Background

Placebos have been used in one form or another for at least two centuries.\(^1\) Researchers in the late eighteenth century, in an attempt to establish science as a sound discipline separate from unorthodox and unconventional fields of treatment and therapy, recognized the idea of confounding environmental and psychological factors and attempted to mitigate them as best possible. For most of its history, however, placebo use was limited to medical treatments, and not initially applied to surgical procedures.

In 1959, a landmark trial of internal mammary artery ligation was conducted, introducing the concept of surgical placebo and exposing the practice to ethical scrutiny.\(^2\) It was thought that the chest pain associated with heart attacks and angina was caused by decreased blood flow to the chest wall. By ligating the blood supply to the chest wall, the pain would be preemptively mitigated. Patients enrolled in the control arm

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I would like to extend my appreciation to R. Dr. Edward Reichman for his helpful comments during the preparation of this article.


of the study had their chest cavity opened without any procedure actually performed. Questions concerning the ethics of performing such an invasive surgery without performing the beneficial technique arose as a result of this attempt to produce a scientifically sound experiment.

Nearly four decades later, another surgical placebo trial was conducted using fetal nigrostriatal dopaminergic neurons grafted into the brains of patients suffering from Parkinson’s disease. Similar to the dramatic and invasive nature of the arterial ligation, the placebo-controlled patients were anesthetized and a burr-hole procedure was performed, without any additional invasive technique. In follow-up, these placebo patients were given the same medical treatments that their treated counterparts received, including a dose of Cyclosporin.

A surgical placebo trial in 2002 followed a less severe protocol. Arthroscopy and debridement had become the standard treatment for osteoarthritis in the knees. Moseley et al conducted a randomized double-blinded case-controlled study, with the placebo patients receiving modified sedation and a few incisions and closures in the knee. A unique feature of this trial was the informed consent process, wherein the patient was asked to write a description of the placebo arm of the trial, indicating their explicit consent to that possibility.

In the latter two cases, controversy was sparked anew for a number of reasons, primarily because in the last two de-

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4 Essentially, a small hole was drilled into a bone in the skull, without penetrating entirely through.

5 Osteoarthritis occurs due to the breakdown of cartilage in, and subsequent narrowing of, joint spaces, producing pain on movement. The standard of treatment is orally administered pain medications, specifically NSAIDs, or surgical arthroscopy of the knee, which entails debridement of the joint space.

cades, fewer and milder morbidities are attributed to surgical interventions than in the mid-twentieth century. The debate, in large part, revolved around defining and determining the appropriate risk-benefit ratio that could justify these invasive and potentially harmful procedures.

Secular Ethical Concerns

Although the goal of this paper is to discuss Jewish ethical considerations as they pertain to surgical placebo, a discussion of the major ethical arguments outside of a religious context in favor of and opposed to the conduction of such trials will serve well to introduce the religious concerns.

Ruth Macklin is the major opponent of these so-called “sham” procedures (her coinage), and she offers a series of arguments that seek to undermine the legitimacy of the use of these hazardous placebos. She first argues that the use of placebo should be limited to situations in which there is no alternative standard of care available. She defines placebo very strictly, however, limiting its justifiable property to benignity, such that any negative effect whatsoever renders it unethical to administer. One must always minimize the risk of harm to the subjects, Macklin opines, which surgical placebos fail to do.

Focusing on the risk-benefit ratio, Macklin believes that any risk greater than that which is engendered by a medical placebo would preclude entirely any ethical allowances. She recognizes the therapeutic potential of these surgical placebos and its equivalence to that of medicinal placebos, but she does not see this equivalence as justification for the risk that patients encounter in their treatment. Additionally, she finds that the informed consent procedure is not effective enough in dispelling common misconceptions regarding the interests of the trial, the patients, and the doctors.

Macklin’s criticisms came in response to the arguments and justifications of Thomas Freeman et al, who elaborate on

their attempt to minimize the risk of the placebo procedure, as well as the need for placebo controlled-studies in therapeutic treatment of Parkinson’s disease (as opposed to simply halting its further development). Moreover, Freeman and his colleagues explain that this mode of study is indispensable to surgery, as many established surgical options have been determined to lack efficacy.\(^8\) Tenery notes that the use of surgical placebo is limited to treatment of diseases in which the only alternatives are medical and the disease being studied can be influenced by psychological factors, as established by the AMA’s Council on Ethical and Judicial Affairs. He adds that the informed consent process must be specially tailored in this case, as it pertains to greater risks than those found in trials involving pharmaceutical placebos. Another significant ethical requirement is that any nonsurgical treatment must be provided to all arms of the study to further minimize the violation of non-maleficence that would result from foregoing treatment for an extended duration.\(^9\)

Frank Miller explicitly rejects Macklin’s criticisms with three major contentions. First, he argues that the ethics of clinical research should be examined apart from the ethics of clinical medicine. Clinical research, he argues, is a scientific tool aimed at improving medical care and does not presume to be dedicated to treatment and beneficence. Surgical placebos, then, should be no different from lumbar punctures and other invasive tests that are used to measure the parameters and outcomes of trials and that do not assure any amelioration of disease. As he puts it, “[s]ham surgery is not unethical just because it exposes patients to risks that are not compensated by medical benefits.” Second, the burr hole procedure lies at one end of the ethical spectrum – the objectionable, seemingly

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condemnable extreme – but there is a vast range that should not be rejected out of hand as easily. In the case of the knee arthroscopy, patients were not subjected to life-endangering or traumatic procedures. The outcome in that case was also a subjective measure of pain, which demanded a blind control, whereas in the Parkinson’s trial, quality of life was the parameter at stake, an arguably less serious justification for such a dramatic procedure. Thus, even if some surgical placebos may be difficult to defend, not all cases should be summarily rejected. Miller’s next major objection concerns minimization of risk, which, according to Macklin, surgical placebo fails to satisfy. Miller argues that when sham surgery is the only alternative, the risk is by default minimized, even though it may not reach the low standard of medical trials.10

Thus, the discussion can be distilled to a few fundamental contentions. Those who support the use of surgical placebo maintain that it is necessary to establish the utility, cost-effectiveness, and significant therapeutic effect of the procedure. They also believe that minimization of risk does not have to be absolute, but can be relative, and the greatest effort to achieve the minimal risk is adequate, even if there is still a minor risk to the patients involved. Finally, the use of such placebos should be limited to a) therapies that do not have effective medical alternatives or b) the modification and improvement of already existing surgical treatments. Notably, those diseases for which effective medical treatments exist would not be candidates for trials of surgical placebo. Those opposed to the use of surgical placebo argue that “sham surgery” defies sufficient risk minimization (the non-maleficence issue) and that informed consent cannot be achieved to satisfactory ethical standards (the paternalistic component). The progress of medicine, its care and

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10 F.G. Miller, “Sham Surgery: An Ethical Analysis,” American Journal of Bioethics 34 (2003): 41-8. Interestingly, Miller also points out that from the internal artery procedure study, one cannot derive definitively that a sham procedure has the effect of a placebo, but only that the real procedure was not solely responsible for the positive outcome.
technology, cannot be at the expense and sacrifice of subjects
who do not receive standard of care in anticipation of such
furtherance.11

Halakhic Ethical Concerns12

In this author’s opinion, Jewish ethics – or, more precisely, Halakhah – would focus on different elements and issues in evaluating the propriety of surgical placebo. To begin with, informed consent, one of the major foci of Macklin’s critique, plays a very small, and perhaps totally insignificant, role in the halakhic considerations. This is not to say that a patient should not be informed to the best of the practitioner’s ability or that the patient should not, when possible, be consulted and solicited for permission to perform a procedure. However, Halakhah requires that a treatment that entails a likelihood of success (a criterion that will be explicated later in this paper) must be provided to the life-endangered patient, regardless of their personal interests and preferences. The value of human life is considered paramount in all ethical and clinical considerations in the eyes of Halakhah; there is little room for the layman’s

11 A response to this latter point could be that medicine does need to progress. In the past, therapeutic procedures were conjured and sometimes tried on animals, and depending on their success, they were then implemented in humans. This was followed by ex post facto research to investigate the procedures’ value. The proponents of surgical placebo could argue that placebo surgery is far more beneficial in the development of medicine, as well as to the patient subjects, considering their conditions and the need to advance medicine. In addition, regarding the issue of informed consent, Macklin must define what the dividing line is between informed and uninformed. A patient could always be better informed and educated to the level of the physician who is trying to explain and describe the procedure, yet that would be an absurd requirement. What, then, would be the arbitrary requisite knowledge that would permit the undertaking of intubation and surgery?

opinion, especially with regard to life-endangering diseases and their potential treatments. Simply put, just as a doctor has a Divine mandate to heal, a patient has a similar obligation to be healed, and this demand overrides any concern that the requirement for informed consent may present. When the disease being treated is not life-threatening, informed consent becomes more of a medical-legal consideration than a moral one. In the modern legal system, if someone performs any procedure or operation without a patient’s consent, with the exception of emergency situations, the perpetrator can be charged with assault and battery. In Halakhah as well, informed consent mitigates this problem, but it does not eliminate it entirely.

The major issues that will be treated here are the following:

A. Permissibility of elective procedures: Can one participate in a trial wherein the procedure is of an elective nature, which will usually entail life-suspending anesthesia and voluntarily inflicted trauma that may violate the injunction against wounding another human being? Even if these are permitted in the case of a willing patient participant, can a healthy person participate in

13 Abraham Steinberg, “Informed Consent,” in Encyclopedia of Jewish Medical Ethics (New York, 2003), vol. 2, 555. Cf. footnotes 44 and 45. See also idem., “Informed Consent: Ethical and Halakhic Considerations,” The Jewish Law Annual 12 October 1998: 137-52. Another consideration he presents there, which will be mentioned in the body of this article, is that a person’s body is not his own; it is regarded as a deposit from God that one must cherish and preserve. Thus, if there is a potential for harm, a person is duty bound to seek prophylaxis or a cure. However, coercion may be limited to medical or surgical treatments that are proven to be effective; see below for the parameters of efficacy. Steinberg maintains that autonomy is not a true halakhic concern for the above reasons. Others argue, however, that autonomy does have a strong basis in Halakhah, although there is no real practical difference between these opinions. See Zev Schostak, “Is There Patient Autonomy in Halacha?,” Assia – Jewish Medical Ethics 2:2 (1995): 22-27; and David Shatz, “Concepts of Autonomy in Jewish Medical Ethics,” The Jewish Law Annual 12 October 1998: 3-43.
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A research trial for the sake and benefit of a future patient population?

B. Efficacy as justification for exposure to risk: The dangers peculiar to surgical placebos are more problematic than those in medical placebos, in that patients not only expose themselves to a dangerous treatment, but also do so with only the possibility of receiving efficacious treatment. The use of placebo and its permissibility, in general, must be evaluated, in that medical treatments and managements must have a modicum of efficacy before they can be administered (refu’ah bedu- kah). What is the minimal efficacy that can justify exposure to risk? Moreover, is the placebo effect clinically or ethically satisfactory to be considered therapeutic to allow one to place himself in that situation?

C. Significance of pain and quality of life: Is one permitted to undergo a procedure that is not being performed to prevent death or prolong life, but only to improve quality of life (as in the cases of osteoarthritis or Parkinson’s disease), and to what level of risk can one expose oneself with the hope of consequent resolution?

A. Permissibility of Elective Procedures
The first issue that must be resolved is whether one is permitted to expose himself to risk, as a patient does upon consenting to participate in a surgical trial. In discussing the permissibil-

14 In halakhic terminology, this should be categorized as a situation of sfeik sfeika (literally, a doubt of a doubt), wherein the doubts are compounded, considering first the remote possibility of efficacy of the procedure itself in addition to the fifty-fifty chance of receiving placebo. Although the doubt lingering around the procedure can be modified to more or less than half, it remains only a possibility. This point is not raised by any of the sources cited in this article, however, so we will discuss the topic ignoring the fifty-fifty doubt, leaving each procedure to be evaluated individually to determine its level of necessary efficacy.
ity of using contraceptives during intercourse, R. Meir opines that there are three types of women who may be allowed to use a “sponge” to absorb the ejaculate, thereby preventing fertilization. These are pregnant women, nursing women, and a girl between the ages of eleven and twelve, where the dangers pursuant to a new pregnancy would threaten the life of the fetus, child, or mother. The consensus of the Sages, however, is that these women should engage in marital intercourse without the use of contraceptives. How, then, will they prevent the dangers of pregnancy? The Talmud responds with a verse from Psalms 116, “shomer peta’im Hashem” – “God watches over the simple.”

A similar concept is invoked elsewhere in the Talmud, which argues that since “the public [society] tread on such a [path],” a given activity is acceptable.

Teshuvot Binyan Tzion argues that based on the principle of “shomer peta’im Hashem,” one may expose himself to risks that are considered “everyday” or commonplace. However, he limits such allowance to situations in which the risks themselves are not imminent, even if they may present themselves in the future. Analogously, a person may travel overseas even though he knows that he will have to bring a korban todah (a thanksgiving sacrifice) upon his return, a sign that his journey was, in fact, dangerous.

Binyan Tzion concludes that the “assumption of a risk that will materialize only in the future is prohibited only if death will result in a majority of instances.” The right to assume a medical risk is thus limited to therapies

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15 See, for example, Yevamot 12b; Niddah 45a. See commentary of Tosafot, Yevamot ad loc., s.v. shema for an understanding of the threat that intercourse poses to a fetus.
16 Shabbat 129b. The Talmud there discusses bloodletting at inauspicious times, when the astrological influences would endanger a practitioner. Nevertheless, one is permitted to perform the procedure then due to the principle of shomer peta’im Hashem.
17 R. Jacob Ettlinger, Teshuvot Binyan Zion 137.
in which a majority of cases do not lead to endangerment.\textsuperscript{19} Although placebo surgeries are not conducted frequently and are not undergone by the masses, elective surgery in general is relatively commonplace. Since placebo surgery is not standard treatment and it is voluntary on the part of the patient, one could argue that it is elective in nature. Assuming this comparison, \textit{Binyan Tzion} would apparently conclude that the risks of such a procedure are acceptable. Furthermore, in the placebo procedures conducted thus far, none had a fatal or morbid outcome that approached a level of significance that would warrant concern.

Another possible problem is presented by placebo surgery, however, as in such cases, research is conducted primarily for the benefit of others, and often not directly for the benefit of the patient. \textit{Noda Bi-Yehuda}, discussing the performance of autopsies and dissection, maintains that there must be an imminent need in order to justify such experimentation or research. Violation of religious principles can only be executed for the sake of immediate needs ("\textit{holeh lefaneinu}").\textsuperscript{20} Technically, however, this could be construed as permission for someone to undergo placebo surgery for research purposes even with the potential that they themselves will not benefit, since there is a possibility that the proposed benefit will serve them directly, satisfying the requisite imminent need that the \textit{Noda Bi-Yehuda} mandates.

The aforementioned concerns relate to the administration of both the classical placebo and surgical placebo, as both involve attendant risks and may not benefit the patient himself. However, placebo surgery is unique in that there is an assumption of physical risk that is almost identical to the complications consequent to surgery. In this regard, it is further compa-

\begin{footnotesize}
\textsuperscript{19} This is despite the rule that “we do not invoke the majority in cases of life-endangerment”; cf. the view of Shmuel, \textit{Yoma} 85.
\end{footnotesize}
rable to elective surgery, which the responsa literature addresses extensively. Two major issues stand out in the discussion of elective surgery in the halakhic literature: self-endangerment, which we have broached above, and infliction of harm on others (for the surgeon) and oneself (for the patient).

In numerous questions posed regarding the permissibility of plastic surgery, the questioner feels hindered in performing social obligations, such as finding a livelihood or suitable marriage prospects, due to his or her physical features.\(^\text{21}\) R. Shlomo Zalman Auerbach, almost without reservation, finds no halakhic difficulty with elective cosmetic surgery in the case of a single girl, maintaining that the severe psychological anguish that she would experience due to her inability to get married is sufficient to justify the assumption of the minor risk entailed by surgery.\(^\text{22}\) He adduces proof for this idea from the view of Rabbeinu Tam, who distinguishes between one cutting his body hair for beautification and one cutting because of discomfort. The latter is allowed to use a razor on parts of his body, even though such an act would normally fall under the prohibition of “you shall not wear clothing of a woman,” since the action is not considered yipuy (beautification) or tikun (improvement). The person is doing so to prevent or alleviate discomfort or pain, and use of a razor is therefore permitted.\(^\text{23}\) Mor u-Ketziah allows subjection to risk even if a disease is not life-threatening as long as the pain is as “difficult as death.” He discusses the question of undergoing surgery to remove kidney or bladder stones, which pose no risk to life; due to the associated appreciable pain, he permits the operation with its attendant risks. However, Mor U-Ketziah does not prescribe surgery for such a patient, but merely allows the patient to choose to


\(^{22}\) Minhat Shelomo (2nd edition) 2:86, paragraph 3.

\(^{23}\) Tosafot, Yevamot 48a, s.v. lo. See also Tosafot, Shabat 50b, s.v. bishvil.
undergo such surgery. Similarly, R. J.D. Bleich, basing himself on Nahmanides’ *Torat Ha-Adam*, asserts that every medical treatment entails some minimal amount of unavoidable risk, so that involvement in a trial even for a non-life-threatening disease may be allowed. Pain alone may be the primary permitting factor for undergoing elective surgery.

Another halakhic issue that arises in the discussion of the permissibility of elective surgery is the injunction against inflicting wounds on oneself and others. According to Jewish law, the body does not belong to the person and is not at his disposal to do with it what he pleases. Rather, it is considered a deposit, which the person must be vigilant in maintaining. To inflict harm on one’s body is to damage a Divine object, beyond the laws of recompense and remuneration. The Torah states that when one receives lashes as punishment for infringement of a negative commandment, the executor must not exceed the number that has been determined for the recipient: “forty [times] he should strike, but he should not increase.”

The Talmud extrapolates from this verse to all those who inflict wounds on others. Even if one person allowed another to hit him, the one who hits still violates a Biblical injunction and is liable to receive lashes. Consent does not remove the potential for violation and culpability for inflicting physical injury.

When Rambam codifies this law, he uses an interesting phraseology, making such violation dependent on the intention of the perpetrator. He states that in order to be culpable, the perpetrator must inflict a wound that indicates strife or, according to a variant text, embarrasses the victim. Accordingly, if a person truly intends to help his friend by making an inci-

24 R. Yaakov Emden, *Mor U-Ketziah* 328. This source is cited as evidence that pain alone, a subjective parameter, can justify subjection to risk. The reading is somewhat ambiguous, as the author uses many qualifiers in this passage, but this is the understanding that *Tzitz Eliezer* 4:13 presents.
26 *Devarim* 25:3.
27 *Ketuvim* 33a.
sion or any other wound, it does not fall into the category of infliction of harm. R. Moshe Feinstein adduces this statement of Rambam as support for his dispensation for a young girl to undergo cosmetic surgery.29

There is a separate but related discussion regarding the permissibility of inflicting harm upon oneself. The early commentators dispute whether this violation is explicit or implicit in the Bible.30 One opinion maintains that it is derived from the laws of a Nazirite, one who declares his or her abstinence from wine, hair cutting, and exposure to sources of ritual impurity. Despite its seeming laudable ascetic nature, such a commitment is described in the Torah as a “sin against the soul,”31 which is understood to be a criticism of abstinence from the world that God bestowed upon man for his enjoyment. Later commentators believe the injunction goes beyond an implicit injunction and is explicitly and directly derived from the Torah’s declaration “only guard yourself and guard your soul very much,”32 which would elevate the degree of violation to that of a negative prohibition.33

Others, however, posit that there is no injunction against hurting oneself, basing their opinions on the anecdote recorded in the Talmud wherein R. Hisda lifted his hem above the thorn bushes, thereby exposing his legs to harm while saving his garment from tearing.34 Thus, at least according to some

29 Iggerot Moshe, Hosen Mishpat 2:66.
30 See Teshuvot Ha-Rashba 1:616; Rabbeinu Nissim, Shavuot 23b, s.v. di-Mokim; Meiri, Bava Kama 91b. This position is accepted as normative by Rosh and Rif, Bava Kama 91b; Rambam, Mishnah Torah, Hilkhon Hovel U-Mazik 5:1; and Tur, Yoreh De’ah 420:31.
31 Bamidbar. 6:11.
32 Devarim 4:9.
33 See R. Yonatan Eybuschitz, Tumim 27:1.
34 Bava Kama 91b. Interestingly, Lehem Mishnah, Hilkhon De’ot 4:1, opines that the injunction against harming oneself is only rabbinic in nature, which would bear strongly on our discussion. Rabbinic laws, in general, can be qualified dramatically when it comes to situations of physical pain or illness, and sometimes even financial loss. However, since this opinion seems to be a minority opinion and is not accepted as normative, it will
opinions, there is permission for both the researcher to perform and the patient to participate in a trial that inflicts physical harm or insult. Theoretically, if a patient needs to inflict harm on himself or herself in conducting a trial (for example, through an insulin injection), there would appear to be a basis for allowing elective participation.

B. Efficacy as Justification for Exposure to Risk

Thus far, we have discussed a patient’s ability to undergo experimental trials and subject himself to risk. However, there are guidelines and limits to the risks that a person is allowed to assume. Obviously, a person cannot participate in a trial that has a 100% mortality rate, as that would be tantamount to committing suicide. Nor is it necessary to state that a person can enter a trial whose risk of mortality or serious morbidity equals that of driving a car or traveling via plane. However, it is necessary to clarify, or at least attempt to identify, the line or range that a person is allowed to approach in entering such a trial.

II Kings 7:3-4 relates the story of a group of lepers who were living on the outskirts of their besieged city. They were faced with a dilemma: Should they “defect” to the surrounding army, with the possible result that they will be killed, but with the other possibility that they would be fed and spared, or should they remain and face almost certain starvation and death? Ultimately, they enter the enemy camp and find, to their surprise, an abandoned camp and an abundance of food and supplies. The Talmud views this narrative as normative and authoritative in practice; if a person finds that he will face almost certain death, he may expose himself to an alternative that may provide the potential for survival, even if it comes with an increased likelihood of death.35 From the leper story and its interpretations, R. Bleich deduces the general rule that even a possibility of prolongation of life can legitimize the vol-

remain a footnote in this discussion.

35 Avodah Zarah 27b.
Voluntary exposure of oneself to potentially life-shortening procedures (limiting one’s hayei sha’ah). Practically speaking, a medical procedure that assures a terminal patient a likelihood of significant alleviation can be performed even if it comes with the risk of death.36

From the II Kings narrative, it would appear that the alternative must provide something near a 50% chance of survival, or perhaps a little less than 50%, as it was an enemy force. However, the specific degree of risk that is considered significant must be strictly determined before the benefits of any procedures or treatments can be weighed against it. Beit Dovid maintains that a 1/1000 chance of success (with the alternative being demise) is sufficient to allow a patient to participate and receive the experimental procedure or therapy.37 R. Moshe Feinstein requires a success rate of a small minority, without suggesting specific ratios.38 Hatam Sofer is somewhat unclear regarding this question, but he seems to require success in the majority of cases, or at least, more than the remote chance.39 Mishnat Hakhamim and Tzitz Eliezer similarly maintain that success must be seen in more than 50% of cases.40 The basis for these differing opinions is difficult to elucidate.

An alternative approach is adopted by R. Moshe Dov Welner, who maintains that risk is evaluated not in terms of survival rate, but only if the therapeutic nature of the procedure has been demonstrated.41 According to this opinion, if such a determination can only be achieved in retrospect, a procedure would not be permitted. Thus, surgical placebo, with all its attendant risks, would not be within the parameters of permissible exposure.

38 Iggerot Moshe, Yoreh De’ah 2:58
39 Teshuvot Hatam Sofer, Yoreh De’ah 76.
40 R. Eliezer Waldenberg 10:25, chap. 5, sec. 5. These latter opinions are especially interesting in light of the story of the lepers.
Another issue that must be resolved relates to the placebo that is administered in these trials. Whereas the risks associated with placebo medications that are orally administered or injected are minimal, the untoward side effects, adverse effects, and complications that may arise consequent to surgical procedures are more dramatic. How, then, can one participate in a dangerous trial that does not have assured potential for relief? The mishnah cites a Tannaitic dispute regarding the permissibility of feeding the liver of a suspected rabid dog to its victim in order to prevent the development of symptoms (most likely referring to rabies). The authoritative opinion maintains that one is not permitted to consume such a non-kosher substance, despite its possibly life-saving effect, but fails to provide a rationale. Meiri argues that the reasoning for this position is straightforward: the treatment using dog liver has no therapeutic value, let alone the status of a well-researched prophylaxis, nor the empirical value necessary to justify such overt violation of Torah law. The implication is that if a particular treatment has had any history of success or any demonstration of efficacy, this would suffice as justification. Indeed, Rambam understands the normative opinion to mean that any new treatment that has either a legitimate rationale or empirical basis supporting its efficacy can be administered, despite its violation of biblical law.

Placebos in general are considered to have the lowest form of efficacy of any medical treatment, which is why they are used as the standard reference in clinical trials. If a new medication has the same efficacy as placebo, it has no intrinsic value; all of the science, research, planning, and development that led to that new medication’s production were a waste, as what it achieved could have simply been accomplished with a placebo. That is not to say, however, that a placebo lacks inherent value. A number of surveys and trials have been done to

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42 Yoma 83a.
43 Meiri, ad loc.
44 Rambam, Perush La-Mishnayot, ad loc.
investigate placebo efficacy. Internists and general practitioners use placebos daily in the form of vitamins for aches and pains and antibiotics for viral infections. These are appropriately termed “impure” placebos, because they have medically significant contents but those contents are totally irrelevant to the condition being treated. Significantly, medical placebos have been shown to be effective in reducing pain in some patients. Similarly, surgical placebos have been shown to be efficacious. In fact, its efficacy in the sham knee arthroscopy was near 50% (!). The case of the nigrostriatal fetal neuronal transplant was less simple; upon analysis, the placebo had very little effect on the worsening of the Parkinson’s symptoms. Nevertheless, surgical placebos can potentially have effects that attenuate the progression of disease and may be effective enough to justify the undertaking of risky procedures. This would seem to be no different from a patient taking an oral placebo, despite the fact that the disease may progress.

C. Significance of Pain and Quality of Life

The foregoing considerations are relevant when it comes to evidence-based practices of healing diseases or conditions. What remains to be explicated is the relevance of this discussion to the actual cases of surgical placebo, wherein a) the conditions themselves are overtly manifested as related to pain or quality of life, and not actual disease processes, and b) the placebo may treat psychological or pain components of such disease, but seemingly not the disease process itself. For example, in the case of the sham knee arthroscopy, the procedure is intended to treat pain produced by scar tissue, while the placebo may only resolve the pain and any psychological ramifications produced thereby. However, there is currently no treatment to delay or prolong the development or progression of osteoarthritis. Any placebo can only mitigate the symptoms, not impede the disease process itself. Thus, is it justified for a

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patient with such a malady, which is not life-endangering, to undergo such a procedure, and is the patient subject to the dispensations discussed above?

As noted above, R. Ya’akov Emden permitted an operation to remove kidney or bladder stones even though it would only resolve the severe pain associated with them, not the potential for development of life-threatening peritonitis.46 Similarly, Rema rules that a son may amputate his father’s limb, quite a severe procedure, as long as there is no other physician available and his father is in pain.47 Thus, pain alone is considered a substantial enough medical concern to justify the assumption of risk and even the violation of a biblical injunction against injuring one’s parents.48

Tosafot expand this allowance further to include psychological pain. The Talmud discusses the case of a man who has scabs on his skin and would like to remove them. If his primary motivation is for aesthetic or cosmetic reasons, this would constitute a violation of the biblical injunction against “wearing a woman’s garments,” which also applies to adopting forms of conduct particular to the opposite gender. However, he is permitted to remove it if he is doing so due to “pain.”49 Tosafot explain that the term “pain” includes a person who, because of his blemish, will refrain from engaging in social interactions, for “there is no greater anguish than this.”50 Thus, severe psychological and emotional stress, not merely physiologic pain, can justify the violation of a biblical injunction.

46 Mor u-Ketzi’ah 328.
47 Rema, Yoreh De’ah 241:13.
48 The consequence for inflicting such injury is death; see Exodus 21:15. However, a negative commandment, which is the common prerequisite to the Torah’s declaration of consequence, is notably absent. Cf. Sefer ha-Hinukh, commandment 48, where he explains that the injunction is subsumed in the broader negative commandment against harming another person. See also Sanhedrin 84b, where a number of Rabbis were reluctant to have their sons perform procedures on them that would draw blood for fear of violating this injunction, whose consequence is so severe.
49 Shabbat 50b.
50 Ibid., s.v. bishvil.
This allowance would be helpful in the surgical placebo treatment for Parkinson’s disease, in which, unlike the other orthopedic and cardiac cases of surgical placebo, pain is not a critical factor.

Conclusion

Surgical placebo entails a few unique features in Jewish law, and its attendant discussion therefore differs greatly from the foci of secular ethicists. Whereas the classical placebo pill is almost entirely harmless in and of itself, the surgical parallel involves both infliction of physical injury, even if not invasive, as well as the assumption of risk of mortality and serious morbidity. As related to the former concern, we have seen that the injunction against infliction of harm on another is limited to acts of aggression or hostility, but does not apply in the context of surgical therapy. We have also seen that a person can enter a situation that entails risk when, according to most opinions, the attendant complications are limited to the minority of outcomes from the researched procedure. Furthermore, we have seen that psychological anguish and pain can be sufficient cause to undergo surgery. A person can assume such risk when it is commonplace, obtaining Divine protection under “shomer peta’im Hashem,” in spite of the elective nature of the procedure, as long as it has proper justification of pain or potentially psychological anguish.

Any medical halakhic issue is complex and requires a comprehensive and thorough treatment of the relevant Biblical, Talmudic, and responsa literature. Based on the aforementioned considerations, it would seem that the discussion regarding surgical placebo is very much founded upon previously discussed and established halakhic issues. The cursory treatment in this essay of these issues and their underlying sources demonstrates that it may be permissible for a prospec-

51 A reminder to the reader that this article is a theoretical attempt to clarify the issues and apply them to a current problem. This article should not be taken as authoritative pesak halakhah.
tive patient to enter such a trial with the goal of improving their health and quality of life.