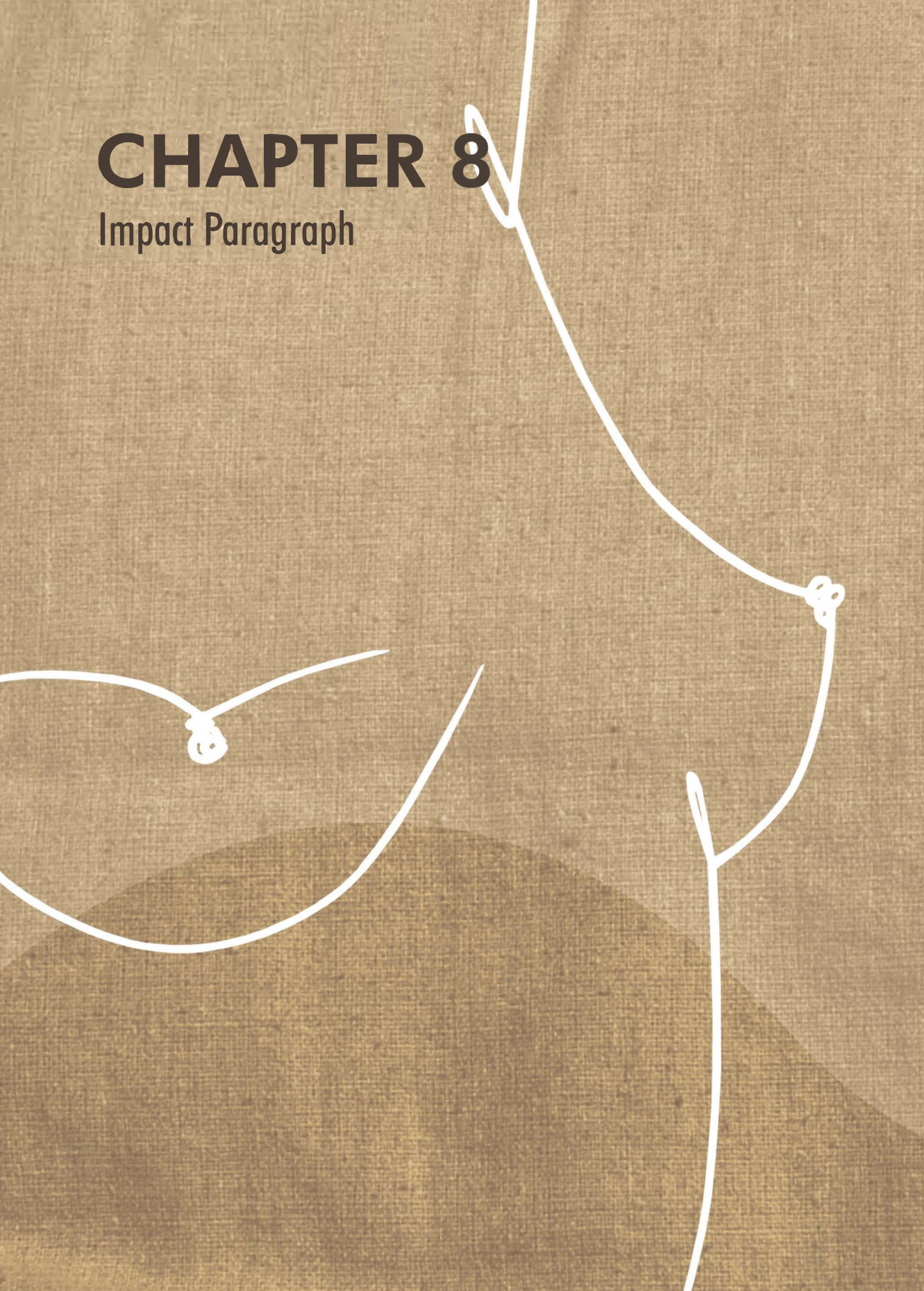
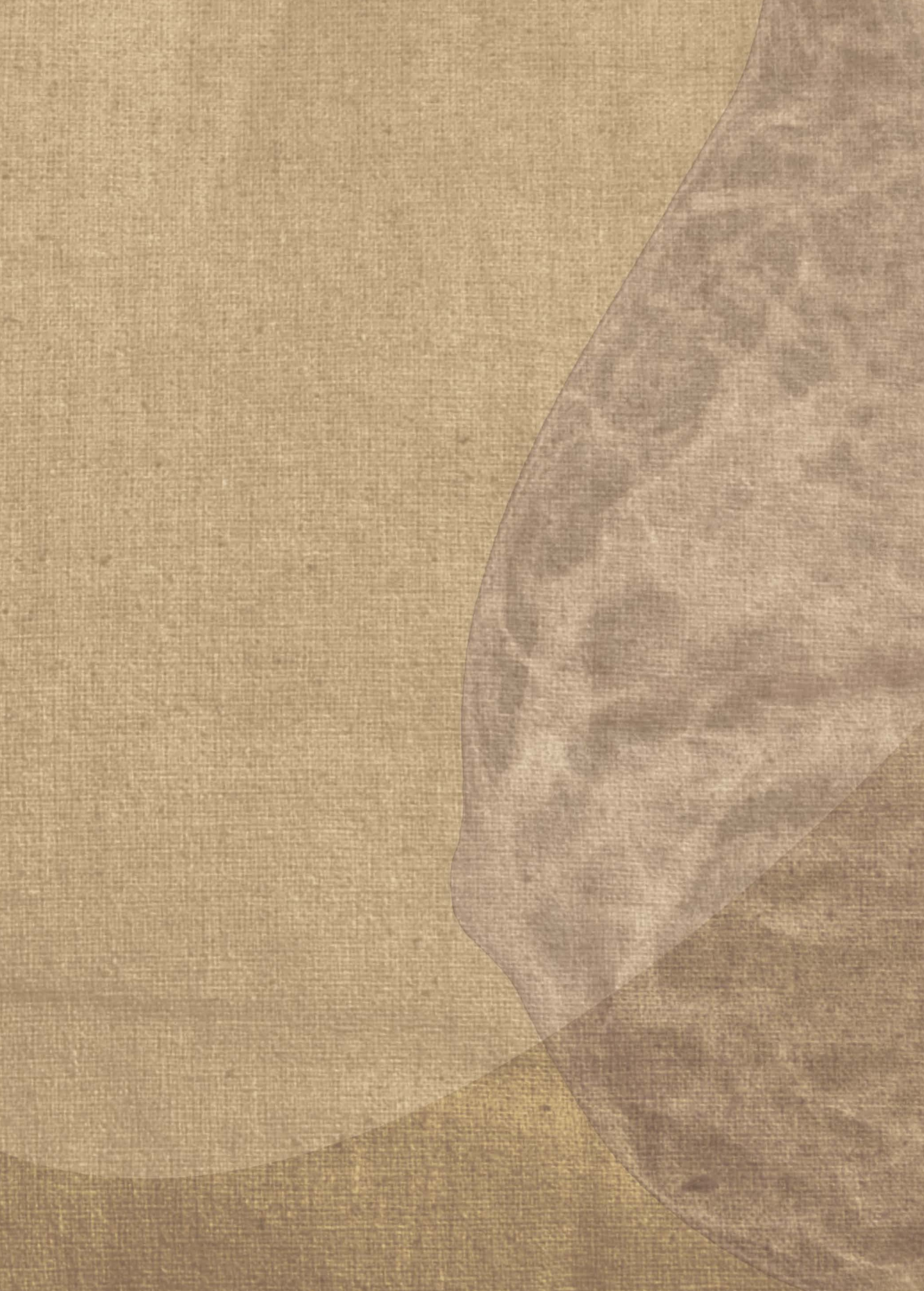
Breast implant illness in silicone breast implant patients

CHAPTER 8

Impact Paragraph





IMPACT PARAGRAPH

The safety and adverse effects of Silicone Breast Implants (SBI) are still a matter of debate. There are women around the whole world that claim a widespread spectrum of health complaints after implantation of silicone breast implants. During recent years, these health complaints are referred to as Silicone Breast Implant Illness (SBII). Previously, it was also reported in the literature as Autoimmune/Inflammatory Syndrome Induced by Adjuvants (ASIA). In the Netherlands, about 6000 women made their concerns and health complaints public on the World Wide Web by the Dutch Foundation for Women with Illness due to Breast Implants (Meldpunt Klachten Siliconen [MKS]). Which women are at risk and how many women actually suffer from silicone breast implants is still not known.

The research conducted in this thesis has a high clinical significance and social impact. The main aim of this thesis was to determine insight in the (systemically) health complaints that silicone breast implant patients are complaining about as well as to determine insight in which and how many SBI patients experience these health complaints. From this thesis, we were able to determine the spectrum of health complaints in women with SBII and found that this spectrum is broadly unchanged during the years. The most commonly symptoms SBII patients are reporting are fatigue, arthralgia and/or myalgia, brain fog, memory loss and concentration problems, dry eyes and/or dry mouth, pyrexia and autoimmune diagnosis. Having knowledge of the symptoms silicone breast implant patients may have is clinically relevant, not only for plastic surgeons, but also for doctors of other specialisms (e.g. internist, rheumatologist, immunologist) as well as the general practitioner to whom these women can report.

Women with concerns about the potential risks of their breast implants are frequently misunderstood and unheard from doctors where they report their complaints. In the last decade, national attention has been drawn to the concerns in various ways. Especially in the media extensive attention have been paid, several times by the Dutch television program ‚Radar', more known from their international research in 2018 named ‚The Implant Files', as well as for example the more recent petition ‚Calm Your Tits' of Jamie Crafoord in cooperation with the Dutch Foundation for Women with Illness due to Breast Implants (Meldpunt Klachten Siliconen [MKS]). We cannot determine whether the concerns of SBII

patients are exacerbated by media reports. However, the general concerns of women about the potential risks of their breast implants are nationally and internationally acknowledged by plastic surgeons. In the Netherlands, the Dutch Breast Implant Registry (DBIR), introduced in 2015, has included SBII as part of the registry. In 2017, the National Institute of Public Health and the Environment (RIVM) was commissioned by the Dutch Health and Youth Care Inspectorate to investigate the health complaints of women with silicone breast implants.

This thesis showed that SBI patients have less frequent and less severe cognitive failure than SBI patients who made their complaints public (SBII). No difference could be found in subjective cognitive functioning between SBI patient without self-reported compared to healthy control patients. Other research performed by our research group on the prevalence of self-reported health complaints in woman with SBI compared to controls also showed that, after adjustment for potential confounders (e.g. age, smoking, and comorbidities), the prevalence of clinical symptoms was only higher in the group of the self-reported women who made their complaints public. The adjusted prevalence in women with SBIs without self-reported health complaints did not differ from women without breast implants. The fact that complaints of implants are mainly seen in a selected self-reporting group of SBI patients, suggests that only a selected group of patients suffers from SBII and that adverse effects of implants is not generalizable for the whole SBI population. However we also observed that after explantation of the SBI, the complaints remarkably improved in about 75% of the patients. In patients with a developed autoimmune disease, improvement only occurred when explantation is combined with immunosuppressive therapy. If explantation should be used as a standard therapy option for SBII patients should be further studied in prospective research studies with longer follow-up.

The contribution of the results of this thesis further enlighten the complex issue of SBII. Non-selected SBI patients should be studied preferably in a prospective way and compared to matched representative control patients. To help the current group of SBII patients, the Dutch Healthcare Authority (NZa) already agreed that reimbursement of explantation of SBI should be given by health insurers once the diagnose of SBII is made by a medical specialist. Importantly, SBII patients have to be taken seriously in their health complaints. Women who consider breast augmentation with silicone breast implants have to be informed with clear and honest information by physicians about the risks known until now. Furthermore,

information should be accessible and have to be handed out by plastic surgeons as an information folder during the consultation. Doctors who treat these women should have awareness about SBII. In the Netherlands, the Dutch plastic surgery society has introduced an extensive package leaflet, which has to be given to all patients before implant surgery takes place.

The long-term societal challenges will be to prevent health complaints after implantation of silicone breast implants. Identification of a particular risk profile can discourage specific women to take silicone breast implants. Women with extensive allergies and/or pre-existent autoimmune diseases should be discouraged to take SBI. Moreover, alternative augmentation procedures (e.g., thru fat transfer or autologous reconstruction) are subject of future research, which may be especially offered to women at risk for SBII.