

Exploring the boundaries of Bariatric Surgery

Citation for published version (APA):

Paulus, G. F. (2021). *Exploring the boundaries of Bariatric Surgery: Should we introduce it to adolescents and can we innovate traditional surgery?* [Doctoral Thesis, Maastricht University]. Maastricht University. <https://doi.org/10.26481/dis.20210416gp>

Document status and date:

Published: 01/01/2021

DOI:

[10.26481/dis.20210416gp](https://doi.org/10.26481/dis.20210416gp)

Document Version:

Publisher's PDF, also known as Version of record

Please check the document version of this publication:

- A submitted manuscript is the version of the article upon submission and before peer-review. There can be important differences between the submitted version and the official published version of record. People interested in the research are advised to contact the author for the final version of the publication, or visit the DOI to the publisher's website.
- The final author version and the galley proof are versions of the publication after peer review.
- The final published version features the final layout of the paper including the volume, issue and page numbers.

[Link to publication](#)

General rights

Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

- Users may download and print one copy of any publication from the public portal for the purpose of private study or research.
- You may not further distribute the material or use it for any profit-making activity or commercial gain
- You may freely distribute the URL identifying the publication in the public portal.

If the publication is distributed under the terms of Article 25fa of the Dutch Copyright Act, indicated by the "Taverne" license above, please follow below link for the End User Agreement:

www.umlib.nl/taverne-license

Take down policy

If you believe that this document breaches copyright please contact us at:

repository@maastrichtuniversity.nl

providing details and we will investigate your claim.

Valorisation

In the scope of a medical thesis, valorisation means “the process of value-creation out of knowledge, by making knowledge suitable and available for social or economic utilization and to translate this into high-potential products, services, processes and industrial activities” (Landelijke Commissie Valorisatie. *Waardevol: Indicatoren voor Valorisatie*; 2011). This thesis focuses on the boundaries of bariatric surgery as a treatment for (morbid) obesity. It has two main topics: the treatment of morbidly obese adolescents and the innovation of bariatric surgical practice, by developing novel medical devices.

Since 1975, the prevalence of obesity in the world has almost tripled. More than 650 million people are currently obese, of which approximately 40 million are adolescents (1). In the US 13% of adolescents qualify as extremely obese (2). In the Netherlands nearly half of all adults are overweight, while 14.2% qualify as obese. Among Dutch children and adolescents, the prevalence of obesity was 2.8% in 2017 (3). Obesity is associated with serious comorbidity (such as type 2 diabetes mellitus, cardiovascular diseases, sleep apnea, asthma and musculoskeletal disorders) (4-6). Currently most of the world's population lives in a country where obesity kills more people than malnutrition. The risk of dying from any obesity related cause increases by 6-7% for every 2 years lived with obesity (7). Furthermore, obesity reduces quality of life. For example, persistent obesity in women is associated with higher risk of never being gainfully employed and not having a partner (8). Obese adolescents are also likely to suffer from psychological morbidity which has the potential of scarring them for life (9).

The obesity epidemic therefore imposes a tremendous social and economic burden. Estimates of direct health care costs in the US range from \$147 billion to \$210 billion per year (10). In the Netherlands, 2.2% (€1.6 billion) of total health care costs was spent on obesity related diseases in 2012 (11). In addition, obesity is associated with indirect costs to society due to unemployment, absenteeism, lower productivity, premature mortality and disability. The costs of job absenteeism in the US are approximately \$4.3 billion annually, while lower productivity at work costs employers \$506 per obese worker per year (12, 13).

In the first part of this thesis we investigated the applicability of bariatric surgery in morbidly obese adolescents and initiated the BASIC trial, a randomized controlled trial in which the effects of gastric banding on weight loss, health and psychosocial wellbeing is studied extensively. The impact of adolescent obesity in the community and potentially successful treatment strategies was illustrated by frequent media attention; resulting in newspaper articles, interviews and television documentaries (14-19). If morbidly obese adolescents can be successfully and safely treated, their future role in society and their contribution to the community can change tremendously. Furthermore, once our findings are published, they are likely to change national and

international guidelines for the treatment of obese adolescents.

The second part of this thesis focuses on novel techniques with two specifically designed medical devices. One of these devices is the ACE stapler, designed by a small medical device company called BaroSense Inc. They raised money from investors to design, develop and test the device from drawing table, through animal testing, to the first test in humans. We provided the infrastructure to test the safety and preliminary efficacy of the technique and collaborated to further investigate its mechanisms of action, with their financial support. A novel technique becomes much more valuable to future investors and more credible to the international scientific community when mechanisms of action are unraveled. Although BaroSense Inc. was dissolved after they were unable to raise sufficient funds, the potential of the technique was recognized by Boston Scientific, that acquired their assets and invested to complete the study protocol.

The second device that we studied was the ExilisTM gastric electrical stimulator in collaboration with Medtronic. Again, this was primarily a study to assess safety and preliminary efficacy and financial support was provided to investigate mechanisms of action. The potential benefits for society are of interest to the press. Documentaries and interviews were made about the ACE stapler as well as the ExilisTM device (20-22). The ACE stapler has shown its potential and Boston Scientific profits from its success when the technique becomes commercially available. However, the initial results with the ExilisTM system were disappointing and Medtronic decided to stop the project for the time being. Our collaboration led to increased insight, but will not lead to any financial gain for Medtronic in the near future.

Traditional bariatric surgery has proven to be cost-effective. The exact numbers have not been analyzed in the Netherlands, but have been in our neighboring countries Germany and Belgium. Over 10 years, bariatric surgery generated 1.2 to 1.4 quality-adjusted life years (QALYs) with an incremental cost-effectiveness ratio of €2457 to €2809 per QALY. To put this in perspective, in the Netherlands up to €80.000 per QALY is regarded as cost-effective, depending on the severity of the disease (23). Over an entire lifetime, surgery led to savings of €8522 to €9332 and generated an increment of 3.2 to 5.0 QALYs. Furthermore, it was found that delaying surgery for up to 3 years, resulted in a reduction of 0.4 QALYs gained (24, 25). In this analytical model, the mean age was 40 years. Assuming that there are no 'very-long term complications' that we are currently still unaware of, it is likely that bariatric surgery at the age of 14 to 16 years leads to significantly more life-time savings, more or prolonged reduction of comorbidity and more QALYs gained.

Only a small percentage of potentially eligible adult subjects will ever undergo a bariatric procedure (26). The reason as to why is multifactorial and includes (amongst

others) costs, availability and fear of complications. Bariatric surgical procedures such as laparoscopic adjustable gastric banding (LAGB), laparoscopic sleeve gastrectomy (LSG) and Roux-en-Y gastric bypass (RYGB) (27, 28) modify gastrointestinal anatomy and physiology, require life long medical surveillance and are associated with a considerable amount of complications and long-term adverse effects such as GERD, chronic vomiting, dumping syndrome and nutritional deficiencies. New, minimally invasive or completely reversible procedures like the ACE stapler and gastric electrical stimulation (in an improved form) can possibly solve these problems and provide a solution for those who are now excluded from bariatric surgery. Even if it is difficult to reach the same amount of weight loss with these procedures when compared to traditional invasive procedures, we should continue to develop and study them, because if the results get close enough, with the current safety profile there is an enormous population to benefit from them.

Finally, although we usually don't say this part out loud, bariatric surgery is currently a profitable treatment for health care providers in the Netherlands. Recently, a Dutch hospital was declared bankrupt and one of their only profitable activities was the bariatric surgery department. Several hospitals battled against each other to be allowed to acquire their assets and staff. New indications for bariatric surgery (e.g. in adolescents) or new minimal invasive methods with low complication rates offer an opportunity for additional income at relatively limited costs for specialized health care providers.

REFERENCES

1. (WHO) WHO. Factsheet 'Obesity and overweight'. Available at <http://www.who.int/mediacentre/factsheets/fs311/en/>. 2016.
2. Ogden CL, Carroll MD, Kit BK, Flegal KM. Prevalence of Childhood and Adult Obesity in the United States, 2011-2012. *JAMA*. 2014;311(8):806-14.
3. RIVM. Overgewicht <https://www.volksgezondheinzorg.info/onderwerp/overgewicht/cijfers-context/huidige-situatie2017> [
4. Friedman N, Fanning EL. Overweight and obesity: an overview of prevalence, clinical impact, and economic impact. *Disease management* : DM. 2004;7 Suppl 1:6.
5. Rocchini AP. Childhood obesity and coronary heart disease. *The New England journal of medicine*. 2011;365(20):1927-9.
6. Juonala M, Magnussen CG, Berenson GS, Venn A, Burns TL, Sabin MA, et al. Childhood adiposity, adult adiposity, and cardiovascular risk factors. *The New England journal of medicine*. 2011;365(20):1876-85.
7. Abdullah A, Wolfe R, Stoelwinder JU, de Courten M, Stevenson C, Walls HL, et al. The number of years lived with obesity and the risk of all-cause and cause-specific mortality. *International journal of epidemiology*. 2011;40(4):985-96.
8. Viner RM, Cole TJ. Adult socioeconomic, educational, social, and psychological outcomes of childhood obesity: a national birth cohort study. *BMJ (Clinical research ed)*. 2005;330(7504):1354.
9. Russell-Mayhew S, McVey G, Bardick A, Ireland A. Mental health, wellness, and childhood overweight/obesity. *Journal of obesity*. 2012;2012:281801.
10. Cawley J, Meyerhoefer C. The medical care costs of obesity: an instrumental variables approach. *Journal of health economics*. 2012;31(1):219-30.
11. in 't Panhuis-Plasmans M, Luijben G, Hoogenveen R. Zorgkosten van ongezond gedrag. RIVM. 2012.
12. Cawley J, Rizzo JA, Haas K. Occupation-Specific Absenteeism Costs Associated With Obesity and Morbid Obesity. *Journal of Occupational and Environmental Medicine*. 2007;49(12):1317-24.
13. Gates DM, Succop P, Brehm BJ, Gillespie GL, Sommers BD. Obesity and Presenteeism; The Impact of Body Mass Index on Workplace Productivity. *Journal of Occupational and Environmental Medicine*. 2008;50(1):39-45.
14. Zorg.nu. Maagband voor kinderen 2017 [Available from: <https://zorgnu.avrotros.nl/uitzendingen/uitzending/item/maagband-voor-kinderen/>].
15. Houwelingen Hv. Maagband voor kinderen: 'moeten we dat wel willen?'. AD. 2017.
16. Vasterman J. Kind veel te dik? Maagbandje werkt beste. NRC. 2016.
17. Houwelingen Hv. 14 jaar en 100 kilo: is een maagband dan de oplossing? *Het Parool*. 2017.
18. Zaken H. Hoe dikke tieners strijden tegen hun overgewicht 2013 [Available from: https://www.maxvandaag.nl/programmas/tv/hollandse-zaken/hoe-dikke-tieners-strijden-tegen-hun-overgewicht/POW_00652086/].
19. Jeugdjournaal. Renée (16) werd geopereerd om af te kunnen vallen 2017 [Available from: <https://jeugdjournaal.nl/artikel/2154104-renee-16-werd-geopereerd-om-af-te-kunnen-vallen.html>].
20. Gerritsen W. Maagverkleining door je keelgat. *Limburger*. 2014.
21. EditieNL. Afvallen met een maagpacemaker 2013 [Available from: <https://www.rtlnieuws.nl/editienl/laatste-videos-editienl/artikel/2430491/kilos-vliegen-eraf-met-maagpacemaker>].
22. L1. Pacemaker voor de maag is succesvol 2013 [Available from: <https://l1.nl/pacemaker-voor-de-maag-is-succesvol-33882?pagina=3>].
23. Zwaap J, Knies S, Meijden Cvd, Staal P, Heiden Lvd. Kosteneffectiviteit in de praktijk. In: *Zorgverzekeringen Cv*, editor. 2015.
24. Borisenko O, Mann O, Duprée A. Cost-utility analysis of bariatric surgery compared with conventional medical management in Germany: a decision analytic modeling. *BMC Surgery*. 2017;17(1):87.
25. Borisenko O, Lukyanov V, Debergh I, Dillemans B. Cost-effectiveness analysis of bariatric

- surgery for morbid obesity in Belgium. *Journal of Medical Economics*. 2018:1-20.
26. Nguyen NT, Vu S, Kim E, Bodunova N, Phelan MJ. Trends in utilization of bariatric surgery, 2009-2012. *Surgical endoscopy*. 2015.
 27. Campanile FC, Boru CE, Rizzello M, Puziello A, Copaescu C, Cavallaro G, et al. Acute complications after laparoscopic bariatric procedures: update for the general surgeon. *Langenbeck's archives of surgery / Deutsche Gesellschaft für Chirurgie*. 2013;398(5):669-86.
 28. Franco JVA, Ruiz PA, Palermo M, surgery G-M. A review of studies comparing three laparoscopic procedures in bariatric surgery: sleeve gastrectomy, Roux-en-Y gastric bypass and adjustable gastric banding. *Obesity surgery*. 2011.