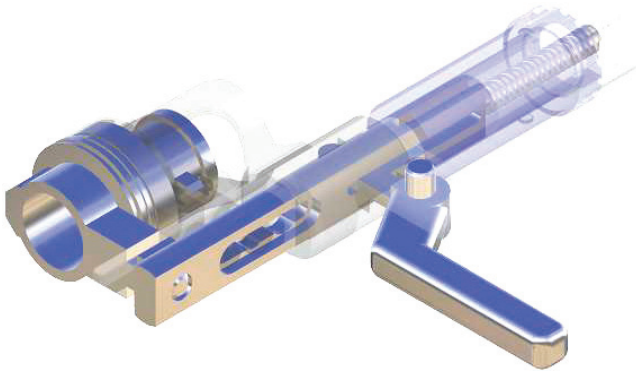


Fig. 1. A versatile circular surgical stapler

The requirements of versatility and repeated use of the new stapler demanded some new solutions regarding the design of its individual components in terms of their geometry, kinematics, and operating mode. Nearly all the components of the device have been designed and made in accordance with the adopted rules of simplicity, smooth surface, and absence of recesses and threaded joints, to make the sterilisation easy, complete and reliable.

The new design includes only one element of complex geometry, i.e. the staple cartridge. Its task is to feed staples during the operation of anastomosis. Because of the sterilisation regime, this is the only element that is disposable and replaced before each operation. The design includes one threaded joint which plays double function, i.e. holds together all stapler elements to form one integral and useful whole and enables the distance between the stapler head and anvil to be precisely calculated during the operation of anastomosis. It also enables very quick assembly and disassembly of the device. The threaded joint is, however, located inside the device handle and, given its position, it never enters into direct contact with the stapled tissues.

All parts of the device are made from biotolerable materials, resistant to sterilisation, both thermal and chemical (using gas).

## 2.1. Description of the device

The device is composed of a head with staple cartridge and an anvil. Both elements are of a split design. At the stage of designing and later tests, different parting planes were chosen. Some of them left the staple guides and seats untouched, but required very intricate technology (figure 2), while others, simpler in performance, were "crossing and cutting" the guides and seats in two (figure 3). The tests carried out on materials imitating bowels, as well as the anastomoses carried out in vitro and in vivo on animals have proved that each of the de-

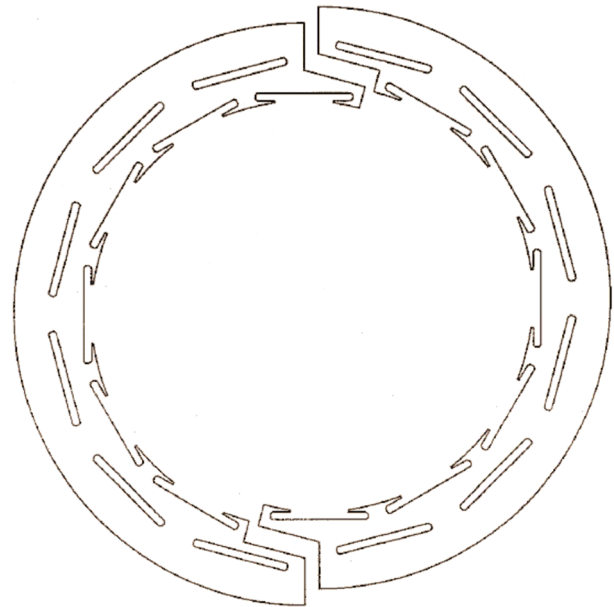


Fig. 2. Complex split head

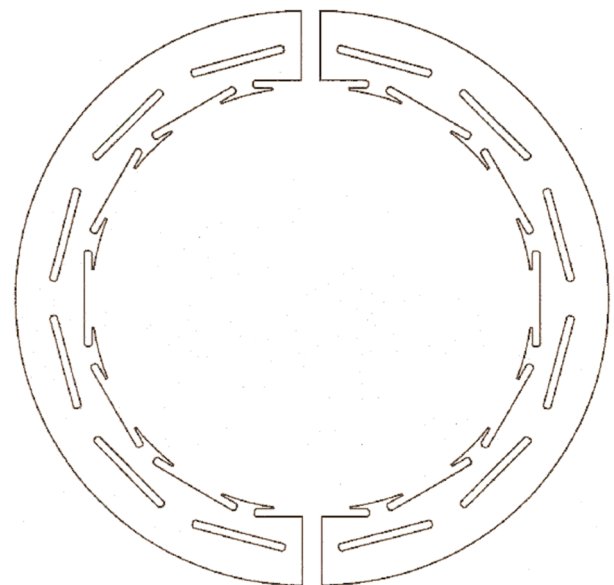


Fig. 3. Straight split head

signs proposed is equally efficient and ensures the required quality and reproducibility of the stapled “suture”. When the anastomosis is performed, very important is the design and operation of the staple ejector. The parting planes designed for the stapler operating elements demanded the use of ejectors of two different types, i.e. in the form of single plates and of bridge-like construction. In the design of the parting plane that preserves the staple seats and guides untouched, it was enough to use ejectors in the form of single plates, while in the second design of the parting plane (crossing and splitting the guides in two) it was necessary to use, besides the ejecting plates, also the ejecting bridge-like constructions. The bridges kept the ejectors in position when the head was dismantled after the operation. The bridge-type ejectors were used only in these parts of the head parting plane where the staple guides were “cut in two”.

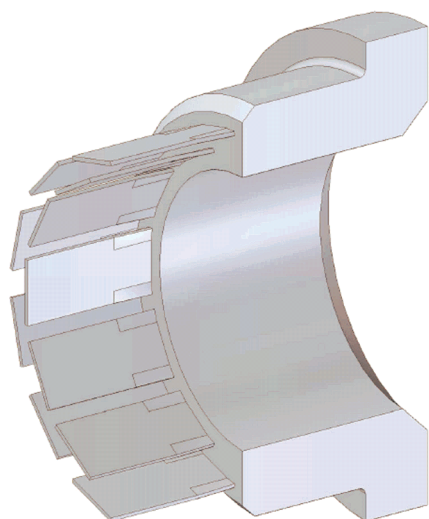


Fig. 4. Ejecting ring with integral ejectors

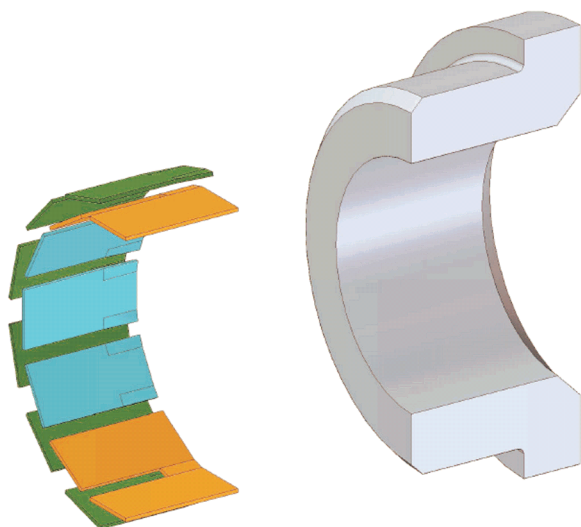


Fig. 5. Ejecting ring with floating ejectors

Tests were carried out on both design variants, i.e. with integral ejectors (figure 4) and with “floating” ejectors (figure 5).

The variant with the “floating” ejectors gave very good results as regards the “suture” quality and failure-free operation during testing. A complete head with the “floating” staples and bridges is shown in figure 6.

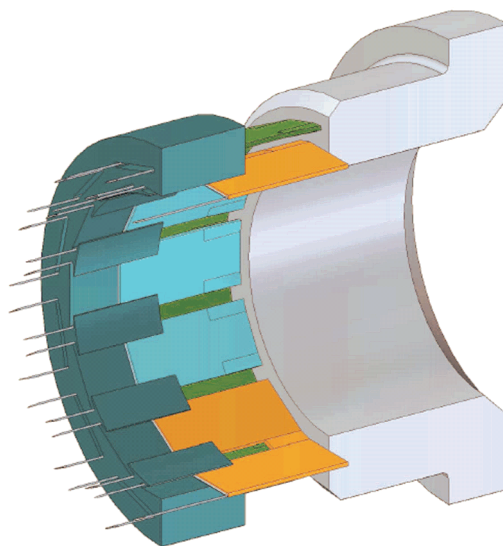


Fig. 6. A view of the head

## 2.2. Mode of functioning

The surgical stapler was designed for maximum ease and simplicity of operation. The first step before the operation of anastomosis starts is to detach the head with cartridge and the anvil from the device. The borders of the bowels that are to be joined together are placed in the respective internal parts of the joining elements, to be rolled over next through these elements. The bowels are already prepared for the anastomosis and provided with a primary suture (figure 7). The borders of the bowels placed in the device head and anvil, respectively, are then pulled off from the bowel lumen to rest on the external surfaces of the joining elements. The primary suture is tied and the head and anvil, now ready to start the operation, are connected to the handle of the device. The borders of both bowel sections are moved close to each other, and the operation of anastomosis begins (figure 9). The operating parts of the device are pushed close to each other by a screw-operated mechanism. The anastomosis is done by pressing the starting lever which actuates the mechanism, resulting in coupled forward movement of all the circumferentially arranged staples. The releasing of the “stapled” bowel from the

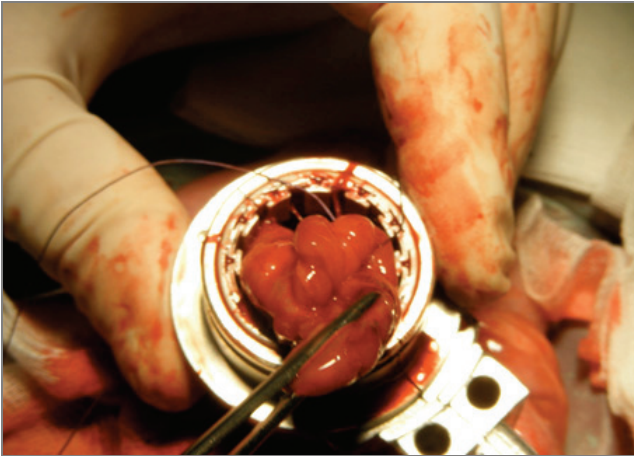


Fig. 7. Ejecting ring with floating ejectors

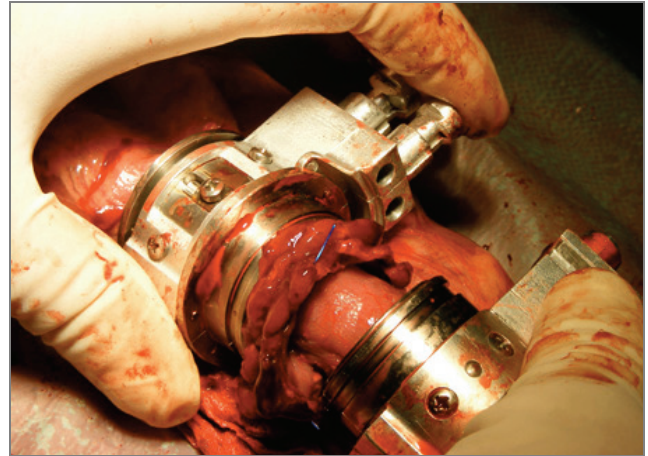


Fig. 10. Dismantling of stapler after the intestinal anastomosis

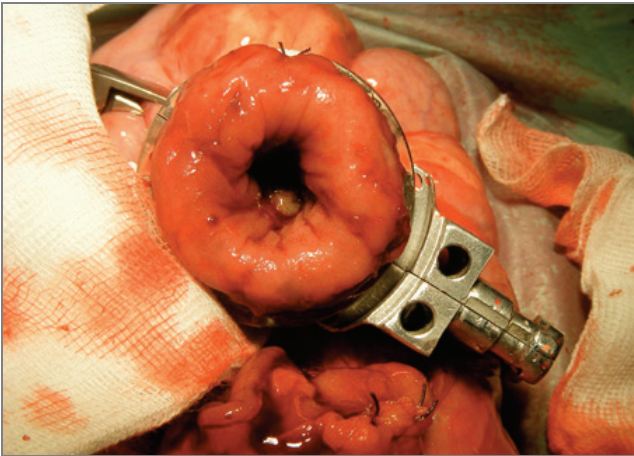


Fig. 8. Egzoluminal folding of the bowel border

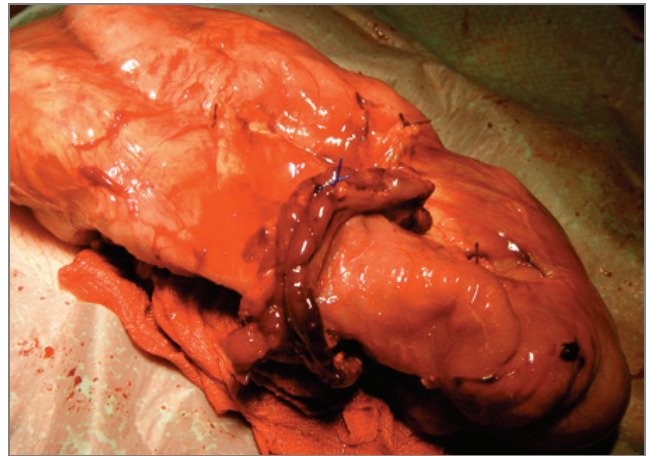


Fig. 11. A view of the suture



Fig. 9. Intestinal anastomosis

device after the anastomosis is possible only if the head and anvil are detached from the device handle and dismantled (figure 10). The empty cartridge should be disposed, and the device after thorough

cleaning is sterilised. A view of the bowel after anastomosis is shown in figure 11.

Considering the fact that the newly designed versatile surgical stapler is fit to perform the circular anastomosis in practically all sections of the bowels, both small and large, and allowing for some individual features typically different in each patient and his/her organism, the device has been provided with several replaceable suture-laying assemblies (head and anvil) of different diameters.

### 3. Final results

The trials of anastomosis carried out on materials imitating bowels as well as the later in vitro tests made on animals have proved that the proposed method of anastomosis is technically feasible. When tested, the device was functioning in a perfect mode, and all the

performed operations of anastomosis offered the expected high quality, reliability, and bowel patency. The process of sterilisation, both chemical and thermal, had no major effect on the performance efficiency of the device. So, in technical approach, the device described in this study can be regarded as failure-free in operation and re-usable. Thus it has been demonstrated that it is possible to design and manufacture a device that will perform an “end-to-end” anastomosis of the human bowels in egzoluminal approach.

All operations of the anastomosis performed by this method in vivo on animals have ended in success. The operated animals have survived in good condition the period required for healing of the tissues, and re-operated showed complete and correctly done anastomosis of the bowels. Studies have also proved that the proposed method of anastomosis done with a circular stapler in the “mucous membrane-to-mucous membrane” arrangement ensures effective healing and reconstruction of the tissues after surgery. In view of the fact that the preset goal has been achieved, and all the technical as well as medical steps have ended in full success, further studies to implement this innovative method in clinical procedure seem both reasonable and justified.

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